

US EPA ARCHIVE DOCUMENT



Reregistration Eligibility Decision (RED)

Bis(trichloromethyl) sulfone



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 Bis(trichloromethyl) sulfone. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

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

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, and any tolerance-related statements in the RED did not take into account any changes in tolerance assessment procedures required under FQPA. To the extent that this RED indicates that a change in any tolerance is necessary, that determination will be reassessed by the Agency under the standards set forth in FQPA before a proposed tolerance is issued. To the extent that the RED does not indicate that a change in the tolerance is necessary, that tolerance, too, will be reassessed in the future pursuant to the requirements of FQPA.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Jeff Billingslea at (703) 308-8004. Address any questions on required generic data to the Special Review and Reregistration Division representative Bill Wooge at (703) 308-8794.

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

Bis(trichloromethyl) sulfone

LIST B

CASE 2055

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

TABLE OF CONTENTS

BIS(TRICHLOROMETHYL) SULFONE REREGISTRATION ELIGIBILITY DECISION TEAM	i
EXECUTIVE SUMMARY	v
I. INTRODUCTION	1
II. CASE OVERVIEW	2
A. Chemical Overview	2
B. Use Profile	2
C. Regulatory History	4
III. SCIENCE ASSESSMENT	5
A. Physical Chemistry Assessment	5
B. Human Health Assessment	6
1. Toxicology Assessment	6
a. Acute Toxicity	6
b. Subchronic Toxicity	7
c. Developmental Toxicity	7
d. Mutagenicity	8
e. Reference Dose	9
f. Toxicity Endpoints of Concern	9
2. Exposure Assessment	9
a. Dietary Exposure	9
b. Occupational and Residential Exposure	10
3. Risk Assessment	14
a. Dietary	14
b. Occupational and Residential	14
C. Environmental Assessment	17
1. Ecological Toxicity Data	18
a. Toxicity to Terrestrial Animals	18
b. Toxicity to Aquatic Animals	19
2. Environmental Fate	20
a. Environmental Fate Assessment	20
b. Water Resources	21
3. Exposure and Risk Characterization	22
IV. RISK MANAGEMENT AND REREGISTRATION DECISION	22
A. Determination of Eligibility	22
1. Eligibility Decision	23
2. Eligible and Ineligible Uses	23
B. Regulatory Position	23
1. Additional Generic Data Requirements	23

2.	Risk Mitigation Measures	24
a.	Personal Protective Equipment/Engineering Controls for Handlers	24
b.	Post-Application/Entry Restrictions	26
c.	Other Labeling Requirements	26
V.	ACTIONS REQUIRED OF REGISTRANTS	27
A.	Manufacturing-Use Products	27
1.	Additional Generic Data Requirements	27
2.	Labeling Requirements for Manufacturing-Use Products	27
a.	General Labeling Requirements	27
b.	Specific Labeling Amendments	28
B.	End-Use Products	28
1.	Additional Product-Specific Data Requirements	28
2.	Labeling Requirements for End-Use Products	28
a.	PPE/Engineering Control Requirements for Pesticide Handlers	28
b.	Labeling Requirements for Products Intended Primarily for Occupational Use	30
c.	Clarification of Oil Drilling Mud Use	31
d.	Directions For Use	31
e.	Clarification of Industrial/Commercial Water Cooling Systems	32
3.	Existing Stocks	32
VI.	APPENDICES	33
APPENDIX A.	Table of Use Patterns Subject to Reregistration	35
APPENDIX B.	Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision	49
APPENDIX C.	Citations Considered to be Part of the Data Base Supporting the Reregistration of Bis(trichloromethyl) sulfone	53
APPENDIX D.	Product Specific Data Call-In	59
Attachment 1.	Chemical Status Sheets	71
Attachment 2.	Product Specific Data Call-In Response Forms Plus Instructions	73
Attachment 3.	Product Specific Requirement Status and Registrant's Response Forms and Instructions	75
Attachment 4.	EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration	85
Attachment 5.	List of All Registrants Sent This Data Call-In Notice	89
Attachment 6.	Cost Share, Data Compensation Forms, Confidential Statement of Formula Form and Instructions	91
APPENDIX E.	List of Available Related Documents	99

LIST OF TABLES

Table 1 - Acute Toxicity Studies	6
Table 2 - Pump Liquid (Closed System) Scenario Calculations - Handlers	12
Table 3 - Pour Liquid (Open System) Scenario Calculations - Handlers	12
Table 4 - Risk Calculation for Closed Systems Using Liquids - Handlers	15
Table 5 - Risk Calculation for Open Pour Application - Handlers	15
Table 6 - Avian Acute and Subacute Oral Toxicity Findings	18
Table 7 - Freshwater Fish Acute Toxicity Findings	19
Table 8 - Freshwater Invertebrate Toxicity Findings	19
Table 9 - Estuarine/Marine Acute Toxicity Findings	20

BIS(TRICHLOROMETHYL) SULFONE REREGISTRATION ELIGIBILITY DECISION TEAM**Office of Pesticide Programs:**Biological and Economic Analysis Division

Michelle Cottrill	Biological Analysis Branch
Frank Hernandez	Economic Analysis Branch
Phyllis Johnson	LUIS

Environmental Fate and Effects Division

Ann Stavola	Ecological Effects Branch
Laura Parsons	Environmental Fate and Groundwater Branch
Karen Angulo	Science Analysis and Coordination Staff

Health Effects Division

Laura Morris	Occupational and Residential Exposure Branch
Arliene Aikens	Risk Characterization & Analysis Branch
Stephen Dapson	Toxicology Branch II

Registration Division

Marianne Clark	Antimicrobial Program Branch
Ruth G. Douglas	Antimicrobial Program Branch
Tina Levine	Registration Support Branch

Special Review and Reregistration Division

Kathy Davis	Accelerated Reregistration Branch
Bill Wooge	Accelerated Reregistration Branch

Office of the General Counsel:

Kevin Lee	Pesticides Branch
-----------	-------------------

Office of Enforcement and Compliance:

Rick Colbert

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

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System
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

As required under the Federal Insecticide, Rodenticide, and Fungicide Act, as amended in 1988, the U.S. Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide active ingredient bis(trichloromethyl) sulfone. This decision includes a comprehensive reassessment of the required target data base and use patterns of currently registered products. The Agency has determined that the uses of bis(trichloromethyl) sulfone as prescribed in this document will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. The Agency is requiring additional mutagenicity and neurotoxicity studies for confirmatory purposes and it is imposing the use of Personal Protective Equipment (PPE) and closed-loading and application systems to reduce risks to workers.

Use Patterns

Bis(trichloromethyl) sulfone is primarily used to control microbes, algae, and fungi in cooling water systems, waste disposal systems, pulp and paper mill water systems, oil extraction systems, and other industrial settings.

Human Health Assessment

From its review of the toxicology data, the Agency determined that bis(trichloromethyl) sulfone was slightly toxic to non-toxic in acute oral and dermal toxicity tests. However, bis(trichloromethyl) sulfone was determined to be highly toxic in eye irritation, dermal irritation and inhalation acute toxicity studies. In a subchronic dermal rabbit toxicity study, the No Observed Effect Level (NOEL) was 2.0 mg/kg/day. From evidence of changes in the blood and clinical chemistry values, the systemic NOEL is established at 2.0 mg/kg/day for males. The systemic NOEL is equal to or greater than 5.0 mg/kg/day for females.

The toxicological endpoints of concern for occupational and residential exposure to bis(trichloromethyl) sulfone are systemic toxicities from a rat developmental study and from a rat subchronic dermal study. The calculated Margins of Exposure ($MOE = NOEL/exposure$) for bis(trichloromethyl) sulfone product handlers are not of concern (greater than 100) for most exposure scenarios. However, the MOEs for handlers using open pouring in cooling towers and drilling muds are of concern. To protect these workers, closed system loading and application are required.

Environmental Assessment

Bis(trichloromethyl) sulfone is practically non-toxic to birds, and highly to very highly toxic to freshwater and estuarine/marine organisms. Marginal data are available to estimate the environmental fate of bis(trichloromethyl) sulfone. These data suggest that the primary route of dissipation is through microbial action, with a half-life of less than 0.5 days. While

the hazard to aquatic organisms from bis(trichloromethyl) sulfone has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments from this use are regulated under the NPDES permitting program of EPA's Office of Water. The Agency currently requires that labels for all bis(trichloromethyl) sulfone products require that discharges to aquatic environments comply with an NPDES permit.

Product Reregistration

Before reregistering the products containing bis(trichloromethyl) sulfone, 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. In addition, registrants must comply with the generic data requirements as outlined in Section V of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products that contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

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

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

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of bis(trichloromethyl) sulfone. The document consists of six sections. Section I is the introduction. Section II describes bis(trichloromethyl) sulfone, 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 bis(trichloromethyl) sulfone. Section V discusses the reregistration requirements for bis(trichloromethyl) sulfone. Finally, Section VI is the Appendices that 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 Decision:

- **Common Name:** Bis(trichloromethyl) sulfone
- **Chemical Name:** Hexachlorodimethyl sulfone;
Sulfonyl bis(trichloromethane)
- **CAS Registry Number:** 3064-70-8
- **OPP Chemical Code:** 35601
- **Empirical Formula:** C₅H₁₁NO
- **Trade and Other Names:** N-1386
- **Basic Manufacturer:** Verichem, Inc.

B. Use Profile

The following is an overview of the use profile, including the application sites and methods, of the currently registered products formulated with bis(trichloromethyl) sulfone as an active ingredient. A detailed table of these uses is in Appendix A.

For Bis(trichloromethyl) sulfone:

Type of Pesticide: Algaecide, Bacteriostat, Fungicide,
Microbicide/Microbiostat (Slime-forming bacteria, fungi,
and algae)

Use Sites:

INDOOR FOOD

Food Packaging (regulated by FDA)

INDOOR NON-FOOD:

Adhesives, Industrial
Coatings, Industrial

Emulsions, Resin/Latex/Polymer*
Oil Recovery Drilling Muds/Packer Fluids
Paper/Paper Products
Pasteurizer/Warmer/Cannery Cooling Water systems
Specialty Industrial Products
Wet-End Additives/Industrial Processing Chemicals

* The sole registrant of this use has requested the Agency to cancel the use in paints from the product registration.

AQUATIC NON-FOOD INDUSTRIAL:

Commercial/Industrial Water Cooling Systems
Evaporative Condenser Water Systems
Heat Exchanger Water Systems
Industrial Auxiliary Water Systems
Industrial Scrubbing System
Industrial Waste Disposal Systems
Oil Recovery Drilling Muds/Packer Fluids
Pulp/Paper Mill Water Systems
Secondary Oil Recovery Injection Water
Sewage Systems

TERRESTRIAL NON-FOOD CROP:

Oil Recovery Drilling Muds/Packer Fluids

Target Pests: Slime-forming bacteria, algae, and fungi

Formulation Types Registered:

TYPE: End-use, Manufacturing-use, Technical grade

FORM: Soluble concentrate/liquid, Liquid-ready to use, Soluble concentrate/solid

Method and Rates of Application:

TYPES OF TREATMENT:

Industrial preservative treatment, Preservative treatment, Water treatment (recirculating system), Impregnation treatment, Surface treatment.

Equipment - Not specified, Rollcoater

Method and Rate -

Indoor Non-Food

2.4 to 285 ppm active ingredient by weight, 27 to 267 ppm active ingredient by volume

Aquatic Non-Food Industrial

0.3 to 285 ppm active ingredient by weight

Terrestrial Non-Food

29 to 285 ppm active ingredient by weight

Timing - Not specified, during manufacture, continuous feed (initial), continuous feed (subsequent), intermittent (slug, initial), intermittent (slug, subsequent)

Use Practice Limitations: Preclean claim. Preclean for heavily soiled areas. Do not apply in marine and/or estuarine oil fields, or discharge effluent into lakes, streams, ponds or public water (NPDES license restriction). Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water.

C. Regulatory History

Bis(trichloro)methyl sulfone was first registered in the U.S. in 1967 as a fungicide. In 1968 another registration was issued for a product containing this chemical. Bis(trichloro)methyl sulfone is registered for use as a microbiocide/microbiostat in industrial systems such as waste disposal systems, food processing water systems, sewage systems, heat exchanger water systems, evaporative condenser water systems and commercial and industrial water cooling tower systems.

The first product registration, referred to above, was canceled in 1991. Currently there are five companies that have fourteen active registrations. One of these products is registered as a technical with an active ingredient declaration of 98%. The remaining 13 products (with active ingredient declarations ranging from 2.5% to 49%)

are registered for the following uses in addition to the uses indicated above for the second product registered in the U.S.: microbiocide/microbiostat, algacide in secondary oil recovery/injection water systems, oil recovery drill muds, packer fluids, pulp and paper mills, food processing water systems, wet-end/industrial processing chemicals, wood protection treatment, adhesives, specialty products, resin emulsions, paper and paper products, in-can paints (oil and latexes) and coatings. The use in paints is being voluntarily deleted from the sole product registration for this use.

Bis(trichloro)methyl sulfone is cleared under the Food Additive Regulations, 21 CFR Section 176.300, as an indirect food additive in the manufacture of paper and paperboard that contact food. It is also cleared under 21 CFR Section 175.105 for use as a preservative in adhesives.

In 1987 the Agency issued the Antimicrobial Data Call-In Notice for chronic and subchronic toxicity data requirements for this chemical and other antimicrobial chemicals.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Color: Off white

Physical State: Solid

Odor: Pungent aromatic

Melting Point: 36 to 38°C

Bulk Density: 125 lbs /ft³

Solubilities:	<u>Solvent</u>	<u>% by Weight or ppm</u>
	Water	67 ppm
	Ethylene glycol	6.2%
	Dimethyl sulfoxide	90.0%
	Acetonitrile	93.0%

Dissociation Constant: Insoluble in water

Octanol/Water Partition Coefficient: Log P = 3.3

Stability: Stable under ambient conditions. It does not react with steel or iron.

B. Human Health Assessment

1. Toxicology Assessment

At present, the toxicology data base for bis(trichloromethyl) sulfone meets the tiering pattern set for antimicrobials. The data is adequate and will support a reregistration eligibility determination for currently registered non-food uses.

a. Acute Toxicity

Table 1 - Acute Toxicity Studies

TEST	GUIDELINE #	RESULTS	CATEGORY
Oral LD ₅₀ - rat	81-1	545 mg/kg males, 535 mg/kg females	III
Dermal LD ₅₀ - rabbit	81-2	> 5000 mg/kg	IV
Inhalation LC ₅₀ - rat	81-3	0.04 mg/L	I
Eye irritation -rabbit ¹	81-4	corrosive	I
Dermal irritation-rabbit ¹	81-5	irritant	I
Dermal sensitization - guinea pigs ¹	81-6	not a sensitizer	-

¹ This study is a requirement for manufacturing-use and end-use products (40 CFR Section 158). For bis(trichloromethyl) sulfone data have been generated on the TGAI and are presented here for informational purposes.

Acute toxicity studies performed with bis(trichloromethyl) sulfone indicate low to high toxicity. The acute oral LD₅₀ (range) for males was 545 (475-625) mg/kg and 535 (479-597) mg/kg for females (MRID # 152875). The acute dermal LD₅₀ is greater than 5000 mg/kg (MRID # 152875). The acute inhalation LC₅₀ for rats of both sexes was calculated to be 0.04 mg/L (MRID # 42824801). Bis(trichloromethyl) sulfone was corrosive to the eyes of New Zealand albino rabbits (MRID # 152875) and was irritating to the skin of New Zealand albino rabbits (MRID # 152875). There was no evidence of skin sensitization from a single application of 0.5% bis(trichloromethyl) sulfone during the challenge phase (MRID #'s 156813 & 92010015).

In an acute neurotoxicity study, male and female Sprague-Dawley CrI:CD®(SD)BR rats received either 0, 50, 160, or 500 mg/kg of bis(trichloromethyl) sulfone in corn oil by a single oral gavage. The

systemic toxicity LOEL \leq 50 mg/kg and the systemic toxicity NOEL $<$ 50 mg/kg were based on decreased body weight gain in females, decreased food consumption in all treated animals, and a decrease in core body temperature and motor activity in all treated animals at the 50 mg/kg dose (MRID # 43156601 and addendum 43207901). The Agency has determined that the acute neurotoxicity study in rats is insufficient but upgradeable pending submission of acceptable positive control data for FOB evaluations, motor activity and neuropathology.

b. Subchronic Toxicity

In a 21-day dermal toxicity study, bis(trichloromethyl) sulfone was administered in doses of 0, 0.8, 2.0, or 5.0 mg/kg/day to young adult rabbits of the Hra:(NZW)SPF strain. The systemic LOEL is 5.0 mg/kg/day for males and greater than 5.0 mg/kg/day for females. The systemic NOEL is 2.0 mg/kg/day for males and equal to or greater than 5.0 mg/kg/day for females based on hematology and clinical chemistry changes. The LOEL for dermal irritation is 5.0 mg/kg/day in both sexes and the NOEL for dermal irritation is 2.0 mg/kg/day based on dermal irritation scores compared to control (MRID # 40050701).

c. Developmental Toxicity

In a developmental toxicity (teratology) study, bis(trichloromethyl) sulfone was administered in doses of 0, 2, 10, or 50 mg/kg/day by gavage to Charles River Crl:CD BR albino rats on gestation days six through fifteen, inclusive. The maternal toxicity LOEL is 10 mg/kg/day and the maternal toxicity NOEL is 2 mg/kg/day based on decreased body weight gains and reduced food consumption. The developmental toxicity LOEL is 50 mg/kg/day with a developmental toxicity NOEL of 10 mg/kg/day based on decreased fetal body weights and an increase in skeletal and external anomalies (MRID # 40149101).

In a developmental toxicity study bis(trichloromethyl) sulfone was administered in doses of 0, 10, 20, or 45 mg/kg/day by gavage to groups of 20 pregnant New Zealand white rabbits on gestation days six through eighteen, inclusive. The maternal toxicity LOEL was 45 mg/kg/day and the maternal toxicity NOEL is 20 mg/kg/day based on the decrease in maternal body weight gain, reduced food consumption and increased incidence in clinical signs of toxicity. The developmental toxicity LOEL is greater than 45 mg/kg/day and the developmental toxicity NOEL is equal to or greater than 45 mg/kg/day as no compound-related developmental toxicity was noted (MRID # 43156602).

d. Mutagenicity

In two gene mutation assays (Ames), using strains of *Salmonella typhimurium* (TA1535, TA1537, TA1538, TA98, and TA100) and a strain of *Saccharomyces cerevisiae* (D4), N-1386 was a positive mutagen to TA1535 under both nonactivated and S9 activated conditions. There were also suggestive increases in the numbers of revertants for TA100, however the criteria for a positive response were not met (MRID # 152330 and 152331).

In another gene mutation assay using strains of *Salmonella typhimurium* (TA1535, TA1537, TA1538, TA98, TA100), N-1386 was found to be a positive mutagen to strain TA-1535 under both nonactivated and S9 activated conditions and also positive to strain TA-100 under nonactivated conditions (MRID # 152332).

In a forward mutation assay, with Fischer mouse lymphoma L5178Y cells, N-1386 did not show a mutagenic response under either the nonactivated or the S9 activated conditions (MRID # 152333). In a sister chromatid exchange assay with Fischer mouse lymphoma L5178Y cells, N-1386 resulted in an increase in sister chromatid exchange under both S9 activated and nonactivated conditions (MRID # 152335).

In the multiple endpoint assay (gene mutation, chromosomal aberration, sister chromatid exchange), with Fischer mouse lymphoma L5178Y cells, N-1386 was an equivocal positive for gene mutations under nonactivated conditions and negative under S9 activated conditions. In the chromosomal aberration and the sister chromatid exchange (SCE) assays, the results were negative; however, the dose levels used were inadequate for testing full mutagenic potential (MRID # 152334).

In a micronucleus assay in Swiss-Webster mice, N-1386 technical was tested over an appropriate range of doses and was found to be nongenotoxic. (MRID# 42372701). An *in vitro* malignant transformation assay in BALB/3T3 cells, N-1386 was negative (No MRID # for submission: Stauffer Project No. T-6351, Litton Bionetics, Inc., January 1978.). A morphologic transformation assay in BALB/3T3 cells, N-1386 was negative (MRID # 152335).

The Office of Pesticide Programs' RfD/QA Peer Review Committee (3/10/95) concluded that the available mutagenicity data satisfied the non-food antimicrobial pesticide toxicology data requirements for mutagenicity testing in the categories of gene mutation

(Guideline 84-2a), structural chromosomal aberrations (Guideline 84-2b), and other genotoxic effects (Guideline 84-4). However, because the gene mutation study does not provide unequivocal evidence for either positive or negative gene mutation under the conditions of the study, additional data are required with an assay that involves interaction with germ cells in animals.

These confirmatory data are required to determine whether carcinogenicity testing must be conducted, since positive findings occurred. After these data are submitted, the Agency will make a determination on the requirement for carcinogenicity test data.

e. Reference Dose

The establishment of a reference dose (RfD) for bis(trichloromethyl) sulfone is not warranted, based on the use patterns and exposure profile for this active ingredient.

f. Toxicity Endpoints of Concern

The toxicological endpoints of concern for occupational and residential exposure are a systemic toxicity NOEL of 10 mg/kg/day from the developmental rat study (♀ effect) resulting from short-term (1-7 day) exposure and a dermal exposure NOEL of 2 mg/kg/day from the 21-day rat dermal study resulting from intermediate-term (1 week to several months) exposure (The Office of Pesticide Program's Less than Lifetime Committee (1/17/95)).

2. Exposure Assessment

a. Dietary Exposure

Administrative guidelines are established for bis(trichloromethyl) sulfone uses (adhesives and slimicides) in food contact through food packaging. These uses of bis(trichloromethyl) sulfone in the manufacture of paper, paperboard (21 CFR §176.300) and adhesives (21 CFR §175.105) which may contact food are regulated under the jurisdiction of the United States Food and Drug Administration. These guidelines are not directly regulated by EPA. There are no other registered food uses of bis(trichloromethyl) sulfone.

b. Occupational and Residential Exposure

The Agency conducts an occupational and/or residential exposure assessment for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or exposure to persons entering treated sites after application is complete. The Agency believes this is the case for the use of bis(trichloromethyl) sulfone products. Above the Agency described its conclusions regarding toxicology endpoints of concern for bis(trichloromethyl) sulfone. Below there is discussion of potential exposures from the use of these products.

The Agency is not aware of any pesticide products containing bis(trichloromethyl) sulfone that are intended primarily for homeowner use. Many products containing bis(trichloromethyl) sulfone are labeled for "industrial use only" and are, therefore, intended for occupational use. None of the registered uses are likely to involve direct applications of the active ingredient at residential sites. However, many secondary products, such as adhesives, paper, etc., may contain bis(trichloromethyl) sulfone as a preservative and are intended for homeowner use as well as occupational use. Therefore, people using these products may be secondarily exposed to bis(trichloromethyl) sulfone residues.

(1) Handler Exposure Scenarios and Assumptions

EPA believes there are potential exposures from direct applications in commercial and industrial settings and from secondary applications in commercial, industrial, and residential settings. These two levels of handler exposures are:

- primary handlers -- persons at industrial sites using (mixing, loading, applying) end-use pesticide products containing bis(trichloromethyl) sulfone as an active ingredient.
- secondary handlers -- persons using (mixing, loading, applying or otherwise handling) products, such as adhesives, to which bis(trichloromethyl) sulfone has been added.

Exposures to painters from bis(trichloromethyl) sulfone treated paints would be of concern to the Agency; however, the registrant has submitted an amendment to cancel the use in paints from the label. This renders a painter exposure assessment unnecessary.

(a) **Primary Handler Exposure Scenarios**

Primary Occupational Handlers: Based on the use patterns, EPA has identified three major bis(trichloromethyl) sulfone exposure scenarios for primary occupational handlers: (1) open-pour applications with the soluble concentrate or ready-to-use liquid formulations (open system), (2) metering-pump applications with the soluble concentrate or ready-to-use liquid formulations (closed system), and (3) open-pour applications with the soluble concentrate solid formulation (open system).

Primary Homeowner Handlers: At this time there are no end-use pesticide products containing bis(trichloromethyl) sulfone that are intended for homeowner use. Therefore, there is no concern for the primary homeowner handler exposures.

(b) **Primary Occupational Handler Exposure Assumptions**

Exposure data specific to bis(trichloromethyl) sulfone are not available nor is there surrogate exposure data for all use-patterns. However, the above exposure scenarios are representative of reasonable worst-case scenarios. To estimate exposures (unit exposure (UE) and actual daily exposure (ADE)), the Agency relied on surrogate data from a study (amended 1992) submitted by the Chemical Manufacturers Association (CMA) for antimicrobial pesticide products (MRID #s 41412201, 41742601, and 42587501). Based on these data, inhalation exposure is believed to be minimal for the scenarios that were evaluated. Therefore, only dermal exposures were considered.

The protective clothing scenario for all exposure assessments from the CMA data base is long-sleeve shirts, long pants, shoes, socks, and chemical resistant gloves. In its estimates, the Agency also assumed 100% dermal absorption for bis(trichloromethyl)sulfone, because data are not available, and a 60 kg body weight (female) for the handler. The Agency calculated ADEs by the following equation:

$$\text{ADE} = (\text{UE} \times \text{lbs a.i. used/day}) \div \text{body weight}$$

The pounds active ingredient used per day by a primary handler was derived from the units of exposure (CMA study) and the bis(trichloromethyl) sulfone product label directions for each scenario.

(c) Estimates of Primary Occupational Handler Exposures

Exposure estimates for bis(trichloromethyl) sulfone for primary handlers involved in the above scenarios are presented in Tables 2 and 3 below. These estimates are considered worst case and represent workers handling bis(trichloromethyl) sulfone for short term (1-7 days) or intermediate term (7-90 days) durations.

Table 2 -Pump Liquid (Closed System) Scenario Calculations - Handlers

Setting	UE ($\mu\text{g/lb ai}$)	lb ai/day	ADE ($\mu\text{g/kg/day}$)
Preservative	7.5	0.54	0.0675
Pulp & Paper Mill	3.9	2	0.13
Water Cooling System	90	2	3.00
Drill Muds	7.5	100	12.50

Table 3 - Pour Liquid (Open System) Scenario Calculations - Handlers

Setting	UE ($\mu\text{g/lb ai}$)	lb ai/day	ADE ($\mu\text{g/kg/day}$)
Preservative	140	0.54	1.26
Pulp & Paper Mill	140	2	4.66
Water Cooling System	10,230	2	341.00
Drill Muds	140	100	233.30

(d) Secondary Handler Exposure Scenarios & Assumptions

Based on the use patterns, EPA has identified potential exposures to secondary occupational and homeowner handlers while mixing and applying adhesives containing bis(trichloromethyl) sulfone. EPA has determined that secondary occupational and residential handler exposures from handling adhesives containing bis(trichloromethyl) sulfone are not expected to be greater than those for the general open pouring industrial preservative use.

(2) Post-Application Exposure Scenarios & Assumptions

EPA has identified two levels of post-application exposures:

- primary post-application exposures -- persons in and near areas where end-use pesticide products containing bis(trichloromethyl) sulfone as an active ingredient are being or have recently been applied;
- secondary post-application exposures -- persons in and near areas where products, such as adhesives, to which bis(trichloromethyl) sulfone has been added, are being or have recently been used.

(a) Primary Post-Application Exposures

Primary Occupational Post-Application

Exposures: Based on the use patterns, EPA has identified two major bis(trichloromethyl) sulfone exposure scenarios for primary occupational post-application exposures: exposures following applications of bis(trichloromethyl) sulfone to open vats of hot liquids, such as paper-pulp, adhesives, coatings, and emulsions; and exposures to persons maintaining equipment, such as water systems and other industrial equipment, which contain products treated with bis(trichloromethyl) sulfone.

Primary Homeowner Post-Application

Exposures: At this time there are no end-use pesticide products containing bis(trichloromethyl) sulfone that are

intended for homeowner use. Therefore, there is no concern for the primary homeowner post-application exposures.

(b) Secondary Post-Application Exposures

Secondary Occupational & Homeowner Post-Application Exposures: Based on the use patterns, EPA has identified a bis(trichloromethyl) sulfone exposure scenario for secondary occupational and residential post-application exposures: exposures to persons working or residing in areas where products such as adhesives containing bis(trichloromethyl) sulfone are being used or have been recently applied.

3. Risk Assessment

a. Dietary

The potential dietary exposure to bis(trichloromethyl) sulfone from food uses in food-grade paper, paperboard, and adhesives is regulated by the Food and Drug Administration.

b. Occupational and Residential

(1) Risk From Handler Exposures

(a) Risk From Primary Occupational Handler Exposures

The EPA has conducted an assessment of the potential risks associated with handler exposures to bis(trichloromethyl) sulfone. The toxicological endpoints of concern for occupational and residential exposure are a systemic toxicity NOEL of 10 mg/kg/day from the rat developmental study (♀ effect) resulting from short-term exposure and a dermal exposure NOEL of 2 mg/kg/day from the 21-day dermal rat study, resulting from intermediate-term exposure.

The risk in terms of Margins of Exposure (MOEs), a ratio of the NOEL to the exposure, is calculated as follows and the values are presented in Tables 4 and 5 below.

$$\text{Margin of Exposure (MOE)} = \frac{\text{NOEL (10 mg/kg/day)}}{\text{ADE (Actual Daily Exposure)}}$$

(For short-term exposure)

$$\text{Margin of Exposure (MOE)} = \frac{\text{NOEL (2 mg/kg/day)}}{\text{ADE (Actual Daily Exposure)}}$$

(For intermediate exposure)

Table 4 - Risk Calculation for Closed Systems Using Liquids - Handlers

Scenario	Margin of Exposure	
	Short Term	Intermediate
Preservative	142,857	28,571
Pulp & Paper Mill Water System	76,923	15,384
Cooling Water Systems	3,333	667
Oil Drilling Muds/Packer Fluids	833	167

Table 5 - Risk Calculation for Open Pour Application - Handlers

Scenario	Margin of Exposure	
	Short Term	Intermediate
Preservative	7,936	1,587
Pulp & Paper Mill Water System	2,128	425
Cooling Water Systems	29	6
Oil Drilling Muds/Packer Fluids	43	9

Margins of Exposure range from 6 for intermediate exposures to bis(trichloromethyl) sulfone handlers in cooling tower applications to nearly 143,000 for short term exposures to workers in pulp and paper mill water system settings. In general the MOEs are lower for intermediate term exposures, as a result of the lower NOEL for intermediate term. A Margin of Exposure of less than 100 is of concern to the Agency.

(b) Risk From Primary Residential (Homeowner) Handler Exposures

At this time there are no end-use products containing bis(trichloromethyl) sulfone that are intended for homeowner use. Therefore, there is no risk concern for the primary homeowner handlers.

(c) Risk From Secondary Occupational Handler Exposures

EPA has determined that risk from secondary occupational handler exposures from handling adhesives containing bis(trichloromethyl) sulfone is not expected to be greater than those for the general open pouring industrial preservative use.

(d) Risk from Secondary Residential (Homeowner) Handler Exposures

Based on the use patterns, the Agency has identified a potential secondary homeowner handler exposure scenario: exposure while handling bis(trichloromethyl) sulfone-containing adhesives. Based on the low volatility, use patterns, amount applied, and frequency and duration of exposure, the Agency believes that secondary homeowner handler exposure and risk from uses of such as adhesives to be minimal.

(2) Risk From Post-Application Exposures

(a) Risk From Primary Occupational Post-Application Exposures

No post-application data are available to directly assess post-application exposures in the occupational setting. However, post-application dermal exposures resulting from bis(trichloromethyl) sulfone use-patterns are likely be minimal, since the exposures are to highly diluted bis(trichloromethyl) sulfone not the concentrate, and the exposures are likely to be brief, since the post-application tasks do not involve prolonged contact with bis(trichloromethyl) sulfone-surfaces. Post-application inhalation exposures to bis(trichloromethyl) sulfone also

are likely to be minimal, since bis(trichloromethyl) sulfone has very low vapor pressure and is, therefore, unlikely to generate sufficient vapor to cause a concern to workers performing post-application tasks. Since post-application dermal and inhalation exposures resulting from bis(trichloromethyl) sulfone use-patterns are likely to be minimal, no risk assessment is required.

(b) Risk From Primary Residential (Homeowner) Post-Application Exposures:

At this time there are no end-use products containing bis(trichloromethyl) sulfone that are intended for homeowner use. Therefore, there is no concern for the primary homeowner post-application exposures.

(c) Risk From Secondary Occupational and Residential (Homeowner) Post-Application Exposures

The Agency has identified possible bis(trichloromethyl) sulfone scenarios for secondary occupational and homeowner post-application exposures involving exposures while occupying areas where bis(trichloromethyl) sulfone-containing adhesives have been used. Based on the low volatility, use patterns, amount applied, and frequency and duration of exposure, the Agency believes that secondary post-application exposure and risk from uses such as adhesives to be minimal.

C. Environmental Assessment

While the hazard to aquatic organisms from bis(trichloromethyl) sulfone has been characterized below, a quantitative risk assessment has not been conducted. The risks to aquatic environments associated with bis(trichloromethyl) sulfone uses are regulated under the NPDES permitting program of EPA's Office of Water. The Agency currently requires, through product labeling, that all bis(trichloromethyl) sulfone discharges to aquatic environments be in compliance with NPDES permits.

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of bis(trichloromethyl) sulfone to birds, the following tests are required for industrial microbiocides using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably the bobwhite quail or mallard duck) and one subacute dietary study (LC_{50}) on one species (preferably the bobwhite quail). These studies have been submitted and the results presented below.

Table 6 - Avian Acute and Subacute Oral Toxicity Findings

Species	LD_{50} (mg/kg)	MRID #	Toxicity Category
Avian Acute Oral Toxicity Findings			
Mallard Duck	> 2,250 mg/kg	156817	practically non-toxic
Avian Subacute Dietary Toxicity Findings			
Northern Bobwhite Quail	> 5,620	156818	practically non-toxic
Mallard Duck	> 5,000	156820	practically non-toxic

These results (Table 6) indicate that bis(trichloromethyl) sulfone is practically non-toxic to avian species on an acute oral and subacute dietary basis. The guideline requirements are fulfilled (MRID #'s 156817, 156818 and 156820).

(2) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, an acute oral LD_{50} from an acute oral toxicity study is used to determine toxicity to mammals. The acute LD_{50} for rats (small mammal surrogate), discussed in the Human Health Assessment above, was determined to be 535 mg/kg (MRID #152875). This result indicates that bis(trichloromethyl) sulfone is slightly toxic to small mammals on an acute oral basis.

(3) Insects

A honey bee acute contact LD₅₀ study is required if the proposed use will result in honey bee exposure. However, due to the nature of the bis(trichloromethyl) sulfone use patterns, a honey bee study is not required.

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of this pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient is one freshwater fish toxicity study. The study should use the rainbow trout (cold water species) or the bluegill sunfish (warm water species).

Table 7 - Freshwater Fish Acute Toxicity Findings

Species	LD ₅₀ (ppb)	MRID #	Toxicity Category
Rainbow trout	290	156814	very highly toxic
Bluegill sunfish	580	156815	very highly toxic

The results of the 96-hour acute toxicity studies (Table 7) indicate that bis(trichloromethyl) sulfone is very highly toxic to both cold and warm water fish. The guideline requirements are fulfilled (MRID #s 156814 and 156815).

(2) Freshwater Invertebrates

The minimum testing required to establish the toxicity of a microbiocide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

Table 8 - Freshwater Invertebrate Toxicity Findings

Species	EC ₅₀ (ppm)	MRID #	Toxicity Category
<i>Daphnia magna</i>	0.173	156816	Highly Toxic

There is sufficient information to characterize bis(trichloromethyl) sulfone as highly toxic to aquatic invertebrates (Table 8). The guideline requirement is fulfilled (MRID # 156816).

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required to support microbiocides used in once-through cooling towers, oil recovery drilling muds/packer fluids, secondary oil recovery injection waters, and pulp and paper mill water systems because of the proximity of the above installations to estuarine and marine environments.

The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

Table 9 - Estuarine/Marine Acute Toxicity Findings

Species	% A.I.	LC_{50}/EC_{50} (ppb)	MRID #	Toxicity Category
Sheepshead Minnow	99%	400	40138102	highly toxic
Quahog Clam (Embryo-Larvae)	99.9%	9.2	40193201	very highly toxic

There is sufficient information to characterize bis(trichloromethyl) sulfone as highly toxic to marine/estuarine fish and very highly toxic to marine/estuarine mollusca. The guideline requirements are fulfilled for marine mollusca and marine/estuarine fish only (MRID #s 40138102 and 40193201). Data for marine/estuarine invertebrates were not acceptable (MRID # 40138101). However, considering the results of the aquatic studies referenced above, the Agency is not requiring a new study for marine/estuarine invertebrates.

2. Environmental Fate

a. Environmental Fate Assessment

Based on indoor non-food and aquatic non-food industrial use patterns, hydrolysis is the only data requirement for bis(trichloromethyl)

sulfone. Acceptable data show that bis(trichloromethyl) sulfone did not hydrolyze in sterile aqueous buffered solutions at pH 4, 7, or 9 (MRID # 41888701). The fate data requirements for bis(trichloromethyl) sulfone are therefore fulfilled.

Although not required, additional studies were submitted and reviewed. These data are of uncertain value due to flaws in methodology and are cited here as a best estimate of the dissipation and fate of this compound in the environment. These studies do not need to be repeated. An anaerobic aquatic metabolism study shows that the major route of dissipation of bis(trichloromethyl) sulfone is rapid microbial degradation with an estimated half-life of <0.5 days (MRID # 40317101). Two metabolites are pentachlorodimethylsulfone and hexachloroethane. However, product yield and additional metabolites were not provided (MRID # 40317103). In a photodegradation in water study, bis(trichloromethyl) sulfone photodegraded when irradiated with a non-specified sunlamp. Photodegradation half-lives were 16 days in water and 6 days in water sensitized with 1% acetone (TRID 470147-009). In a leaching adsorption/desorption study, Freundlich K_{ad} values from five (autoclaved) U.S. soils ranged from 6-52 mL/g, which indicates low mobility (TRID 470146-030).

One aquatic dissipation study was submitted. This study followed the dissipation of bis(trichloromethyl) sulfone in a pulp/paper mill from paper machine water, to mill water, and further to lagoon water that was then released to a stream. The water going into the paper machine was treated at 4.84×10^2 ppb bis(trichloromethyl) sulfone. Effluent from the machine contained 34 ppb, water samples from the mill contained 7-8 ppb, and lagoon water contained 2 ppb bis(trichloromethyl) sulfone. One degradate, pentachlorodimethylsulfone, ranged from 5-6 ppb in machine water, mill water, and lagoon water. The second degradate, hexachloroethane, was not recovered from any of the samples during the study (MRID # 40317103).

b. Water Resources

(1) Ground and Surface Waters

Because bis(trichloromethyl) sulfone is used in pulp and papermill process water systems, water cooling systems, secondary oil-recovery injection water systems, and as a preservative in adhesives, it is discharged to surface waters. As an indoor non-food and aquatic non-food industrial use compound, a NPDES permit is required for discharge.

3. Exposure and Risk Characterization

At the present time, the Office of Pesticide Programs does not conduct risk assessments for industrial microbiocides unless products have once-through cooling water system uses. Currently registered products with bis(trichloromethyl) sulfone do not have once-through water cooling system uses. Data requirements are limited to essential data needed for making a hazard assessment for labeling purposes, especially if there are unanticipated accidents, spills, or inappropriate disposals or uses. In the case of bis(trichloromethyl) sulfone, data submitted by the registrant showed that this chemical is practically non-toxic to birds, very highly toxic to freshwater fish, highly toxic to freshwater invertebrates, and highly toxic to estuarine/marine fish, and very highly toxic to estuarine/marine mollusca. The risk resulting from the use of this microbiocide will be considered in the issuance of NPDES permits.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

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

The Agency finds that all currently registered uses of bis(trichloromethyl) sulfone can be used as specified in this document without resulting in unreasonable adverse effects to humans and the environment.

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, the data identified in Appendix B, published scientific literature, and other available information. Although the Agency has found that all currently registered uses of bis(trichloromethyl) sulfone, as specified in this document, 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 bis(trichloromethyl) sulfone, 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 bis(trichloromethyl) sulfone, the Agency has sufficient information on the health effects of bis(trichloromethyl) sulfone and on its potential for causing adverse effects in fish and wildlife and the environment for all uses. The Agency has determined that bis(trichloromethyl) sulfone products, labeled and used as specified in this Reregistration Eligibility Decision document will not pose unreasonable risks or adverse effects to humans or the environment. The Agency concludes that all products containing bis(trichloromethyl) sulfone are eligible for reregistration upon submission of offers to compensate.

However, the Agency recognizes that not all registrants subject to generic data requirements have met their obligations. As explained in the Human Health Assessment, Section III, the Agency found it necessary to conduct exposure assessments. EPA relied on submitted data from the Chemical Manufacturers Association. For registrants of bis(trichloromethyl) sulfone products who have not paid or made offers to pay compensation for the use of that data, or who have not submitted their own acceptable worker exposure data, they must do so to gain product reregistration. EPA issued a Data Call-In Notice August 22, 1995, to registrants imposing these obligations.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of bis(trichloromethyl) sulfone are eligible for reregistration.

B. Regulatory Position

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

1. Additional Generic Data Requirements

The Agency is requiring registrants to submit additional data that will confirm mutagenicity and neurotoxicity of bis(trichloromethyl) sulfone.

Confirmatory data from gene mutation and sister chromatid exchange studies are required to provide unequivocal evidence for either positive or negative gene mutation. These new data must include an assay to involve

interaction with animal germ cells. These data are required to determine the need for Tier 3 data, carcinogenicity testing.

Additional acute neurotoxicity study data are required to characterize bis(trichloromethyl) sulfone's effects on motor activity that was suggested in the current study.

Data generated by the Antimicrobial Task Force of the Chemical Manufacturers Association have been used to address these exposures in this document; however, the Agency requires offers of compensation be made for the use of these data or new, adequate data be submitted. A Data Call-In has been issued to the registrants of bis(trichloromethyl) sulfone requiring these actions.

2. Risk Mitigation Measures

a. Personal Protective Equipment/Engineering Controls for Handlers

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

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

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

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

(1) Occupational-Use Products

Primary Occupational Handlers: EPA has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE and engineering requirements for occupational handlers must be taken for bis(trichloromethyl) sulfone. The Margins of Exposure (MOEs) are less than 100 for both the short-term and intermediate-term exposures for the open-pouring use of bis(trichloromethyl) sulfone in water cooling systems and oil drilling muds/packer fluids. Therefore, EPA is requiring meter-pump loading and application of bis(trichloromethyl) sulfone for the following uses: pasteurizer/warmer/cannery cooling water systems, commercial/industrial water cooling systems, evaporative-condenser water systems, heat-exchanger water systems, and oil recovery drilling muds/packer fluids (see Table 4). This use limitation will adequately mitigate risks to workers in these use settings.

For all other uses of bis(trichloromethyl) sulfone, the MOEs were greater than 100, but EPA is establishing active ingredient based minimum PPE requirements for primary occupational handlers. Since these MOEs are based on units of exposure from the CMA exposure study in which handlers wore chemical resistant gloves, such chemical-resistant gloves are required for occupational handlers of bis(trichloromethyl) sulfone.

Secondary Occupational Handlers: EPA has determined that no regulatory action regarding the establishment

of active-ingredient-based minimum PPE and engineering-control requirements must be taken for secondary occupational handlers, such as persons using adhesives that contain bis(trichloromethyl) sulfone.

(2) Homeowner-Use Products

Primary Homeowner Handlers: There are no bis(trichloromethyl) sulfone end-use pesticide products intended primarily for homeowner use.

Secondary Homeowner Handlers: For products intended for homeowner use, such as adhesives, that contain bis(trichloromethyl) sulfone as an additive, EPA has determined that no regulatory action regarding the establishment of active-ingredient-based minimum PPE and engineering-control requirements must be taken.

b. Post-Application/Entry Restrictions

EPA has determined that no regulatory action must be taken to reduce occupational or residential (homeowner) post-application exposures to bis(trichloromethyl) sulfone, since post-application dermal and inhalation exposures are already likely to be minimal.

c. Other Labeling Requirements

The Agency is requiring other use and safety information to be placed on the labeling of all end-use products containing bis(trichloromethyl) sulfone in order to provide product users with more specific directions for use. For the specific labeling statements, refer to Section V of this document.

One product is currently labeled for use in paints. The registrant has applied to cancel the use of bis(trichloromethyl) sulfone in paints from the registrant's labels.

In addition, because reference to paints on the manufacturing-use product label will not be a use registered for an end-use product, it must be removed for the manufacturing-use product label.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of bis(trichloromethyl) sulfone for the above eligible uses has been reviewed and determined to be substantially complete. The following data have been required and are considered confirmatory:

<u>EPA Guideline #</u>	<u>Study Name</u>
81-8-SS	Acute Neurotoxicity in Rats (upgrade old study)
84-2(a)	Gene Mutation
84-4	Sister Chromatid Exchange

Also, registrants must meet data requirements for the worker exposure data as explained above.

2. Labeling Requirements for Manufacturing-Use Products

a. General Labeling Requirements

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

"Only for formulation into a microbiocide for the following uses
_____."

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

- (1) "This product may be used to formulate products for specific use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA

submission requirements regarding support of such use(s)."

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

b. Specific Labeling Amendments

The reference to latexes on the manufacturing-use product (EPA Reg. No. 67869-16) must be removed.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

a. PPE/Engineering Control Requirements for Pesticide Handlers

For sole-active-ingredient end-use products that contain bis(trichloromethyl) sulfone, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE/engineering control requirements on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain bis(trichloromethyl) sulfone, the handler personal protective equipment/engineering control requirements set forth in this section must

be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use

(1) Minimum (Baseline) Engineering Control Requirements

EPA is establishing minimum (baseline) engineering controls for some occupational uses of bis(trichloromethyl) sulfone end-use products. Products with bis(trichloromethyl) sulfone must be labeled to require pump engineering controls during loading and application for the following uses: oil recovery drilling muds/packer fluids, pasteurizer/warmer/cannery cooling water systems, commercial/industrial water cooling systems, evaporative-condenser water systems, and heat exchanger water systems.

In the "Directions For Use" portion of the label referring to these uses, registrants must insert the following language:

"This product must be loaded and applied only using a meter-pump system or a closed loading/application system for the following uses: {list uses}. Open pouring is prohibited."

(2) Minimum (Baseline) Personal Protective Equipment Requirements

EPA is establishing active-ingredient-based minimum (baseline) PPE for bis(trichloromethyl) sulfone end-use products that are intended for occupational use. Product labels must be amended to include the following statement:

"Applicators and other handlers must wear: chemical resistant gloves*, long pants, a long sleeved shirt, shoes and socks."

* For the glove statement, use the statement established for bis(trichloromethyl) sulfone through the instructions in Supplement 3 of PR Notice 93-7.

Placement in labeling: The PPE must be placed on the end-use product labeling in the location specified in PR Notice 93-7 and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Determining PPE Requirements for End-Use Product Labels:

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) PPE specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, its placement, format, and wording refer to PR Notice 93-7. NOTE: If the end-use product is classified as toxicity category I or II for eye irritation potential, protective eyewear is also required.

b. Labeling Requirements for Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing bis(trichloromethyl) sulfone that are intended primarily for occupational use.

Application Restrictions

"Do not apply this product in a way that will contact workers or other persons."

User Safety Requirements

--Registrants: add the following statements if coveralls are required for pesticide handlers on the end-use product label:

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

--Registrants: add the following statements always:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible wash thoroughly."

c. Clarification of Oil Drilling Mud Use

To clarify the intent of the oil recovery drilling muds/packer fluids use (as an indoor or outdoor use pattern) the following statement must be added to the labels for terrestrial non-food oil/gas drilling muds and packer fluids:

"For use on terrestrial oil wells only."

And the following statement must be added to the precautionary labeling:

"Do not apply in marine and/or estuarine oil fields."

The following statement must be added to the labels for aquatic non-food industrial drilling muds and packer fluids:

"For use on offshore oil wells only."

For use in both terrestrial and offshore oil drilling muds and packer fluids, the following statement must be added:

"This product may be used for terrestrial and offshore oil drilling muds and packer fluids."

d. Directions For Use

Registrants must specify on labeling the complete directions for use for each use pattern: site of application, type of application, timing of application, equipment used for application, and the rate of application (dosage).

e. Clarification of Industrial/Commercial Water Cooling Systems

To clarify that water cooling uses do not include once-through systems, the following statement must be added:

"This product may not be used in once-through cooling systems."

3. Existing Stocks

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

The Agency has determined that registrants may distribute and sell bis(trichloromethyl) sulfone products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. # Apps @ Max. Rate unless noted Max. /crop /year otherwise)/A]	Max. Dose [(AI unless noted Max. /crop /year otherwise)/A]	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Limitations Disallowed	Use Limitations Codes
---	---------	---	---	--	--	--------------------	------------------------------	--------------------------------	------------------------	-----------------------

USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED

ADHESIVES, INDUSTRIAL

Use Group: INDOOR NON-FOOD

Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 34	W 170	*	NS	NS	NS	NS	NS	C12, C18
	SC/S	W 5	W 25	*	NS	NS	NS	NS	NS	C12, C18
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 36	W 144	*	NS	NS	NS	NS	NS	C18, C24
	SC/L	W 40	W 160	*	NS	NS	NS	NS	NS	C12, C18
	SC/L	W 40	W 100	*	NS	NS	NS	NS	NS	C18, C24

COATINGS, INDUSTRIAL

Use Group: INDOOR NON-FOOD

Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 34	W 170	*	NS	NS	NS	NS	NS	C12, C18
	SC/S	W 5	W 25	*	NS	NS	NS	NS	NS	C12, C18
Preservative treatment., Not on label., Not on label.	RTU	NA	UC	*	NS	NS	NS	NS	NS	C12, C18
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 36	W 144	*	NS	NS	NS	NS	NS	C18, C24
	SC/L	W 40	W 160	*	NS	NS	NS	NS	NS	C12, C18
	SC/L	W 40	W 100	*	NS	NS	NS	NS	NS	C18, C24

COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS

Use Group: AQUATIC NON-FOOD INDUSTRIAL

Water treatment (recirculating system)., Continuous feed (initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 12	*	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 6	W 12	*	NS	NS	NS	NS	NS	A30, C18, C24

SC/L W 6.1 W 20 * NS NS NS NS NS NS A08, C12, C18

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. /crop /year	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS (con't)											
Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)											
Water treatment (recirculating system)., Continuous feed (subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 7.2	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 3.1	W 10	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 6	W 9	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
Water treatment (recirculating system)., Intermittent (slug)(initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 12	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 6	W 12	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/L	W 6.1	W 20	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 7.2	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 3.1	W 10	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 6	W 9	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
EMULSIONS, RESIN/LATEX/POLYMER											
Use Group: INDOOR NON-FOOD											
Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 34	W 170	*	NS	NS	NS	NS	NS	NS	C12, C18
	SC/S	W 5	W 25	*	NS	NS	NS	NS	NS	NS	C12, C18
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 36	W 144	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	W 40	W 160	*	NS	NS	NS	NS	NS	NS	C12, C18
	SC/L	W 40	W 100	*	NS	NS	NS	NS	NS	NS	C18, C24

EVAPORATIVE CONDENSER WATER SYSTEMS

Use Group: AQUATIC NON-FOOD INDUSTRIAL

SITE Application Type, Application Timing, Application Equipment – Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. /crop /year cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
EVAPORATIVE CONDENSER WATER SYSTEMS (con't)			Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)								
Water treatment (recirculating system)., Continuous feed (initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 12	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 12	*	NS	NS	NS	NS	NS		A30, C18, C24
	SC/L	W 6.1	W 20	*	NS	NS	NS	NS	NS		A08, C12, C18
Water treatment (recirculating system)., Continuous feed (subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 7.2	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 9	*	NS	NS	NS	NS	NS		A30, C18, C24
Water treatment (recirculating system)., Intermittent (slug)(initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 12	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 12	*	NS	NS	NS	NS	NS		A30, C18, C24
	SC/L	W 6.1	W 20	*	NS	NS	NS	NS	NS		A08, C12, C18
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 7.2	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 3.1	W 10	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 9	*	NS	NS	NS	NS	NS		A30, C18, C24
HEAT EXCHANGER WATER SYSTEMS			Use Group: AQUATIC NON-FOOD INDUSTRIAL								
Water treatment (recirculating system)., Continuous feed (initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 12	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 12	*	NS	NS	NS	NS	NS		A30, C18, C24

SC/L W 6.1 W 20 * NS NS NS NS NS NS A08, C12, C18

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Rate unless noted otherwise)	Max. # Apps /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
HEAT EXCHANGER WATER SYSTEMS (con't)											
Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)											
Water treatment (recirculating system)., Continuous feed (subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 7.2	* NS	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 3.1	W 10	* NS	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 9	* NS	NS	NS	NS	NS	NS		A30, C18, C24
Water treatment (recirculating system)., Intermittent (slug)(initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 12	* NS	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 12	* NS	NS	NS	NS	NS	NS		A30, C18, C24
	SC/L	W 6.1	W 20	* NS	NS	NS	NS	NS	NS		A08, C12, C18
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 7.2	* NS	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 3.1	W 10	* NS	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 9	* NS	NS	NS	NS	NS	NS		A30, C18, C24
INDUSTRIAL AUXILIARY WATER SYSTEMS											
Use Group: AQUATIC NON-FOOD INDUSTRIAL											
Water treatment., Intermittent (slug)(initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 6	W 12	* NS	NS	NS	NS	NS	NS		C18, C24
Water treatment., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 6	W 9	* NS	NS	NS	NS	NS	NS		C18, C24
INDUSTRIAL SCRUBBING SYSTEM											
Use Group: AQUATIC NON-FOOD INDUSTRIAL											
Water treatment (recirculating system)., Continuous feed (initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 12	* NS	NS	NS	NS	NS	NS		A08, C12, C18

SC/L

W 6

W 12

* NS

NS

NS

NS

NS

NS

A30, C18, C24

SITE Application Type, Application Timing, Application Equipment – Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. /crop /year	# Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
INDUSTRIAL SCRUBBING SYSTEM (con't)											
	SC/L	W 6.1	W 20	*	NS	NS	NS	NS	NS		A08, C12, C18
Water treatment (recirculating system)., Continuous feed (subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 7.2	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 3.1	W 10	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 9	*	NS	NS	NS	NS	NS		A30, C18, C24
Water treatment (recirculating system)., Intermittent (slug)(initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 12	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 12	*	NS	NS	NS	NS	NS		A30, C18, C24
	SC/L	W 6.1	W 20	*	NS	NS	NS	NS	NS		A08, C12, C18
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 7.2	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 3.1	W 10	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 9	*	NS	NS	NS	NS	NS		A30, C18, C24
INDUSTRIAL WASTE DISPOSAL SYSTEMS											
Use Group: AQUATIC NON-FOOD INDUSTRIAL											
Water treatment., Continuous feed (initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 1.7	W 57	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 4.9	W 24	*	NS	NS	NS	NS	NS		A08, C12, C18
Water treatment., Continuous feed (subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 1.7	W 14	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 2.4	W 19	*	NS	NS	NS	NS	NS		A08, C12, C18

Water treatment., Intermittent (slug)(initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 1.7	W 57	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
---	------	-------	------	---	----	----	----	----	----	----	---------------

SITE Application Type, Application Timing, Application Equipment – Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. /crop /year	# Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
INDUSTRIAL WASTE DISPOSAL SYSTEMS (con't)			Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)								
	SC/L	W 4.9	W 24	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 12	*	NS	NS	NS	NS	NS		C18, C24
Water treatment., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 1.7	W 20	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 2.4	W 19	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 9	*	NS	NS	NS	NS	NS		C18, C24
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS			Use Group: AQUATIC NON-FOOD INDUSTRIAL								
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 29	W 285	*	NS	NS	NS	NS	NS		C12, C18
			Use Group: INDOOR NON-FOOD								
Industrial preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	V 27	V 267	*	NS	NS	NS	NS	NS		C12, C18
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 29	W 285	*	NS	NS	NS	NS	NS		C12, C18
			Use Group: TERRESTRIAL NON-FOOD CROP								
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 29	W 285	*	NS	NS	NS	NS	NS		C12, C18
PAPER/PAPER PRODUCTS			Use Group: INDOOR NON-FOOD								
Impregnation treatment., Not on label., Rollcoater.	RTU	NA	UC	*	NS	NS	NS	NS	NS		C12, C18
Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 34	W 170	*	NS	NS	NS	NS	NS		C12, C18

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Rate (AI Tex. @ Max. /crop /year /crop /year)	# Apps	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
PAPER/PAPER PRODUCTS (con't)											
Use Group: INDOOR NON-FOOD (con't)											
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 36	W 144	*	NS	NS	NS	NS	NS		C18, C24
	SC/L	W 40	W 160	*	NS	NS	NS	NS	NS		C12, C18
	SC/L	W 40	W 100	*	NS	NS	NS	NS	NS		C18, C24
Surface treatment., Not on label., Not on label.	NA	NA	UC	*	NS	NS	NS	NS	NS		C12, C18
PASTEURIZER/WARMER/CANNERY COOLING WATER SYSTEMS											
Use Group: INDOOR NON-FOOD											
Water treatment (recirculating system)., Continuous feed (initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 12	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 12	*	NS	NS	NS	NS	NS		A30, C18, C24
	SC/L	W 6.1	W 20	*	NS	NS	NS	NS	NS		A08, C12, C18
Water treatment (recirculating system)., Continuous feed (subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 7.2	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 3.1	W 10	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 9	*	NS	NS	NS	NS	NS		A30, C18, C24
Water treatment (recirculating system)., Intermittent (slug)(initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 12	*	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6	W 12	*	NS	NS	NS	NS	NS		A30, C18, C24
	SC/L	W 6.1	W 20	*	NS	NS	NS	NS	NS		A08, C12, C18
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Not applicable	SC/L	W 2.4	W 7.2	*	NS	NS	NS	NS	NS		A08, C12, C18

for this use.

SC/L	W 3.1	W 10	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
------	-------	------	---	----	----	----	----	----	----	---------------

SITE Application Type, Application Timing, Application Equipment – Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose /crop /year	# Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations		Use Limitations Codes
									Allowed	Disallowed	
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
PASTEURIZER/WARMER/CANNERY COOLING WATER SYSTEMS (con't)											
	SC/L	W 6	W 9	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
PULP/PAPER MILL WATER SYSTEMS											
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	RTU	W 26	W 211	*	NS	NS	NS	NS	NS	NS	C12, C18
Water treatment., Continuous feed (initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 4.1	W 15	*	NS	NS	NS	NS	NS	NS	C12, C18
	SC/L	W 11	W 22	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/L	W 12	W 24	*	NS	NS	NS	NS	NS	NS	A30, C12, C18
	SC/L	W 12	W 24	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/L	W 18	W 270	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/L	W 20	W 100	*	NS	NS	NS	NS	NS	NS	A30, C12, C18
	SC/L	W 40	W 100	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/S	W .6	W 9	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
Water treatment., Continuous feed (subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2	W 6.1	*	NS	NS	NS	NS	NS	NS	C12, C18
	SC/L	W 4.3	W 43	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/L	W 4.8	W 24	*	NS	NS	NS	NS	NS	NS	A30, C12, C18
	SC/L	W 12	W 18	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/L	W 18	W 67	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/L	W 20	W 75	*	NS	NS	NS	NS	NS	NS	A30, C12, C18
	SC/L	W 40	W 75	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/S	W .3	W 1.5	*	NS	NS	NS	NS	NS	NS	A08, C12, C18

SITE Application Type, Application Timing, Application Equipment – Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. /crop /year cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations		Use Limitations Codes
									Allowed	Disallowed	
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
PULP/PAPER MILL WATER SYSTEMS (con't)											
Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)											
Water treatment., Intermittent (slug)(initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 4.1	W 20	*	NS	NS	NS	NS	NS	NS	C12, C18
	SC/L	W 11	W 43	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/L	W 12	W 24	*	NS	NS	NS	NS	NS	NS	A30, C12, C18
	SC/L	W 12	W 24	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/L	W 18	W 270	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/L	W 20	W 100	*	NS	NS	NS	NS	NS	NS	A30, C12, C18
	SC/L	W 40	W 100	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/S	W .6	W 9	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
Water treatment., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2	W 10	*	NS	NS	NS	NS	NS	NS	C12, C18
	SC/L	W 4.3	W 22	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/L	W 4.8	W 12	*	NS	NS	NS	NS	NS	NS	A30, C12, C18
	SC/L	W 9	W 180	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/L	W 10	W 75	*	NS	NS	NS	NS	NS	NS	A30, C12, C18
	SC/L	W 12	W 18	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/L	W 40	W 75	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
	SC/S	W .3	W 9	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
Water treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	RTU	W 5.3	W 26	*	NS	NS	NS	NS	NS	NS	C12, C18
	SC/L	W 6.2	W 37	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	W 36	W 144	*	NS	NS	NS	NS	NS	NS	A30, C18, C24

SC/L W 40 W 160 * NS NS NS NS NS NS A30, C12, C18

SITE Application Type, Application Timing, Application Equipment – Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose @ Max. /crop /year	# Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations		Use Limitations Codes
									Allowed	Disallowed	
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
PULP/PAPER MILL WATER SYSTEMS (con't)											
	SC/L	W 40	W 100	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
SECONDARY OIL RECOVERY INJECTION WATER											
Use Group: AQUATIC NON-FOOD INDUSTRIAL											
Water treatment., Continuous feed (initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 1.7	W 57	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 4.9	W 24	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 11	W 43	*	NS	NS	NS	NS	NS	NS	A30, C12, C18
	SC/L	W 11	W 21	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
Water treatment., Continuous feed (subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 1.7	W 14	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 2.4	W 19	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 11	W 34	*	NS	NS	NS	NS	NS	NS	A30, C12, C18
	SC/L	W 11	W 17	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
Water treatment., Intermittent (slug)(initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 1.7	W 57	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 4.9	W 24	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 11	W 43	*	NS	NS	NS	NS	NS	NS	A30, C12, C18
	SC/L	W 11	W 21	*	NS	NS	NS	NS	NS	NS	A30, C18, C24
Water treatment., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 1.7	W 20	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 2.4	W 19	*	NS	NS	NS	NS	NS	NS	A08, C12, C18
	SC/L	W 11	W 34	*	NS	NS	NS	NS	NS	NS	A30, C12, C18
	SC/L	W 11	W 17	*	NS	NS	NS	NS	NS	NS	A30, C18, C24

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. /crop /year	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
SEWAGE SYSTEMS											
Use Group: AQUATIC NON-FOOD INDUSTRIAL											
Water treatment (recirculating system)., Continuous feed (initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 12	* NS	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6.1	W 20	* NS	NS	NS	NS	NS	NS		A08, C12, C18
Water treatment (recirculating system)., Continuous feed (subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 7.2	* NS	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 3.1	W 10	* NS	NS	NS	NS	NS	NS		A08, C12, C18
Water treatment (recirculating system)., Intermittent (slug)(initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 12	* NS	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 6.1	W 20	* NS	NS	NS	NS	NS	NS		A08, C12, C18
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 2.4	W 7.2	* NS	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 3.1	W 10	* NS	NS	NS	NS	NS	NS		A08, C12, C18
Water treatment., Intermittent (slug)(initial)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 6	W 12	* NS	NS	NS	NS	NS	NS		C18, C24
Water treatment., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 6	W 9	* NS	NS	NS	NS	NS	NS		C18, C24
SPECIALITY INDUSTRIAL PRODUCTS											
Use Group: INDOOR NON-FOOD											
Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/S	W 5	W 25	* NS	NS	NS	NS	NS	NS		C12, C18
Preservative treatment., Not on label.,	SC/L	W 36	W 144	* NS	NS	NS	NS	NS	NS		C18, C24

Not on label., Not Applicable., Not
applicable for this use.

SITE Application Type, Application Timing, Application Equipment – Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop /year	Max. Dose [(AI unless noted otherwise)/AI /crop /year cycle]	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION										
NON-FOOD/NON-FEED (con't)										
SPECIALITY INDUSTRIAL PRODUCTS (con't)										
	SC/L	W 40	W 160	* NS	NS	NS	NS	NS		C12, C18
	SC/L	W 40	W 100	* NS	NS	NS	NS	NS		C18, C24
WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS										
Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 34	W 170	* NS	NS	NS	NS	NS		C12, C18
	SC/S	W 5	W 25	* NS	NS	NS	NS	NS		C12, C18
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 36	W 144	* NS	NS	NS	NS	NS		C18, C24
	SC/L	W 40	W 160	* NS	NS	NS	NS	NS		C12, C18
	SC/L	W 40	W 100	* NS	NS	NS	NS	NS		C18, C24

LEGEND

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless : Minimum dose for a single application to a single site. System calculated. Microbial claims only.
noted otherwise)
Max. Appl. Rate (AI unless : Maximum dose for a single application to a single site. System calculated.
noted otherwise)
Soil Tex. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3
years" is expressed as "4/3 yr"
Max. Dose [(AI unless : Maximum dose applied to a site over a single crop cycle or year. System calculated.
noted otherwise)/A]
Min. Interv (days) : Minimum Interval between Applications (days)
Restr. Entry Interv (days) : Restricted Entry Interval (days)
PRD Report Date : LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products
registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have
data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES

RTU : LIQUID-READY TO USE
SC/L : SOLUBLE CONCENTRATE/LIQUID
SC/S : SOLUBLE CONCENTRATE/SOLID

ABBREVIATIONS

AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet,
briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part,
parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
U : Unknown whether PPM is given by weight or by volume
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

A08 : Preclean claim.
A30 : Preclean for heavily soiled areas.
C12 : Do not apply in marine and/or estuarine, oil fields, or discharge effluent into lakes, streams, ponds or public water. (NPDES license restriction)
C18 : Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority.
C24 : Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction)
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS, DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Bis(trichloromethyl) sulfone covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Bis(trichloromethyl) sulfone 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 Bis(trichloromethyl) Sulfone

REQUIREMENT		USE PATTERN	CITATION(S)
<u>PRODUCT CHEMISTRY</u>			
61-1	Chemical Identity	All	152327, 156932
61-2A	Start. Mat. & Mnfg. Process	All	162129
61-2B	Formation of Impurities	All	152327
62-1	Preliminary Analysis	All	152327, 156932
62-2	Certification of limits	All	152327
62-3	Analytical Method	All	152327
63-2	Color	All	152327
63-3	Physical State	All	152327
63-4	Odor	All	152327
63-5	Melting Point	All	152327
63-6	Boiling Point	All	Inapplicable
63-7	Density	All	152327
63-8	Solubility	All	152327, 42384501
63-9	Vapor Pressure	All	Inapplicable
63-10	Dissociation Constant	All	Inapplicable
63-11	Octanol/Water Partition	All	156932
63-12	pH	All	Inapplicable
63-13	Stability	All	152327
<u>ECOLOGICAL EFFECTS</u>			
71-1A	Acute Avian Oral - Quail/Duck	C, F	156817
71-2A	Avian Dietary - Quail	C, F	156818
71-2B	Avian Dietary - Duck	C	156820

Data Supporting Guideline Requirements for the Reregistration of Bis(trichloromethyl) Sulfone

REQUIREMENT		USE PATTERN	CITATION(S)
72-1A	Fish Toxicity Bluegill	C, F	156815
72-1C	Fish Toxicity Rainbow Trout	C, F	156814
72-2A	Invertebrate Toxicity	C, F	156816
72-3A	Estuarine/Marine Toxicity - Fish		40138102
72-3B	Estuarine/Marine Toxicity - Mollusk		40193201
<u>TOXICOLOGY</u>			
81-1	Acute Oral Toxicity - Rat	All	152875
81-2	Acute Dermal Toxicity - Rabbit/Rat	All	152875
81-3	Acute Inhalation Toxicity - Rat	All	42824801
81-4	Primary Eye Irritation - Rabbit	All	152875
81-5	Primary Dermal Irritation - Rabbit	All	152875
81-6	Dermal Sensitization - Guinea Pig	All	156813
81-8-SS	Acute Neurotoxicity - Rat		43156601, 43207901
82-2	21-Day Dermal - Rabbit/Rat		40050701
83-3A	Developmental Toxicity - Rat	L	40149101
83-3B	Developmental Toxicity - Rabbit	L	431566602, 43156603
84-2A	Gene Mutation (Ames Test)	C, F, L, M	152330, 152331, 152332, 152333, 152334
84-2B	Structural Chromosomal Aberration	C, F, L, M	42372701
84-4	Other Genotoxic Effects	C, F, L, M	152335
<u>ENVIRONMENTAL FATE</u>			
160-5	Chemical Identity	All	152327
161-1	Hydrolysis	All	41888701

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

-
- | MRID | CITATION |
|----------|---|
| 00152327 | Stauffer Chemical Co. (1985) Bis(trichloromethyl)Sulfone: N-1386 Technical: Product Chemistry. Unpublished study. 62 p. |
| 00152330 | Brusick, D. (1976) Mutagenicity Evaluation of Sample #300: N-1386 Technical: Final Report: Project No.: 2683: Stauffer No.: T-6083. Unpublished study prepared by Litton Bionetics, Inc. 13 p. |
| 00152331 | Brusick, D. (1976) Mutagenicity Evaluation of Sample #400: N-1386 Technical: Final Report: Project No.: 2683: Stauffer No.: T-6084. Unpublished study prepared by Litton Bionetics, Inc. 12 p. |
| 00152332 | Majeska, J. (1980) Mutagenicity Evaluation in Salmonella typhimurium: N-1386: Study No.: T-10042. Unpublished study prepared by Stauffer Chemical Co. 13 p. |
| 00152333 | Matheson, D. (1978) Mutagenicity Evaluation of N-1386 in the Mouse Lymphoma Forward Mutation Assay: Final Report: Project No.: 20839: Stauffer No.: T-6352. Unpublished study prepared by Litton Bionetics, Inc. 11 p. |
| 00152334 | Majeska, J. (1980) Mutagenicity Evaluation in Mouse Lymphoma Multiple Endpoint Test: Report No.: T-10138. Unpublished study prepared by Stauffer Chemical Co. 19 p. |
| 00152335 | Stetka, D. (1979) Mutagenicity Evaluation of N-1386 in the Sister Chromatid Exchange Assay in L5178Y Mouse Lymphoma Cells: Final Report: Project No.: 20990: Stauffer No.: T-6352. Unpublished study prepared by Litton Bionetics, Inc. 22 p. |
| 00152875 | Castles, T. (1978) Toxicity Evaluation: N-1386 Tech Composite: Acute Oral and Dermal LD50, Skin and Eye Irritation: Lab. Report No. T-6213. Unpublished compilation prepared by Stauffer Chemical Co. 40 p. |
| 00156813 | Davis, G.; Mutter, L.; Castles, T (1986) Dermal Sensitization Test with N-1386 Technical: T-12375. Unpublished study prepared by Stauffer Chemical Co. 54 p. |
| 00156814 | McAllister, W.; Bowman, J. (1985) Acute Toxicity of N-1386 to Rainbow Trout (Salmo gairdneri): Static Acute Toxicity Report #33759: T-12368. Unpublished study prepared by Analytical BioChemistry Laboratories, Inc. 51 p. |
| 00156815 | McAllister, W.; Bowman, J. (1985) Acute Toxicity of N-1386 to Bluegill Sunfish (Lepomis macrochirus): Static Acute Toxicity Report #33758: T-12369. Unpublished study prepared by Analytical BioChemistry Laboratories, Inc. 56 p. |
| 00156816 | Forbis, A.; Burgess, D. (1985) Acute Toxicity of N-1386 to Daphnia magna: Static Acute Toxicity Report #33760: T-12370. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 38 p. |

BIBLIOGRAPHY

MRID

CITATION

0156817	Grimes, J. (1986) N-1386: An Acute Oral Toxicity Study with the Mallard: Final Report: Project No.: 144-133: T-12371. Unpublished study prepared by Wildlife International Ltd. 17 p.
00156818	Grimes, J. (1986) N-1386: A Dietary LC50 Study with the Bobwhite: Final Report: Project No.: 144-131: T-12373. Unpublished study prepared by Wildlife International Ltd. 16 p.
00156820	Grimes, J. (1986) N-1386: A Dietary LC50 Study with the Mallard: Final Report: Project No.: 144-132: T-12372. Unpublished study prepared by Wildlife International Ltd. 16 p.
00156932	Stauffer Chemical Co. (19??) Product Chemistry Data: Racer 2-E. Unpublished study. 15 p.
00162129	Stauffer Chemical Co. (1986) Bis(trichloromethyl)sulfone: N-1386 Technical: Product Chemistry: Statement of Composition and Manufacturing Process. Unpublished compilation. 24 p.
40050701	Sauerhoff, M.; Mackenzie, K. (1987) 21-Day Dermal Toxicity Study in Rabbits with N-1386 Technical Biocide: HLA 6142-102. Unpublished study prepared by Hazleton Laboratories America, Inc. and Stauffer Chemical Co. 169 p.
40138102	Bowman, J. (1986) Acute Toxicity of N-1386 to Sheepshead Minnows (<i>Cyprinodon variegatus</i>): Project No. 35012. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 60 p.
40149101	Nemec, M. (1987) A Teratology in Rats with N-1386 Biocide Technical: Final Report: Laboratory Project ID. WIL-27038. Unpublished study prepared by WIL Research Laboratories, Inc. 252 p.
40193201	Surprenant, D. (1987) Acute Toxicity of N-1386 to Embryos-larvae of the Quahog Clam (<i>Mercenaria mercenaria</i>): Bionomics Report No. BW-87-3-2288. Unpublished study prepared by Springborn Bionomics, Inc. 16 p.
41888701	Bicking, M. (1991) Hydrolysis Testing For N-1386 Biocide: Lab Project Number: 46/90-ACC.3. Unpublished study prepared by Twin City Testing Corp. 31 p.
42372701	O'Loughlin, K. (1992) Bone Marrow Erythrocyte Micronucleus Assay of N-1386 Technical in Swiss-Webster Mice: Lab Project Number: 3377-C100-92. Unpublished study prepared by SRI International. 73 p.
42384501	Desai, L. (1992) Analytical Solubility Study of N-1386 Technical in Two Non-Polar Solvents.: Final Report: Lab Project Number: 92-GR-0002. Unpublished study prepared by Toxikon Corp. 163 p.
42824801	Ferguson, J. (1993) Acute Inhalation Toxicity Study of N-1386 Technical in Rats: Final Report: Lab Project Number: L08430. Unpublished study prepared by IIT Research Institute. 49 p.

BIBLIOGRAPHY

MRID

CITATION

-
- | | |
|----------|---|
| 3156601 | Beyrouthy, P. (1994) An Acute Study of the Potential Effects of Orally Administered N-1386 Technical on Behavior and Neuromorphology in Rats: Lab Project Number: 97243. Unpublished study prepared by Bio-Research Labs., Ltd. 592 p. |
| 43156602 | Mercieca, M. (1993) A Developmental Toxicity Study in Rabbits with N-1386 Technical: Final Report: Lab Project Number: 3243.19. Unpublished study prepared by Springborn Labs., Inc. 249 p. |
| 43156603 | Mercieca, M. (1994) A Range-Finding Developmental Toxicity Study in Rabbits with N-1386 Technical: Final Report: Lab Project Number: 3243.18. Unpublished study prepared by Springborn Labs., Inc. 127 p. |
| 43207901 | Beyrouthy, P. (1994) A Time of Peak Behavioral Effects Study of a Single Oral Administration of N-1386 Technical in Rats: Ancillary Study: Lab Project Number: 97242. Unpublished study prepared by Bio-Research Laboratories, Ltd. 79 p. |



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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-96).

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
- 3 - Requirements Status and Registrant's Response Form
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - List of Registrants Receiving This Notice
- 6 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 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, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

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

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

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

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

in parentheses to guide registrants to additional instructions provided in this Section. The options are:

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

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

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

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

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be

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

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

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

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

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the

required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

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

- a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."
- b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.
- c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

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

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

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

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

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.
2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.
3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.
4. Failure to submit on the required schedule acceptable data as required by this Notice.
5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.
7. Withdrawal of an offer to share in the cost of developing required data.
8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:
 - a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;
 - b. fulfill the commitment to develop and submit the data as required by this Notice; or
 - c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.
9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR 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 cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

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

Sincerely yours,

Lois A. Rossi, Division Director
Special Review and
Reregistration Division

Attachments

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

BIS(TRICHLOROMETHYL) SULFONE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 bis(trichloromethyl) sulfone. 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) a list of registrants receiving this DCI (Attachment 5) and (6) the Cost Share and Data Compensation Forms in replying to this bis(trichloromethyl) sulfone Product Specific Data Call-In (Attachment (6)). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Jeffrey Billingslea at (703) 308-8004.

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

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

RE: **Bis(trichloromethyl) sulfone**

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.

DATA CALL-IN RESPONSE Page 1 of 1

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

- Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.
- Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.
- Item 5. The study title associated with the guideline reference number is identified.
- Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.
- Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.
- Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.
- Item 9. **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.
1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
 2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product

is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section

III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE Page 1 of 2

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE Page 2 of 2

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS Page 1 of 2

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS Page 2 of 2

The EPA's Batching of Products Containing Bis(trichloromethyl) sulfone as the Active Ingredient for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient bis(trichloromethyl) sulfone, the Agency has batched products that can be considered similar in terms 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., liquid, wettable powder, aerosol, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

Table 1.

Batch	Reg. No.	Percent Active Ingredient	Form
1	3876-90	Bis(trichloromethyl) sulfone ...17.0% Methylenebis (thiocyanate) ...5.0%	liquid
	45017-27	Bis(trichloromethyl) sulfone ...17.0% Methylenebis (thiocyanate) ...5.0%	liquid
	68329-11	Bis(trichloromethyl) sulfone ...17.0% Methylenebis (thiocyanate) ...5.0%	liquid
2	3876-61	Bis(trichloromethyl) Sulfone ...20.0% Methylenebis (thiocyanate) ...5.0%	liquid
	68329-15	Bis(trichloromethyl) Sulfone ...20.0% Methylenebis (thiocyanate) ...5.0%	liquid

Table 2 lists the products the Agency was unable to batch. These products were considered not to be similar to other products for purposes of acute toxicity. The registrants of these products are responsible for meeting the acute toxicity data requirements for these products.

Table 2

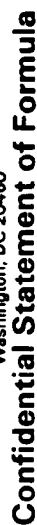
Reg. No.	Percent of Active Ingredients	Form
1706-162	Bis(trichloromethyl) sulfone ...5% 1-Alkyl-3-Amino-3-Aminopropane monoacetate ...36%	liquid
1706-169	Bis(trichloromethyl) sulfone ...5.3% 2-(Thiocyanomethylthio) Benzothiazole ...15.6%	liquid
45017-15	Bis(trichloromethyl) sulfone ...20.0% N-Alkyl Dimethyl Ammonium Chloride ...15.2%	liquid
45017-33	Bis(trichloromethyl) sulfone ...18.0% N-Alkyl Dimethyl Benzyl Ammonium Chloride ...15.2%	liquid
45017-36	Bis(trichloromethyl) sulfone ...2.5% <i>beta</i> -Bromo- <i>beta</i> -Nitrostyrene ...10.0%	liquid
45017-39	Bis(trichloromethyl) sulfone ...10.0% N-Alkyl Dimethyl Benzyl Ammonium Chloride ...8.0%	liquid
67869-14	Bis(trichloromethyl) sulfone ...98%	liquid
67869-15	Bis(trichloromethyl) sulfone ...34.3%	liquid
67869-16	Bis(trichloromethyl) sulfone ...49.0%	liquid

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE Page 1 of 2

Instructions for Completing the Confidential Statement of Formula

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

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



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

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

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

B.		Page
<input type="checkbox"/>	Basic Formulation	
<input type="checkbox"/>	Alternate Formulation	

See Instructions on Back

B. Page of

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



United States Environmental Protection Agency
Washington, DC 20460

**CERTIFICATION OF OFFER TO COST
SHARE IN THE DEVELOPMENT OF DATA**

Form Approved

OMB No. 2070-0106
2070-0057

Approval Expires 3-31-96

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

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

Certification:

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

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

United States Environmental Protection Agency
Washington, DC 20460



Form Approved
OMB No. 2070-0107,
2070-0057
Approval Expires
3-31-96

**CERTIFICATION WITH RESPECT TO
DATA COMPENSATION REQUIREMENTS**

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name

Company Number

Product Name

EPA Reg. No.

I Certify that:

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

☐ The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"
- That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature

Date

Name and Title (Please Type or Print)

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

Signature

Date

Name and Title (Please Type or Print)

The following is a list of available documents for bis(trichloromethyl) sulfone that may further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic

File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Jeffrey Billingslea at (703)-308-8004.

1. PR Notice 86-5.
2. PR Notice 91-2 (pertains to the Label Ingredient Statement).
3. A full copy of this RED document.
4. A copy of the fact sheet for Bis(trichloromethyl) sulfone.

The following documents are part of the Administrative Record for bis(trichloromethyl) sulfone and may 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 Chemical Status Sheet.

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

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.
2. EPA Acceptance Criteria