United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-95-035
December 1995

Reregistration Eligibility Decision (RED)

Hydroxypropyl methanethiosulfonate

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

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Moana Appleyard (703) 308-8175. Address any questions on required generic data to the Special Review and Reregistration Division representative Patrick Dobak (703) 308-8180.

Sincerely yours,

Lois Rossi, Division 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, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; 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 time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. 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, but are not required to, 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

HYDROXYPROPYL METHANETHIOSULFONATE

LIST C

CASE 3033

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

TABLE OF CONTENTS

HYDROXYPROPYL METHANETHIOSULFONATE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Ghulam Ali	Economic Analysis Branch
Steve Jarboe	Biological Analysis Branch
Cynthia Szymanski	Biological Analysis Branch

Environmental Fate and Effects Assessment

Ann Stavola	Ecological Effects Branch
Mary Frankenberry	Science Analysis and Coordination Staff
Rachelle Kudrik	Science Analysis and Coordination Staff
Jose Melendez	Environmental Fate and Groundwater Branch

Health Effects Assessment

Arliene Aikens	Risk Characterization and Analysis Branch
Tom Campbell	Occupational and Residential Exposure Branch
Paula Deschamp	Risk Characterization and Analysis Branch
Steven Malish	Toxicology Branch II

Registration Support

Valdis Goncarovs	Antimicrobial Program Branch
Tina Levine	Reregistration Support Branch
Shyam Mathur	Reregistration Support Branch

Risk Management

Kathleen Depukat	Accelerated Reregistration Branch
Patrick Dobak	Accelerated Reregistration Branch

Office of Compliance:

Carol Buckingham	Agriculture and Ecosystem Division

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_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration

GLOSSARY OF TERMS AND ABBREVIATIONS

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
PHI	Preharvest Interval
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 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

As required under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended in 1988, the U.S. Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide active ingredient hydroxypropyl methanethiosulfonate (HPMTS). This decision includes a comprehensive reassessment of the required target data base and use patterns of currently registered products. The Agency compared its risk assessment to current science and regulatory policies. The Agency has determined that the uses as described below will not cause unreasonable risk to humans or the environment and all uses are eligible for reregistration. Where appropriate, the Agency has imposed additional use restrictions and precautionary statements for product labels to reduce risks to human health and the environment.

Use Patterns

HPMTS is a microbiocide/microbiostat used to control slime-forming algae, bacteria, and fungi in commercial/industrial water cooling systems, industrial processing water, pulp/paper mill water systems, and is used as a preservative in industrial coatings, emulsions, paints and wet-end additives/industrial processing chemicals. It is applied by direct pouring and metered application.

Human Health Assessment

From its review of the toxicology data, the Agency concluded that HPMTS is mildly to moderately toxic when administered by oral or dermal routes. The chemical is corrosive and is considered to be a severe dermal and eye irritant. The chemical caused delayed contact hypersensitivity in the guinea pig dermal sensitization studies. The subchronic dermal LOEL was determined to be 250 mg/kg/day for systemic toxicity and 10 mg/kg/day for dermal toxicity. A battery of mutagenicity studies was negative for mutagenic effects. Two developmental toxicology studies were reviewed. The rat maternal LOEL and NOEL were determined to be 30 mg/kg/day and 10 mg/kg/day, respectively. The rabbit maternal LOEL and NOEL were determined to be 4.0 mg/kg/day and 0.75 mg/kg/day, respectively.

No dietary exposure to HPMTS is expected from the current use patterns. Although corrosiveness and dermal sensitization were identified as potential effects, significant occupational exposures are not expected. Therefore, quantitative assessments of exposures and risks were deemed unnecessary and not conducted. To mitigate the potential risks of corrosiveness and dermal sensitization to workers, minimum (baseline) personal protective equipment (PPE) is being required for the handling of concentrated products. Non-occupational exposures are not expected.

Environmental Assessment

HPMTS is moderately toxic to slightly toxic to avian species on an acute and subacute oral dietary basis, slightly toxic to fish, and moderately toxic to aquatic invertebrates. Current uses of HPMTS are expected to result in minimal exposure or risk to the environment. Therefore, no additional environmental risk mitigation measures are being imposed at this time.

Product Reregistration

The Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document for all products containing HPMTS. These data include product chemistry and acute toxicity testing for each registration. After reviewing these revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister each associated 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 2-hydroxypropyl methanethiosulfonate (HPMTS). The document consists of six sections. Section I is the introduction. Section II describes HPMTS, 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 HPMTS. Section V discusses the reregistration requirements for HPMTS. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** HPMTS
- **Chemical Name:** 2-hydroxypropyl methanethiosulfonate
- **Chemical Family:** Thiosulfonates
- **CAS Registry Number:** 30388-01-3
- **OPP Chemical Code:** 35604
- **Empirical Formula:** $C_4H_{11}S_2O_3$
- **Trade and Other Names:** S-(2-hydroxypropyl) thiomethanesulfonate
- **Basic Manufacturer:** Buckman Labs

B. Use Profile

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

For 2-hydroxypropyl methanethiosulfonate:

Type of Pesticide: Microbiocide/microbiostat (slime-forming algae, bacteria and fungi), Bacteriostat.

Use Sites: AQUATIC NON-FOOD INDUSTRIAL

Commercial/Industrial Water Cooling Systems
Industrial Processing Water
Pulp/Paper Mill Water Systems

INDOOR NON-FOOD

Industrial Coatings
Resin/Latex/Polymer Emulsions

Latex/Oil/Varnish Paints (Applied Film)
Wet-End Additives/Industrial Processing Chemicals

Target Pests: Slime-forming algae, bacteria and fungi

Formulation Types Registered:

TYPE: End-use, Manufacturing-use

FORM: Soluble Concentrate/Liquid, Ready-To-Use Solution /Liquid

PURITY: Single Active Ingredient
TGAI: 80%
End-Use Products: 5-80%
Multiple Active Ingredients
End-Use Products: 11.7-28%

Method and Rates of Application: Equipment - Direct pour, metered application (registrant must specify on labeling). For Rates of application see Table 1 below.

Timing - During manufacture, Not specified (registrant must supply on labeling).

Table 1 - Method and Rate

TREATMENT TYPE	SYSTEM TYPE	RATE (ppm AI by weight)
Water (recirculating)	Commercial/Industrial Cooling Systems	0.4 to 8.5
Water (recirculating)	Industrial Processing	0.4 to 4.3
Water	Pulp/Papermill	0.176 to 281
Industrial Preservative	Industrial Coatings	400 to 4050
Industrial Preservative	Resin/Latex/Polymer Emulsions	400 to 4050
Industrial Preservative	Latex/Oil/Varnish Paints (applied film)	280 to 2800
Industrial Preservative	Wet-End Additives/ Industrial Processing Chemicals	400 to 4050

Use Practice Limitations: NPDES license restriction.

C. Estimated Usage of Pesticide

Information about the use and percentage of sites treated with HPMTS is not readily available. However, the aggregate annual use of this pesticide is considered to be quite small in the United States, based on proprietary sources.

D. Regulatory History and Data Requirements

Products containing HPMTS as an active ingredient were registered in the United States as early as 1968. Currently, nine products are registered to one registrant for the uses described above.

In March, 1987, the Agency issued the Anti-Microbial Data Call-In Notice for toxicity and exposure data requirements for this active ingredient and other antimicrobials. Additionally, the Agency issued a September, 1992 Phase IV Data Call-In requiring studies on product chemistry, human health, and ecological effects data to support the uses listed. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Molecular Weight: 171.25

Color: Light yellow/brilliant yellow

Odor: Strong sour, pungent vegetable-like odor

Boiling Point: 164°C

Density: 1.2893 at 22°C

Solubility:

Table 2 - HPMTS Solubility	
Solvent	**Solubility**
Ethanol	Miscible in all proportions
Hexane	< 16 mg in 100 ml
C_{8-18} Fatty Acids	Mean fat solubility at 37°C is 5.42 + 0.04 g/100 g
Water	At concentrations > 40%, soluble at any concentration; at concentrations < 40%, not completely soluble

Vapor Pressure: 1.40 mm Hg at 20°C and 1.70 mm Hg at 25°C.

pH: 3.7 at 22°C.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on HPMTS is adequate to support reregistration eligibility.

a. Acute Toxicity

Table 3 - Acute Human Health Studies		
Type of Study	**Results [mg/kg]**	**Toxicity Category**
Acute Oral - rat	LD_{50} ♂ = 548, ♀ = 224	II
Acute Dermal - rat	LD_{50} ♂ & ♀ = > 2000	III
Acute Inhalation	Waived	NA
Primary Eye Irritation*	Waived	I
Primary Dermal Irritation*	Waived	I
Dermal Sensitization - guinea pig*	Sensitizer	NA

* This study is a requirement for manufacturing-use and end-use products (40 CFR 158). NA = not applicable

In an acute oral toxicity study in the rat, HPMTS (81.45% a.i.) was administered by oral gavage to 5 animals/sex and observed for 14 days.

Compound related clinical signs presented were transient hypoactivity and staggered gait in surviving rats. Reddening of glandular stomach mucosa and the gastrointestinal tract were seen. (MRID 41634701)

In an acute dermal toxicity study in the rat, HPMTS (81.45% a.i.) was administered by dermal application at 2 gm/kg (limit dose) to 5 animals/sex for 14 days. Dermal irritation was present in all animals and included erythema, edema, fissuring, hemorrhaging, blanching, atonia, and a leathery feel to the skin. The dose used in the study was the limit dose specified in the guidelines. (MRID 41632401)

An acute inhalation study was waived because the absence for potential for inhalation exposure (no respirable particles) is indicated by the current HPMTS use pattern. The primary dermal irritation and eye irritation studies were waived because HPMTS was corrosive in the 14 and 90-day dermal studies.

In a guinea pig dermal sensitization study, HPMTS (40% a.i.) was found to be a sensitizer. HPMTS caused delayed contact hypersensitivity. (MRID 42349201)

b. Subchronic Toxicity

In a two-week, repeat dose (range finding), dermal toxicity study conducted in the rat, HPMTS (79.67% a.i.) as a 30% solution [in distilled water] was applied to 5 animals/sex at doses of 0, 100, 250, 500, 750 or 1000 mg/kg/day, for 6 hours/day, 5 days/week for 14 days. Control animals received distilled water. A dose related irritation was presented with eschar, and exfoliation at 500 to 750 mg/kg/day. The dermal no observable effect level (NOEL) was < 100 mg/kg/day (lowest dose tested). (MRID 40747102)

In a dermal toxicity study in rats, HPMTS (79.67% a.i.), at a concentration of 5.0%, was applied to approximately 10% of the body surface area of 10 animals/sex at doses of 0, 10, 50 or 250 mg/kg/day. Exposure was for 6 hours/day, 5 days/week for 91 days. Control animals received distilled water under the same experimental conditions.

Slight treatment-related reductions in body weight and food consumption were found in the high dose males. Compound-related reductions in erythrocyte counts, hematocrit and hemoglobin occurred in both high dose males and females as compared to the respective controls. A slight but significant increase in the platelet count occurred in the high dose in both sexes.

Compound and dose-related dermal irritation was found in the treated animals at the application site. The severity of the irritation ranged from minimal in the low-dose animals to severe in the high-dose animals of both sexes. Surface exudate, dermal inflammation, and fibrosis occasionally accompanied the ulceration in the high-dose animals. Microscopic examination confirmed the gross observation of the skin in the high dose animals as ulceration and acanthotic epidermal thickening.

Based on changes in body weights and hematology at the high dose, the lowest observable effect level (LOEL) for systemic toxicity is 250 mg/kg/day and the NOEL is 50 mg/kg/day. The LOEL for dermal toxicity is 10 mg/kg/day, the lowest dose tested. (MRID 40974701)

c. Chronic Toxicity/Carcinogenicity

Chronic toxicity and carcinogenicity studies are not required for HPMTS because the non-food use pattern scenarios currently registered are not likely to result in significant human exposure.

d. Developmental Toxicity

A developmental toxicity study conducted in the rat, evaluated HPMTS (79.67% a.i.) at doses of 0, 10, 30 or 75 mg/kg/day by gavage from gestation days 6 to 15. The maternal NOEL was 10 mg/kg/day and the maternal LOEL was 30 mg/kg/day based on salivation, rales, and oral-nasal discharge. The developmental NOEL was 10 mg/kg/day and the developmental LOEL was 30 mg/kg/day based on reduced fetal weight. (MRID 41010501)

Another developmental toxicity study conducted by gavage in the rabbit, evaluated HPMTS (79.67%) at doses of 0, 0.75, 4.0 or 7.5 mg/kg/day from gestation days 6 to 18. The maternal NOEL and LOEL were 0.75 mg/kg/day and 4.0 mg/kg/day, respectively, based on decreased body weights. The developmental NOEL was $\geq$7.5 mg/kg/day (HDT). (MRID 41010401)

e. Reproductive Toxicity

A reproductive toxicity study is not required to support the currently registered non-food uses of HPMTS because the use pattern scenarios are not likely to result in significant human exposure.

f. Mutagenicity

In a gene mutation (Reverse Mutation) study, HPMTS (79.67% a.i.) did not produce gene mutation in an Ames assay in which *S. typhimurium* (TA98, TA100, TA1535 and TA1538) bacteria were tested without activation up to 0.25 µl/plate and with activation up to 0.5 µl/plate. Concentrations ≥0.5 µl/plate produced cytotoxicity. (MRID 40229601)

HPMTS (80% a.i.) was negative both with and without activation in a Sister Chromatid Exchange (SCE) *In Vitro*/CHO assay when assayed at concentrations into the toxic range (16.7 µg/ml). (MRID 40420201)

In the DNA Damage/Repair in Primary Rat Hepatocytes study, HPMTS (80% a.i.) was negative for inducing UDS at concentration levels into the toxic range (100 µg/ml and higher). (MRID 40420202)

g. Metabolism

A metabolism study is not required to support non-food uses of HPMTS because of the expected absence of oral exposure and because the current use pattern scenarios are not likely to result in significant human exposure.

h. Toxic Endpoints of Concern

Based on HPMTS' target database for toxicology, the Agency concludes there are no toxicological endpoints of concern for HPMTS. While technical HPMTS has been demonstrated to be corrosive and lead to dermal sensitization from acute exposures, these concerns are more appropriately addressed during product reregistration after a re-assessment of each product's acute toxicity.

Reference Dose (RFD)

A reference dose was not established for HPMTS, based on the non-food use patterns and exposure profile (The Agency's Office of Pesticide Programs RfD Committee report, February 15, 1995)

WHO/JMPR Status

The World Health Organization/Joint Meeting on Pesticide Residues committee has not reviewed this pesticide.

2. Exposure and Risk Assessment

a. Dietary Exposure and Risk Assessment

There are no registered food uses of HPMTS, therefore, a dietary exposure and risk assessment are not required.

b. Occupational and Residential Exposure and Risk Assessment

An occupational/residential exposure assessment is required for an active ingredient if: (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (M/L/A) during use or to persons entering treated sites after application is complete. Since toxicology endpoints of concern, except for corrosiveness and dermal sensitization from acute exposures, were not identified for occupational/residential exposures, an occupational/residential M/L/A exposure analysis and quantitative risk assessment are not warranted at this time.

The Agency has determined that products containing HPMTS labeled and used as specified in this RED will not pose significant risk to humans. The most significant occupational concerns are for corrosiveness and dermal sensitization from acute exposures. The use of minimal (baseline) PPE , including chemical resistant gloves and apron and faceshield, will adequately mitigate these hazards.

A short term (1 to 7 days) occupational/residential risk assessment is not required, since results from the 14-day dermal toxicity study do not indicate any toxicological endpoints appropriate for use in the standard occupational or residential exposure assessments. Also, an intermediate (1 week to several months) occupational/residential risk assessment is not required based on a comparison of the 90-day repeated-dose dermal toxicity and the oral developmental toxicity studies conducted in rats. In these studies, the LOEL(s) were 250 mg/kg/day and 30 mg/kg/day, respectively. On the basis that the dermal LOEL was significantly higher, it was determined that dermal absorption of HPMTS is limited. Also, inhalation exposures are not expected because respirable particles are not anticipated to be produced from the application methods (open-pour or metered pump) and because of the chemical's low vapor pressure.

Most of HPMTS' use and exposure are associated with industrial applications. Additionally, people who apply HPMTS treated paint or who reside or work in buildings which have painted with such paint may also be exposed to HPMTS. However, because of the Agency's conclusion on HPMTS' risks from subchronic exposures and because of HPMTS' low vapor pressure, the Agency believes risks to these individuals are very low.

C. Environmental Assessment

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of HPMTS 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); one subacute dietary study (LC_{50}) on one species (preferably the bobwhite quail). The available information is summarized in the following tables:

Table 4 - Avian Acute Oral Toxicity Findings

Species	% A.I.	LD_{50} mg/kg	Toxicity Category
Mallard Duck	79.82	> 474.4 mg/kg	moderately toxic

Although the avian acute oral study yielded some information, it was not considered acceptable because the birds regurgitated shortly after dosing. The registrant is performing a new study in order to fulfill guideline requirements.

Table 5 - Avian Subacute Dietary Toxicity Findings

Species	% A.I.	LC_{50} ppm	Toxicity Category
Northern Bobwhite Quail	79.82	> 3991	slightly toxic
Mallard Duck	79.82	> 3991	slightly toxic

The results from the subacute study and the supplemental results of the acute oral study indicate that HPMTS is slightly to moderately toxic to avian species on an acute oral and subacute dietary basis. (MRID 249523 for all three)

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Since the currently

registered uses are for indoor use only, repeated exposures are not expected and chronic avian studies are not required.

(3) 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} is used to indicate toxicity to mammals. The LD_{50}, as reported in Table 3 above, indicates that HPMTS is slightly toxic to small mammals on an acute oral basis. No additional testing on mammals is required for these use patterns. (MRID 41634701)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

(a) Acute

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required for industrial microbiocides is one freshwater fish toxicity study on the technical grade of the active ingredient. The study should preferably use the rainbow trout (cold water species) or the bluegill sunfish (warm water species). The available information is summarized in the following table.

Table 6 - Freshwater Fish Acute Toxicity Findings

Species	% A.I.	LC_{50} (ppm)	Toxicity Category
Rainbow trout	81.45	28.0	slightly toxic
Bluegill sunfish	81.45	38.2	slightly toxic

The results of the 96-hour acute toxicity studies indicate that HPMTS is slightly toxic to both cold and warm water fish. The guideline requirements are fulfilled. (MRIDs 41733203 and 41733201, respectively)

(b) Chronic

The fish early life-stage and fish life-cycle tests are not required because the products are not applied directly to water or expected to be transported to water from the intended use site. Additionally, the fish early life-stage test is not required because the LC_{50} in this case is greater than 1 mg/L.

(2) Freshwater Invertebrates

(a) Freshwater Invertebrates, Acute

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. The results of the toxicity findings are presented in the table below.

Table 7 - Freshwater Invertebrate Toxicity Findings

Species	% A.I.	EC_{50} (ppm)	Toxicity Category
Daphnia magna	79.82	3.13	moderately toxic

There is sufficient information to characterize HPMTS as moderately toxic to aquatic invertebrates. The guideline requirement is fulfilled. (MRID 41733202)

(b) Freshwater Invertebrates, Chronic

The same conditions for chronic testing to freshwater fish also apply to aquatic invertebrates as discussed in (1.b.) above. Chronic aquatic invertebrate studies are not required for HPMTS.

(3) Estuarine and Marine Animals

(a) Acute

Although estuarine/marine testing was originally required, a waiver for those data requirements was subsequently granted in response to the registrants' incorporation of a statement on all HPMTS labels restricting

the discharge of HPMTS directly or indirectly into estuarine or marine environments to NPDES permitted discharges.

(b) Chronic

The same conditions for chronic testing to freshwater fish and aquatic invertebrates also apply to estuarine and marine animals as discussed in (1.b.) above. Therefore, the chronic estuarine/marine studies for HPMTS are not required.

c. Toxicity to Plants

Terrestrial and aquatic plant testing are currently not required, in most cases, for industrial microbiocides, including HPMTS.

2. Environmental Fate

a. Environmental Fate Assessment

Due to the current use patterns for HPMTS, the Agency requires only a hydrolysis study for the reregistration target data base.

b. Environmental Fate and Transport

(1) Degradation

Hydrolysis

[2-^{14}C]2-hydroxypropyl methanethiosulfonate, at 101 mg/L, hydrolyzed with half-lives of > 30 days at pH 5, 8.5-9.9 hours at pH 7, and 5.4-6.1 minutes at pH 9 in sterile aqueous buffered solutions at 25°C in the dark for up to 30 days. Two major degradates were observed.

One degradate, di-(2-hydroxyisopropyl)disulfide, was a maximum of 24-29% of the recovered at 20 or 30 days in the pH 5 solution; 61-64% of the recovered at 24.5 hours in the pH 7 solution; and 63-66% at 15.0-15.2 minutes in the pH 9 solution. The other major degradate, di-(2-hydroxypropyl) disulfide, was a maximum of 5.9% of the recovered at 22-30 days in the pH 5 solution; 10-12% at 24.5 hours in the pH 7 solution; and 8.17% at 10.1-15.2 minutes in the pH 9 solution. This study was found to be

acceptable and satisfies all data requirements for HPMTS. (MRID 41475207)

3. Exposure and Risk Characterization

The Agency requires only a limited set of ecotoxicology and environmental fate studies for microbicides. HPMTS is slightly to moderately toxic to birds and aquatic invertebrates. While the hazard to aquatic organisms from HPMTS has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments from its industrial aquatic uses are regulated under the NPDES permitting program of EPA's Office of Water. The Agency currently requires that labels for all HPMTS products require that discharges to aquatic environments comply with an NPDES permit.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

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

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

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

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient HPMTS, the Agency has sufficient information on the health effects of HPMTS and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that HPMTS products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing HPMTS for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of HPMTS, as specified in this document, are eligible for reregistration.

3. Endangered Species Protection

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

C. Regulatory Position

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

1. Risk Mitigation Measures/ Labeling Rationale

Minimum (baseline) PPE requirements

If EPA has no special concerns about the acute effects of 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 guidelines.

If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most 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.

Occupational-Use Products

Primary Occupational Handlers: EPA has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for HPMTS. EPA notes that HPMTS has the potential to cause severe (corrosive) effects to the skin and eyes and is a dermal sensitizer. No traditional risk assessment needs to be performed to assess risks due to corrosiveness and sensitization. However, EPA believes that primary occupational handlers who are exposed to concentrated end-use products should wear PPE in addition to the baseline long-sleeve shirt, long pants, shoes, and socks. Therefore, EPA is requiring the use of chemical-resistant gloves, chemical-resistant apron, and face shield for such handlers.

Secondary Occupational Handlers: At this time, EPA believes that risks from skin/eye corrosiveness and dermal sensitization would be acceptable for secondary occupational handlers, since the HPMTS in such products as paints and adhesives is very diluted, usually far less than one percent.

Homeowner-Use Products

Primary Homeowner Handlers: All HPMTS end-use pesticide products are intended primarily for occupational use.

Secondary Homeowner Handlers: At this time, EPA believes that risks from inhalation exposures and skin/eye corrosiveness would be acceptable for adhesives, metal-cutting fluids, wood products, and textiles is very diluted, usually far less than one percent.

2. Entry Restrictions

EPA is not establishing entry restrictions for end-use products containing HPMTS because the use pattern scenarios are not likely to result in significant human exposure to HPMTS.

3. Addition and Retention of Other Label Statements

The Agency believes it is prudent to require additional use precautions to afford product users increased protection from unnecessary exposure to HPMTS. For similar reasons the Agency is retaining current worker and environmental restrictions and precautions for risk reduction. Also, all products must have their labels improved with adequate and specific directions for use including application methods, equipment, timing, and rates. These label requirements are specified below in Section V.

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 HPMTS for the above eligible uses has been reviewed and determined to be substantially complete. No additional generic data are required at this time. The registrant is in the process of performing an avian acute oral study to confirm the potential hazards to avian species. The study is due for submission to the Agency by August 19, 1996.

2. Labeling Requirements for Manufacturing-Use Products

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

"Only for formulation into a microbiocide/microbiostat, bacteriostat for the following uses: Commercial/Industrial Recirculating Water Cooling Systems, Industrial Processing Water, Pulp/Paper Mill Water Systems, Industrial Coatings, Resin/Latex/Polymer Emulsions, Latex/Oil/Varnish Paints, and Wet-End Additives/Industrial Processing Chemicals."

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

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

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

Effluent Discharge Labeling Statements

"Do not use in facilities discharging directly or indirectly to the estuarine or marine environment."

To reduce environmental risk from HPMTS discharge and disposal, product labels must include the statements pertaining to effluent discharge under the NPDES permitting system (refer to PR Notice 93-10) and disposal under any applicable federal laws after the above statement.

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. Occupational Labeling PPE Requirements for Pesticide Handlers

Sole-active-ingredient end-use products that contain HPMTS must be revised to remove any conflicting PPE requirements on their current labeling.

Multiple-active-ingredient end-use products that contain HPMTS must compare the handler personal protective equipment requirements set forth in this section to the PPE requirements on their current labeling and retain the more protective. For guidance on which PPE is considered more protective, see PR Notice 93-7.

The PPE for each HPMTS occupational end-use product must be established based on the acute toxicity of each end-use product. If the end-use product is classified as toxicity category I or II for acute eye irritation potential (or the eye irritation study is waived due to corrosiveness), protective eyewear must be required for all handlers of HPMTS. If the end-use product is classified as toxicity category I or II for acute skin irritation potential (or the skin irritation study is waived due to corrosiveness), chemical-resistant gloves and a chemical-resistant apron must be required for all handlers of HPMTS.

Minimum (Baseline) PPE/Engineering Control Requirements for Products Intended Primarily for Occupational Use

The minimum (baseline) PPE for occupational uses of HPMTS end-use products is:

> "Mixers, loaders, and others exposed to the concentrate must wear:
> --Long-sleeve shirt and long pants,
> --Chemical-resistant gloves*,
> --shoes plus socks,
> --chemical-resistant apron, and
> --face shield."

* For the glove statement, use the statement established for HPMTS through the instructions in Supplement Three of PR Notice 93-7.

However, the corrosiveness and penetration of HPMTS itself must be considered and appropriate chemical-resistant materials must be listed.

Placement in Labeling

The personal protective equipment language 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.

b. Other Label Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing HPMTS.

(1) 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).

(2) Application restrictions

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

(3) Skin sensitizer statement

"This product may cause skin sensitization reactions in some people."

(4) User safety recommendations

For all HPMTS end-use products:

"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."

For HPMTS end-use products "gloves" if gloves are required PPE:

"Users should remove Personal Protective Equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly."

(5) Effluent Discharge Labeling Statements

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

C. Existing Stocks

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

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

VI. APPENDICES

APPENDIX A

Case 3033[Busan 74 (*)] **Chemical 035604[S-(2-Hydroxypropyl) thiomethanes]**

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. Rate Max. # Apps /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED													
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 400	W 4000	*	NS	NS	NS	NS	NS	NS			
	SC/L	W 400	W 4000	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W 405	W 4050	*	NS	NS	NS	NS	NS	NS			
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS			Use Group: AQUATIC NON-FOOD INDUSTRIAL										
Water treatment (recirculating system), Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	SC/L	W 2	W 8.1	*	NS	NS	NS	NS	NS	NS			A08, C23
	SC/L	W 2.1	W 8.3	*	NS	NS	NS	NS	NS	NS			A08, C23
	SC/L	W 2.1	W 8.5	*	NS	NS	NS	NS	NS	NS			A08, CAH, CAL
Water treatment (recirculating system), Intermittent (slug)(subsequent), Not on label, Not Applicable, Not applicable for this use	SC/L	W .4	W 8.1	*	NS	NS	NS	NS	NS	NS			A08, C23
	SC/L	W .42	W 8.3	*	NS	NS	NS	NS	NS	NS			A08, C23
	SC/L	W .43	W 8.5	*	NS	NS	NS	NS	NS	NS			A08, CAH, CAL
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 400	W 4000	*	NS	NS	NS	NS	NS	NS			
	SC/L	W 400	W 4000	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W 405	W 4050	*	NS	NS	NS	NS	NS	NS			

APPENDIX A REPORT

Case 3033[Busan 74 (*)] **Chemical 035604[S-(2-Hydroxypropyl) thiomethanes]**

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. Tex.	# Apps Max. @ Max. Dose /crop	/year cycle	Max. Dose [(AI unless noted otherwise)/A] /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)													
INDUSTRIAL PROCESSING 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 .4	W 4	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W .42	W 4.2	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W .43	W 4.3	*	NS	NS	NS	NS	NS	NS			CAH, CAL
PAINTS, LATEX/OIL/VARNISH (APPLIED FILM)			Use Group: INDOOR NON-FOOD										
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L	W 280	W 2800	*	NS	NS	NS	NS	NS	NS			
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 2171	V 2171	*	NS	NS	NS	NS	NS	NS			
PULP/PAPER MILL WATER SYSTEMS			Use Group: AQUATIC NON-FOOD INDUSTRIAL										
Water treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	W .1755	W 1.755	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W .4	W 4	*	NS	NS	NS	NS	NS	NS			
	SC/L	W .4	W 4	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W .405	W 4.05	*	NS	NS	NS	NS	NS	NS			
	SC/L	W 28	W 281	*	NS	NS	NS	NS	NS	NS			
WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS			Use Group: INDOOR NON-FOOD										
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L	W 400	W 4000	*	NS	NS	NS	NS	NS	NS			

APPENDIX A REPORT

Case 3033[Busan 74 (*)] **Chemical 035604[S-(2-Hydroxypropyl) thiomethanes]**

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 @ Max. Rate /crop /year cycle	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)

WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS (con't) Use Group: INDOOR NON-FOOD (con't)

SC/L	W 400	W 4000	*	NS	NS	NS	NS	NS	NS			C23
SC/L	W 405	W 4050	*	NS	NS	NS	NS	NS	NS			

APPENDIX A REPORT

Case 3033[Busan 74 (*)] **Chemical 035604[S-(2-Hydroxypropyl) thiomethanes]**

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LEGEND
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Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate, Maximum Number of Applications at Maximum Rate, Maximum Dose per Crop Cycle or per Year, Minimum Interval Between Applications (Days), Restricted Entry Interval (Days), Allowed/Disallowed Geographical Areas, Use Limitations Codes.

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise) : Minimum dose for a single application to a single site. System calculated. Microbial claims only.

Max. Appl. Rate (AI unless noted otherwise) : Maximum dose for a single application to a single site. System calculated.

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 noted otherwise)/A] : Maximum dose applied to a site over a single crop cycle or year. System calculated.

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
SC/L : SOLUBLE CONCENTRATE/LIQUID

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.

APPENDIX A REPORT

Case 3033[Busan 74 (*)] **Chemical 035604[S-(2-Hydroxypropyl) thiomethanes]**

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USE LIMITATIONS CODES (Cont.)

C18 : Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW).

C23 : NPDES license restriction.

C24 : Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction)

CAH : Do not discharge into lakes, streams, ponds, or public water unless in accordance with NPDES Permit.

CAL : Do not contaminate water, food or feed.

* 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 Hydroxypropyl methanethiosulfonate covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Hydroxypropyl methanethiosulfonate 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 HPMTS

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	F,M	
61-2A	**Start. Mat. & Mnfg. Process**	F,M	43420501
61-2B	**Formation of Impurities**	F,M	43420501
62-1	**Preliminary Analysis**	F,M	41680902
62-2	**Certification of limits**	F,M	
62-3	**Analytical Method**	F,M	41680902
63-2	**Color**	F,M	41680903
63-3	**Physical State**	F,M	41608903
63-4	**Odor**	F,M	41680903
63-6	**Boiling Point**	F,M	41680903
63-7	**Density**	F,M	41680903
63-8	**Solubility**	F,M	43420101
63-9	**Vapor Pressure**	F,M	42287901
63-12	**pH**	F,M	41680903
63-13	**Stability**	F,M	
63-17	**Storage stability**	F,M	42766601
63-20	**Corrosion characteristics**	F,M	42766601

Data Supporting Guideline Requirements for the Reregistration of HPMTS

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	F	
71-2A	**Avian Dietary - Quail**	F	41629801, 126121, 126122
71-2B	**Avian Dietary - Duck**	F	249523
72-1A	**Fish Toxicity Bluegill**	F	41733201
72-1C	**Fish Toxicity Rainbow Trout**	F	41733203
72-2A	**Invertebrate Toxicity**	F	41733202
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	F,M	41634701
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	F,M	41632401
81-6	**Dermal Sensitization - Guinea Pig**	F,M	42349201
82-3	**90-Day Dermal - Rodent**	F,M	40974701
83-3A	**Developmental Toxicity - Rat**	F,M	41010501
83-3B	**Developmental Toxicity - Rabbit**	F,M	41010401
84-2A	**Gene Mutation (Ames Test)**	F,M	40229601
84-2B	**Structural Chromosomal Aberration**	F,M	40420201
84-4	**Other Genotoxic Effects**	F,M	40420202
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
None	**Required**		

Data Supporting Guideline Requirements for the Reregistration of HPMTS

REQUIREMENT		USE PATTERN	CITATION(S)
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	F,M	43420501
161-1	**Hydrolysis**	F	42771801
RESIDUE CHEMISTRY			
None	**Required**		

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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00126120 Hazleton Raltech, Inc. (1982) Avian Single-dose Oral LD50: Mallard Duck (Anas platyrhynchos): Study No. 6026-119. Final rept. (Unpublished study received Feb 15, 1983 under 1448-78; submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:249523-B)

00126121 Hazleton Raltech, Inc. (1982) Avian Dietary LC50: Bobwhite Quail (Colinus virginianus): Study No. 6026-121. Final rept. (Unpublished study received Feb 15, 1983 under 1448-78; submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:249523-C)

00126122 Hazleton Raltech, Inc. (1982) Avian Dietary LC50: Mallard Duck (Anas platyrhynchos): Study No. 6026-120. (Unpublished study received Feb 15, 1983 under 1448-78; submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:249523-D)

40229601 Jagannath, D.R. [1987] "Mutagenicity Test on HPMTS in the Ames *Salmonella*/Microsome Reverse Mutation Assay", [HLA 9786-0-401]; Hazleton Laboratories America, Inc., Kensington, MD; [HED Doc. No. 010670].

40420201 Murli, H. [1987] "Mutagenicity Test on HPMTS in an **In Vitro** Sister Chromatid Exchange (SCE) Assay Measuring Sister Chromatid Exchange Frequencies in Chinese Hamster Ovary (CHO) Cells", [HLA 9973-0-438]; Hazleton Laboratories America, Inc., Kensington, MD; [HED Doc. No. 006594].

40420202 Cifone, M.A. [1987] "Mutagenicity Test on HPMTS in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay", [HLA 9973-0-447]; Hazleton Laboratories America, Inc., Kensington, MD; [HED Doc. No. 006594].

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40974701 Siglin, J.C., [1988] "91-Day Dermal Toxicity Study in Rats with HPMTS", [SLS 3138.9]; Springborn Life Sciences, Inc., Spencerville, OH; [HED Doc. No. 007483].

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41010401 Rodwell, D.E. [1988] "Teratology Study in Rabbits with HPMTS", [SLS 3138.13]; Springborn Life Sciences, Inc., Spencerville, OH; [HED Doc. No. 007453].

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BIBLIOGRAPHY

MRID **CITATION**

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.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited

to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

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

HYDROXYPROPYL METHANETHIOSULFONATE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Hydroxypropyl methanethiosulfonate are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Hydroxypropyl methanethiosulfonate 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 Hydroxypropyl methanethiosulfonate 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 Moana Appleyard at (703) 308-8175.

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

Moana Appleyard
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: **Hydroxypropyl methanethiosulfonate**

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

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

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

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

Items 8-11. Self-explanatory.

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

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

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

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

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

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

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is

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

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "**Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two

completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

EPA'S BATCHING OF HYDROXPROPYLMETHANE THIOSULFONATE (HPMTS) PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing HPMTS as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's

data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Nine products were found which contain HPMTS as the active ingredient. The products have been placed into three batches and a "no batch" category in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the batched products. Table 2 lists 1 product that was considered not to be similar to any other product and has been placed in the "no batch" category.

Table 1

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	1448-31	80.0	Liquid
	1448-36	80.0	Liquid
2	1448-76	25.0	Liquid
	1448-77	15.0	Liquid
	1448-78	10.0	Liquid
	1448-79	5.0	Liquid
3	1448-27	32.0	Liquid
	1448-30	14.6	Liquid

Table 2 (No Batch)

EPA Reg. No.	% Active Ingredient	Formulation Type
1448-90	10.0	Liquid

The products in Batch 1 are considered technicals and have been reviewed in the RED Toxicology Chapter. Data are sufficient to label these products and no additional data needs to be submitted. In addition, as the active ingredient is considered to be a dermal sensitizer, all products containing this active ingredient should be labeled for dermal sensitization. No additional dermal sensitization studies need be submitted. Inhalation toxicity has been waived for all products also, because the use pattern precludes inhalation exposure.

There is sufficient information on acute toxicity to label the products in Batch 2 with the following exceptions:

A primary dermal irritation study is needed for 1448-76 and 1448-77. A category III result from 1448-76 could be bridged to 1448-77.

A primary eye irritation study is needed for 1448-79.

For Batch 3, an acute oral and dermal toxicity study is needed for 1448-27. Primary dermal and eye irritation studies are needed for both 1449-27 and 1448-30.

There is sufficient information on acute toxicity to label 1448-90 with the exception of the acute oral toxicity study. The study on file is inconclusive with regard to the LD_{50} in female animals. The study must be repeated.

ATTENTION CRM::: PLEASE NOTE:::
REMOVE THIS PAGE AND INSERT THE LIST OF REGISTRANTS RECEIVING THIS DCI

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.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

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

21. Date

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

EPA	United States Environmental Protection Agency Washington, DC 20460 **CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA**	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date

Name and Title (Please Type or Print)

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

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents for Hydroxypropyl methanethiosulfonate that my 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 Moana Appleyard at (703)-308-8175.

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 Hydroxypropyl methanethiosulfonate.

The following documents are part of the Administrative Record for Hydroxypropyl methanethiosulfonate 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

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

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Moana Appleyard (703) 308-8175. Address any questions on required generic data to the Special Review and Reregistration Division representative Patrick Dobak (703) 308-8180.

Sincerely yours,

Lois Rossi, Division 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, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; 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 time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. 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, but are not required to, 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

HYDROXYPROPYL METHANETHIOSULFONATE

LIST C

CASE 3033

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

TABLE OF CONTENTS

HYDROXYPROPYL METHANETHIOSULFONATE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Ghulam Ali	Economic Analysis Branch
Steve Jarboe	Biological Analysis Branch
Cynthia Szymanski	Biological Analysis Branch

Environmental Fate and Effects Assessment

Ann Stavola	Ecological Effects Branch
Mary Frankenberry	Science Analysis and Coordination Staff
Rachelle Kudrik	Science Analysis and Coordination Staff
Jose Melendez	Environmental Fate and Groundwater Branch

Health Effects Assessment

Arliene Aikens	Risk Characterization and Analysis Branch
Tom Campbell	Occupational and Residential Exposure Branch
Paula Deschamp	Risk Characterization and Analysis Branch
Steven Malish	Toxicology Branch II

Registration Support

Valdis Goncarovs	Antimicrobial Program Branch
Tina Levine	Reregistration Support Branch
Shyam Mathur	Reregistration Support Branch

Risk Management

Kathleen Depukat	Accelerated Reregistration Branch
Patrick Dobak	Accelerated Reregistration Branch

Office of Compliance:

Carol Buckingham	Agriculture and Ecosystem Division

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_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration

GLOSSARY OF TERMS AND ABBREVIATIONS

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
PHI	Preharvest Interval
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 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

As required under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended in 1988, the U.S. Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide active ingredient hydroxypropyl methanethiosulfonate (HPMTS). This decision includes a comprehensive reassessment of the required target data base and use patterns of currently registered products. The Agency compared its risk assessment to current science and regulatory policies. The Agency has determined that the uses as described below will not cause unreasonable risk to humans or the environment and all uses are eligible for reregistration. Where appropriate, the Agency has imposed additional use restrictions and precautionary statements for product labels to reduce risks to human health and the environment.

Use Patterns

HPMTS is a microbiocide/microbiostat used to control slime-forming algae, bacteria, and fungi in commercial/industrial water cooling systems, industrial processing water, pulp/paper mill water systems, and is used as a preservative in industrial coatings, emulsions, paints and wet-end additives/industrial processing chemicals. It is applied by direct pouring and metered application.

Human Health Assessment

From its review of the toxicology data, the Agency concluded that HPMTS is mildly to moderately toxic when administered by oral or dermal routes. The chemical is corrosive and is considered to be a severe dermal and eye irritant. The chemical caused delayed contact hypersensitivity in the guinea pig dermal sensitization studies. The subchronic dermal LOEL was determined to be 250 mg/kg/day for systemic toxicity and 10 mg/kg/day for dermal toxicity. A battery of mutagenicity studies was negative for mutagenic effects. Two developmental toxicology studies were reviewed. The rat maternal LOEL and NOEL were determined to be 30 mg/kg/day and 10 mg/kg/day, respectively. The rabbit maternal LOEL and NOEL were determined to be 4.0 mg/kg/day and 0.75 mg/kg/day, respectively.

No dietary exposure to HPMTS is expected from the current use patterns. Although corrosiveness and dermal sensitization were identified as potential effects, significant occupational exposures are not expected. Therefore, quantitative assessments of exposures and risks were deemed unnecessary and not conducted. To mitigate the potential risks of corrosiveness and dermal sensitization to workers, minimum (baseline) personal protective equipment (PPE) is being required for the handling of concentrated products. Non-occupational exposures are not expected.

Environmental Assessment

HPMTS is moderately toxic to slightly toxic to avian species on an acute and subacute oral dietary basis, slightly toxic to fish, and moderately toxic to aquatic invertebrates. Current uses of HPMTS are expected to result in minimal exposure or risk to the environment. Therefore, no additional environmental risk mitigation measures are being imposed at this time.

Product Reregistration

The Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document for all products containing HPMTS. These data include product chemistry and acute toxicity testing for each registration. After reviewing these revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister each associated 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 2-hydroxypropyl methanethiosulfonate (HPMTS). The document consists of six sections. Section I is the introduction. Section II describes HPMTS, 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 HPMTS. Section V discusses the reregistration requirements for HPMTS. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** HPMTS
- **Chemical Name:** 2-hydroxypropyl methanethiosulfonate
- **Chemical Family:** Thiosulfonates
- **CAS Registry Number:** 30388-01-3
- **OPP Chemical Code:** 35604
- **Empirical Formula:** $C_4H_{11}S_2O_3$
- **Trade and Other Names:** S-(2-hydroxypropyl) thiomethanesulfonate
- **Basic Manufacturer:** Buckman Labs

B. Use Profile

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

For 2-hydroxypropyl methanethiosulfonate:

Type of Pesticide: Microbiocide/microbiostat (slime-forming algae, bacteria and fungi), Bacteriostat.

Use Sites: AQUATIC NON-FOOD INDUSTRIAL

Commercial/Industrial Water Cooling Systems
Industrial Processing Water
Pulp/Paper Mill Water Systems

INDOOR NON-FOOD

Industrial Coatings
Resin/Latex/Polymer Emulsions

Latex/Oil/Varnish Paints (Applied Film)
Wet-End Additives/Industrial Processing Chemicals

Target Pests: Slime-forming algae, bacteria and fungi

Formulation Types Registered:

TYPE: End-use, Manufacturing-use

FORM: Soluble Concentrate/Liquid, Ready-To-Use Solution /Liquid

PURITY: Single Active Ingredient
TGAI: 80%
End-Use Products: 5-80%
Multiple Active Ingredients
End-Use Products: 11.7-28%

Method and Rates of Application: Equipment - Direct pour, metered application (registrant must specify on labeling). For Rates of application see Table 1 below.

Timing - During manufacture, Not specified (registrant must supply on labeling).

Table 1 - Method and Rate

TREATMENT TYPE	SYSTEM TYPE	RATE (ppm AI by weight)
Water (recirculating)	Commercial/Industrial Cooling Systems	0.4 to 8.5
Water (recirculating)	Industrial Processing	0.4 to 4.3
Water	Pulp/Papermill	0.176 to 281
Industrial Preservative	Industrial Coatings	400 to 4050
Industrial Preservative	Resin/Latex/Polymer Emulsions	400 to 4050
Industrial Preservative	Latex/Oil/Varnish Paints (applied film)	280 to 2800
Industrial Preservative	Wet-End Additives/ Industrial Processing Chemicals	400 to 4050

Use Practice Limitations: NPDES license restriction.

C. Estimated Usage of Pesticide

Information about the use and percentage of sites treated with HPMTS is not readily available. However, the aggregate annual use of this pesticide is considered to be quite small in the United States, based on proprietary sources.

D. Regulatory History and Data Requirements

Products containing HPMTS as an active ingredient were registered in the United States as early as 1968. Currently, nine products are registered to one registrant for the uses described above.

In March, 1987, the Agency issued the Anti-Microbial Data Call-In Notice for toxicity and exposure data requirements for this active ingredient and other antimicrobials. Additionally, the Agency issued a September, 1992 Phase IV Data Call-In requiring studies on product chemistry, human health, and ecological effects data to support the uses listed. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Molecular Weight: 171.25

Color: Light yellow/brilliant yellow

Odor: Strong sour, pungent vegetable-like odor

Boiling Point: 164°C

Density: 1.2893 at 22°C

Solubility:

Table 2 - HPMTS Solubility	
Solvent	**Solubility**
Ethanol	Miscible in all proportions
Hexane	< 16 mg in 100 ml
C_{8-18} Fatty Acids	Mean fat solubility at 37°C is 5.42 + 0.04 g/100 g
Water	At concentrations > 40%, soluble at any concentration; at concentrations < 40%, not completely soluble

Vapor Pressure: 1.40 mm Hg at 20°C and 1.70 mm Hg at 25°C.

pH: 3.7 at 22°C.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on HPMTS is adequate to support reregistration eligibility.

a. Acute Toxicity

Table 3 - Acute Human Health Studies		
Type of Study	**Results [mg/kg]**	**Toxicity Category**
Acute Oral - rat	LD_{50} ♂ = 548, ♀ = 224	II
Acute Dermal - rat	LD_{50} ♂ & ♀ = > 2000	III
Acute Inhalation	Waived	NA
Primary Eye Irritation*	Waived	I
Primary Dermal Irritation*	Waived	I
Dermal Sensitization - guinea pig*	Sensitizer	NA

* This study is a requirement for manufacturing-use and end-use products (40 CFR 158). NA = not applicable

In an acute oral toxicity study in the rat, HPMTS (81.45% a.i.) was administered by oral gavage to 5 animals/sex and observed for 14 days.

Compound related clinical signs presented were transient hypoactivity and staggered gait in surviving rats. Reddening of glandular stomach mucosa and the gastrointestinal tract were seen. (MRID 41634701)

In an acute dermal toxicity study in the rat, HPMTS (81.45% a.i.) was administered by dermal application at 2 gm/kg (limit dose) to 5 animals/sex for 14 days. Dermal irritation was present in all animals and included erythema, edema, fissuring, hemorrhaging, blanching, atonia, and a leathery feel to the skin. The dose used in the study was the limit dose specified in the guidelines. (MRID 41632401)

An acute inhalation study was waived because the absence for potential for inhalation exposure (no respirable particles) is indicated by the current HPMTS use pattern. The primary dermal irritation and eye irritation studies were waived because HPMTS was corrosive in the 14 and 90-day dermal studies.

In a guinea pig dermal sensitization study, HPMTS (40% a.i.) was found to be a sensitizer. HPMTS caused delayed contact hypersensitivity. (MRID 42349201)

b. Subchronic Toxicity

In a two-week, repeat dose (range finding), dermal toxicity study conducted in the rat, HPMTS (79.67% a.i.) as a 30% solution [in distilled water] was applied to 5 animals/sex at doses of 0, 100, 250, 500, 750 or 1000 mg/kg/day, for 6 hours/day, 5 days/week for 14 days. Control animals received distilled water. A dose related irritation was presented with eschar, and exfoliation at 500 to 750 mg/kg/day. The dermal no observable effect level (NOEL) was < 100 mg/kg/day (lowest dose tested). (MRID 40747102)

In a dermal toxicity study in rats, HPMTS (79.67% a.i.), at a concentration of 5.0%, was applied to approximately 10% of the body surface area of 10 animals/sex at doses of 0, 10, 50 or 250 mg/kg/day. Exposure was for 6 hours/day, 5 days/week for 91 days. Control animals received distilled water under the same experimental conditions.

Slight treatment-related reductions in body weight and food consumption were found in the high dose males. Compound-related reductions in erythrocyte counts, hematocrit and hemoglobin occurred in both high dose males and females as compared to the respective controls. A slight but significant increase in the platelet count occurred in the high dose in both sexes.

Compound and dose-related dermal irritation was found in the treated animals at the application site. The severity of the irritation ranged from minimal in the low-dose animals to severe in the high-dose animals of both sexes. Surface exudate, dermal inflammation, and fibrosis occasionally accompanied the ulceration in the high-dose animals. Microscopic examination confirmed the gross observation of the skin in the high dose animals as ulceration and acanthotic epidermal thickening.

Based on changes in body weights and hematology at the high dose, the lowest observable effect level (LOEL) for systemic toxicity is 250 mg/kg/day and the NOEL is 50 mg/kg/day. The LOEL for dermal toxicity is 10 mg/kg/day, the lowest dose tested. (MRID 40974701)

c. Chronic Toxicity/Carcinogenicity

Chronic toxicity and carcinogenicity studies are not required for HPMTS because the non-food use pattern scenarios currently registered are not likely to result in significant human exposure.

d. Developmental Toxicity

A developmental toxicity study conducted in the rat, evaluated HPMTS (79.67% a.i.) at doses of 0, 10, 30 or 75 mg/kg/day by gavage from gestation days 6 to 15. The maternal NOEL was 10 mg/kg/day and the maternal LOEL was 30 mg/kg/day based on salivation, rales, and oral-nasal discharge. The developmental NOEL was 10 mg/kg/day and the developmental LOEL was 30 mg/kg/day based on reduced fetal weight. (MRID 41010501)

Another developmental toxicity study conducted by gavage in the rabbit, evaluated HPMTS (79.67%) at doses of 0, 0.75, 4.0 or 7.5 mg/kg/day from gestation days 6 to 18. The maternal NOEL and LOEL were 0.75 mg/kg/day and 4.0 mg/kg/day, respectively, based on decreased body weights. The developmental NOEL was $\geq$7.5 mg/kg/day (HDT). (MRID 41010401)

e. Reproductive Toxicity

A reproductive toxicity study is not required to support the currently registered non-food uses of HPMTS because the use pattern scenarios are not likely to result in significant human exposure.

f. Mutagenicity

In a gene mutation (Reverse Mutation) study, HPMTS (79.67% a.i.) did not produce gene mutation in an Ames assay in which *S. typhimurium* (TA98, TA100, TA1535 and TA1538) bacteria were tested without activation up to 0.25 µl/plate and with activation up to 0.5 µl/plate. Concentrations ≥0.5 µl/plate produced cytotoxicity. (MRID 40229601)

HPMTS (80% a.i.) was negative both with and without activation in a Sister Chromatid Exchange (SCE) *In Vitro*/CHO assay when assayed at concentrations into the toxic range (16.7 µg/ml). (MRID 40420201)

In the DNA Damage/Repair in Primary Rat Hepatocytes study, HPMTS (80% a.i.) was negative for inducing UDS at concentration levels into the toxic range (100 µg/ml and higher). (MRID 40420202)

g. Metabolism

A metabolism study is not required to support non-food uses of HPMTS because of the expected absence of oral exposure and because the current use pattern scenarios are not likely to result in significant human exposure.

h. Toxic Endpoints of Concern

Based on HPMTS' target database for toxicology, the Agency concludes there are no toxicological endpoints of concern for HPMTS. While technical HPMTS has been demonstrated to be corrosive and lead to dermal sensitization from acute exposures, these concerns are more appropriately addressed during product reregistration after a re-assessment of each product's acute toxicity.

Reference Dose (RFD)

A reference dose was not established for HPMTS, based on the non-food use patterns and exposure profile (The Agency's Office of Pesticide Programs RfD Committee report, February 15, 1995)

WHO/JMPR Status

The World Health Organization/Joint Meeting on Pesticide Residues committee has not reviewed this pesticide.

2. Exposure and Risk Assessment

a. Dietary Exposure and Risk Assessment

There are no registered food uses of HPMTS, therefore, a dietary exposure and risk assessment are not required.

b. Occupational and Residential Exposure and Risk Assessment

An occupational/residential exposure assessment is required for an active ingredient if: (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (M/L/A) during use or to persons entering treated sites after application is complete. Since toxicology endpoints of concern, except for corrosiveness and dermal sensitization from acute exposures, were not identified for occupational/residential exposures, an occupational/residential M/L/A exposure analysis and quantitative risk assessment are not warranted at this time.

The Agency has determined that products containing HPMTS labeled and used as specified in this RED will not pose significant risk to humans. The most significant occupational concerns are for corrosiveness and dermal sensitization from acute exposures. The use of minimal (baseline) PPE , including chemical resistant gloves and apron and faceshield, will adequately mitigate these hazards.

A short term (1 to 7 days) occupational/residential risk assessment is not required, since results from the 14-day dermal toxicity study do not indicate any toxicological endpoints appropriate for use in the standard occupational or residential exposure assessments. Also, an intermediate (1 week to several months) occupational/residential risk assessment is not required based on a comparison of the 90-day repeated-dose dermal toxicity and the oral developmental toxicity studies conducted in rats. In these studies, the LOEL(s) were 250 mg/kg/day and 30 mg/kg/day, respectively. On the basis that the dermal LOEL was significantly higher, it was determined that dermal absorption of HPMTS is limited. Also, inhalation exposures are not expected because respirable particles are not anticipated to be produced from the application methods (open-pour or metered pump) and because of the chemical's low vapor pressure.

Most of HPMTS' use and exposure are associated with industrial applications. Additionally, people who apply HPMTS treated paint or who reside or work in buildings which have painted with such paint may also be exposed to HPMTS. However, because of the Agency's conclusion on HPMTS' risks from subchronic exposures and because of HPMTS' low vapor pressure, the Agency believes risks to these individuals are very low.

C. Environmental Assessment

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of HPMTS 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); one subacute dietary study (LC_{50}) on one species (preferably the bobwhite quail). The available information is summarized in the following tables:

Table 4 - Avian Acute Oral Toxicity Findings

Species	% A.I.	LD_{50} mg/kg	Toxicity Category
Mallard Duck	79.82	> 474.4 mg/kg	moderately toxic

Although the avian acute oral study yielded some information, it was not considered acceptable because the birds regurgitated shortly after dosing. The registrant is performing a new study in order to fulfill guideline requirements.

Table 5 - Avian Subacute Dietary Toxicity Findings

Species	% A.I.	LC_{50} ppm	Toxicity Category
Northern Bobwhite Quail	79.82	> 3991	slightly toxic
Mallard Duck	79.82	> 3991	slightly toxic

The results from the subacute study and the supplemental results of the acute oral study indicate that HPMTS is slightly to moderately toxic to avian species on an acute oral and subacute dietary basis. (MRID 249523 for all three)

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Since the currently

registered uses are for indoor use only, repeated exposures are not expected and chronic avian studies are not required.

(3) 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} is used to indicate toxicity to mammals. The LD_{50}, as reported in Table 3 above, indicates that HPMTS is slightly toxic to small mammals on an acute oral basis. No additional testing on mammals is required for these use patterns. (MRID 41634701)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

(a) Acute

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required for industrial microbiocides is one freshwater fish toxicity study on the technical grade of the active ingredient. The study should preferably use the rainbow trout (cold water species) or the bluegill sunfish (warm water species). The available information is summarized in the following table.

Table 6 - Freshwater Fish Acute Toxicity Findings

Species	% A.I.	LC_{50} (ppm)	Toxicity Category
Rainbow trout	81.45	28.0	slightly toxic
Bluegill sunfish	81.45	38.2	slightly toxic

The results of the 96-hour acute toxicity studies indicate that HPMTS is slightly toxic to both cold and warm water fish. The guideline requirements are fulfilled. (MRIDs 41733203 and 41733201, respectively)

(b) Chronic

The fish early life-stage and fish life-cycle tests are not required because the products are not applied directly to water or expected to be transported to water from the intended use site. Additionally, the fish early life-stage test is not required because the LC_{50} in this case is greater than 1 mg/L.

(2) Freshwater Invertebrates

(a) Freshwater Invertebrates, Acute

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. The results of the toxicity findings are presented in the table below.

Table 7 - Freshwater Invertebrate Toxicity Findings

Species	% A.I.	EC_{50} (ppm)	Toxicity Category
Daphnia magna	79.82	3.13	moderately toxic

There is sufficient information to characterize HPMTS as moderately toxic to aquatic invertebrates. The guideline requirement is fulfilled. (MRID 41733202)

(b) Freshwater Invertebrates, Chronic

The same conditions for chronic testing to freshwater fish also apply to aquatic invertebrates as discussed in (1.b.) above. Chronic aquatic invertebrate studies are not required for HPMTS.

(3) Estuarine and Marine Animals

(a) Acute

Although estuarine/marine testing was originally required, a waiver for those data requirements was subsequently granted in response to the registrants' incorporation of a statement on all HPMTS labels restricting

the discharge of HPMTS directly or indirectly into estuarine or marine environments to NPDES permitted discharges.

(b) Chronic

The same conditions for chronic testing to freshwater fish and aquatic invertebrates also apply to estuarine and marine animals as discussed in (1.b.) above. Therefore, the chronic estuarine/marine studies for HPMTS are not required.

c. Toxicity to Plants

Terrestrial and aquatic plant testing are currently not required, in most cases, for industrial microbiocides, including HPMTS.

2. Environmental Fate

a. Environmental Fate Assessment

Due to the current use patterns for HPMTS, the Agency requires only a hydrolysis study for the reregistration target data base.

b. Environmental Fate and Transport

(1) Degradation

Hydrolysis

[2-^{14}C]2-hydroxypropyl methanethiosulfonate, at 101 mg/L, hydrolyzed with half-lives of > 30 days at pH 5, 8.5-9.9 hours at pH 7, and 5.4-6.1 minutes at pH 9 in sterile aqueous buffered solutions at 25°C in the dark for up to 30 days. Two major degradates were observed.

One degradate, di-(2-hydroxyisopropyl)disulfide, was a maximum of 24-29% of the recovered at 20 or 30 days in the pH 5 solution; 61-64% of the recovered at 24.5 hours in the pH 7 solution; and 63-66% at 15.0-15.2 minutes in the pH 9 solution. The other major degradate, di-(2-hydroxypropyl) disulfide, was a maximum of 5.9% of the recovered at 22-30 days in the pH 5 solution; 10-12% at 24.5 hours in the pH 7 solution; and 8.17% at 10.1-15.2 minutes in the pH 9 solution. This study was found to be

acceptable and satisfies all data requirements for HPMTS. (MRID 41475207)

3. Exposure and Risk Characterization

The Agency requires only a limited set of ecotoxicology and environmental fate studies for microbicides. HPMTS is slightly to moderately toxic to birds and aquatic invertebrates. While the hazard to aquatic organisms from HPMTS has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments from its industrial aquatic uses are regulated under the NPDES permitting program of EPA's Office of Water. The Agency currently requires that labels for all HPMTS products require that discharges to aquatic environments comply with an NPDES permit.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

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

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

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

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient HPMTS, the Agency has sufficient information on the health effects of HPMTS and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that HPMTS products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing HPMTS for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of HPMTS, as specified in this document, are eligible for reregistration.

3. Endangered Species Protection

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

C. Regulatory Position

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

1. Risk Mitigation Measures/ Labeling Rationale

Minimum (baseline) PPE requirements

If EPA has no special concerns about the acute effects of 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 guidelines.

If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most 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.

Occupational-Use Products

Primary Occupational Handlers: EPA has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for HPMTS. EPA notes that HPMTS has the potential to cause severe (corrosive) effects to the skin and eyes and is a dermal sensitizer. No traditional risk assessment needs to be performed to assess risks due to corrosiveness and sensitization. However, EPA believes that primary occupational handlers who are exposed to concentrated end-use products should wear PPE in addition to the baseline long-sleeve shirt, long pants, shoes, and socks. Therefore, EPA is requiring the use of chemical-resistant gloves, chemical-resistant apron, and face shield for such handlers.

Secondary Occupational Handlers: At this time, EPA believes that risks from skin/eye corrosiveness and dermal sensitization would be acceptable for secondary occupational handlers, since the HPMTS in such products as paints and adhesives is very diluted, usually far less than one percent.

Homeowner-Use Products

Primary Homeowner Handlers: All HPMTS end-use pesticide products are intended primarily for occupational use.

Secondary Homeowner Handlers: At this time, EPA believes that risks from inhalation exposures and skin/eye corrosiveness would be acceptable for adhesives, metal-cutting fluids, wood products, and textiles is very diluted, usually far less than one percent.

2. Entry Restrictions

EPA is not establishing entry restrictions for end-use products containing HPMTS because the use pattern scenarios are not likely to result in significant human exposure to HPMTS.

3. Addition and Retention of Other Label Statements

The Agency believes it is prudent to require additional use precautions to afford product users increased protection from unnecessary exposure to HPMTS. For similar reasons the Agency is retaining current worker and environmental restrictions and precautions for risk reduction. Also, all products must have their labels improved with adequate and specific directions for use including application methods, equipment, timing, and rates. These label requirements are specified below in Section V.

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 HPMTS for the above eligible uses has been reviewed and determined to be substantially complete. No additional generic data are required at this time. The registrant is in the process of performing an avian acute oral study to confirm the potential hazards to avian species. The study is due for submission to the Agency by August 19, 1996.

2. Labeling Requirements for Manufacturing-Use Products

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

"Only for formulation into a microbiocide/microbiostat, bacteriostat for the following uses: Commercial/Industrial Recirculating Water Cooling Systems, Industrial Processing Water, Pulp/Paper Mill Water Systems, Industrial Coatings, Resin/Latex/Polymer Emulsions, Latex/Oil/Varnish Paints, and Wet-End Additives/Industrial Processing Chemicals."

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

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

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

Effluent Discharge Labeling Statements

"Do not use in facilities discharging directly or indirectly to the estuarine or marine environment."

To reduce environmental risk from HPMTS discharge and disposal, product labels must include the statements pertaining to effluent discharge under the NPDES permitting system (refer to PR Notice 93-10) and disposal under any applicable federal laws after the above statement.

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. Occupational Labeling PPE Requirements for Pesticide Handlers

Sole-active-ingredient end-use products that contain HPMTS must be revised to remove any conflicting PPE requirements on their current labeling.

Multiple-active-ingredient end-use products that contain HPMTS must compare the handler personal protective equipment requirements set forth in this section to the PPE requirements on their current labeling and retain the more protective. For guidance on which PPE is considered more protective, see PR Notice 93-7.

The PPE for each HPMTS occupational end-use product must be established based on the acute toxicity of each end-use product. If the end-use product is classified as toxicity category I or II for acute eye irritation potential (or the eye irritation study is waived due to corrosiveness), protective eyewear must be required for all handlers of HPMTS. If the end-use product is classified as toxicity category I or II for acute skin irritation potential (or the skin irritation study is waived due to corrosiveness), chemical-resistant gloves and a chemical-resistant apron must be required for all handlers of HPMTS.

Minimum (Baseline) PPE/Engineering Control Requirements for Products Intended Primarily for Occupational Use

The minimum (baseline) PPE for occupational uses of HPMTS end-use products is:

> "Mixers, loaders, and others exposed to the concentrate must wear:
> --Long-sleeve shirt and long pants,
> --Chemical-resistant gloves*,
> --shoes plus socks,
> --chemical-resistant apron, and
> --face shield."

* For the glove statement, use the statement established for HPMTS through the instructions in Supplement Three of PR Notice 93-7.

However, the corrosiveness and penetration of HPMTS itself must be considered and appropriate chemical-resistant materials must be listed.

Placement in Labeling

The personal protective equipment language 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.

b. Other Label Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing HPMTS.

(1) 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).

(2) Application restrictions

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

(3) Skin sensitizer statement

"This product may cause skin sensitization reactions in some people."

(4) User safety recommendations

For all HPMTS end-use products:

"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."

For HPMTS end-use products "gloves" if gloves are required PPE:

"Users should remove Personal Protective Equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly."

(5) Effluent Discharge Labeling Statements

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

C. Existing Stocks

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

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

VI. APPENDICES

APPENDIX A

Case 3033[Busan 74 (*)] **Chemical 035604[S-(2-Hydroxypropyl) thiomethanes]**

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. Rate Max. # Apps /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED													
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 400	W 4000	*	NS	NS	NS	NS	NS	NS			
	SC/L	W 400	W 4000	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W 405	W 4050	*	NS	NS	NS	NS	NS	NS			
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS			Use Group: AQUATIC NON-FOOD INDUSTRIAL										
Water treatment (recirculating system), Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	SC/L	W 2	W 8.1	*	NS	NS	NS	NS	NS	NS			A08, C23
	SC/L	W 2.1	W 8.3	*	NS	NS	NS	NS	NS	NS			A08, C23
	SC/L	W 2.1	W 8.5	*	NS	NS	NS	NS	NS	NS			A08, CAH, CAL
Water treatment (recirculating system), Intermittent (slug)(subsequent), Not on label, Not Applicable, Not applicable for this use	SC/L	W .4	W 8.1	*	NS	NS	NS	NS	NS	NS			A08, C23
	SC/L	W .42	W 8.3	*	NS	NS	NS	NS	NS	NS			A08, C23
	SC/L	W .43	W 8.5	*	NS	NS	NS	NS	NS	NS			A08, CAH, CAL
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 400	W 4000	*	NS	NS	NS	NS	NS	NS			
	SC/L	W 400	W 4000	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W 405	W 4050	*	NS	NS	NS	NS	NS	NS			

APPENDIX A REPORT

Case 3033[Busan 74 (*)] **Chemical 035604[S-(2-Hydroxypropyl) thiomethanes]**

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. Tex.	# Apps Max. @ Max. Dose /crop	/year cycle	Max. Dose [(AI unless noted otherwise)/A] /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)													
INDUSTRIAL PROCESSING 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 .4	W 4	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W .42	W 4.2	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W .43	W 4.3	*	NS	NS	NS	NS	NS	NS			CAH, CAL
PAINTS, LATEX/OIL/VARNISH (APPLIED FILM)			Use Group: INDOOR NON-FOOD										
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L	W 280	W 2800	*	NS	NS	NS	NS	NS	NS			
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 2171	V 2171	*	NS	NS	NS	NS	NS	NS			
PULP/PAPER MILL WATER SYSTEMS			Use Group: AQUATIC NON-FOOD INDUSTRIAL										
Water treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	W .1755	W 1.755	*	NS	NS	NS	NS	NS	NS			C18, C24
	SC/L	W .4	W 4	*	NS	NS	NS	NS	NS	NS			
	SC/L	W .4	W 4	*	NS	NS	NS	NS	NS	NS			C23
	SC/L	W .405	W 4.05	*	NS	NS	NS	NS	NS	NS			
	SC/L	W 28	W 281	*	NS	NS	NS	NS	NS	NS			
WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS			Use Group: INDOOR NON-FOOD										
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L	W 400	W 4000	*	NS	NS	NS	NS	NS	NS			

APPENDIX A REPORT

Case 3033[Busan 74 (*)] **Chemical 035604[S-(2-Hydroxypropyl) thiomethanes]**

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 @ Max. Rate /crop /year cycle	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)

WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS (con't) Use Group: INDOOR NON-FOOD (con't)

SC/L	W 400	W 4000	*	NS	NS	NS	NS	NS	NS			C23
SC/L	W 405	W 4050	*	NS	NS	NS	NS	NS	NS			

APPENDIX A REPORT

Case 3033[Busan 74 (*)] **Chemical 035604[S-(2-Hydroxypropyl) thiomethanes]**

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LEGEND
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Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate, Maximum Number of Applications at Maximum Rate, Maximum Dose per Crop Cycle or per Year, Minimum Interval Between Applications (Days), Restricted Entry Interval (Days), Allowed/Disallowed Geographical Areas, Use Limitations Codes.

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
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 noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
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
SC/L : SOLUBLE CONCENTRATE/LIQUID

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.

APPENDIX A REPORT

Case 3033[Busan 74 (*)] **Chemical 035604[S-(2-Hydroxypropyl) thiomethanes]**

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USE LIMITATIONS CODES (Cont.)

C18 : Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW).
C23 : NPDES license restriction.
C24 : Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction)
CAH : Do not discharge into lakes, streams, ponds, or public water unless in accordance with NPDES Permit.
CAL : Do not contaminate water, food or feed.
* 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 Hydroxypropyl methanethiosulfonate covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Hydroxypropyl methanethiosulfonate 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 HPMTS

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	F,M	
61-2A	**Start. Mat. & Mnfg. Process**	F,M	43420501
61-2B	**Formation of Impurities**	F,M	43420501
62-1	**Preliminary Analysis**	F,M	41680902
62-2	**Certification of limits**	F,M	
62-3	**Analytical Method**	F,M	41680902
63-2	**Color**	F,M	41680903
63-3	**Physical State**	F,M	41608903
63-4	**Odor**	F,M	41680903
63-6	**Boiling Point**	F,M	41680903
63-7	**Density**	F,M	41680903
63-8	**Solubility**	F,M	43420101
63-9	**Vapor Pressure**	F,M	42287901
63-12	**pH**	F,M	41680903
63-13	**Stability**	F,M	
63-17	**Storage stability**	F,M	42766601
63-20	**Corrosion characteristics**	F,M	42766601

Data Supporting Guideline Requirements for the Reregistration of HPMTS

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	F	
71-2A	**Avian Dietary - Quail**	F	41629801, 126121, 126122
71-2B	**Avian Dietary - Duck**	F	249523
72-1A	**Fish Toxicity Bluegill**	F	41733201
72-1C	**Fish Toxicity Rainbow Trout**	F	41733203
72-2A	**Invertebrate Toxicity**	F	41733202
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	F,M	41634701
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	F,M	41632401
81-6	**Dermal Sensitization - Guinea Pig**	F,M	42349201
82-3	**90-Day Dermal - Rodent**	F,M	40974701
83-3A	**Developmental Toxicity - Rat**	F,M	41010501
83-3B	**Developmental Toxicity - Rabbit**	F,M	41010401
84-2A	**Gene Mutation (Ames Test)**	F,M	40229601
84-2B	**Structural Chromosomal Aberration**	F,M	40420201
84-4	**Other Genotoxic Effects**	F,M	40420202
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
None	**Required**		

Data Supporting Guideline Requirements for the Reregistration of HPMTS

REQUIREMENT		USE PATTERN	CITATION(S)
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	F,M	43420501
161-1	**Hydrolysis**	F	42771801
RESIDUE CHEMISTRY			
None	**Required**		

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**

00126120 Hazleton Raltech, Inc. (1982) Avian Single-dose Oral LD50: Mallard Duck (Anas platyrhynchos): Study No. 6026-119. Final rept. (Unpublished study received Feb 15, 1983 under 1448-78; submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:249523-B)

00126121 Hazleton Raltech, Inc. (1982) Avian Dietary LC50: Bobwhite Quail (Colinus virginianus): Study No. 6026-121. Final rept. (Unpublished study received Feb 15, 1983 under 1448-78; submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:249523-C)

00126122 Hazleton Raltech, Inc. (1982) Avian Dietary LC50: Mallard Duck (Anas platyrhynchos): Study No. 6026-120. (Unpublished study received Feb 15, 1983 under 1448-78; submitted by Buckman Laboratories, Inc., Memphis, TN; CDL:249523-D)

40229601 Jagannath, D.R. [1987] "Mutagenicity Test on HPMTS in the Ames *Salmonella*/Microsome Reverse Mutation Assay", [HLA 9786-0-401]; Hazleton Laboratories America, Inc., Kensington, MD; [HED Doc. No. 010670].

40420201 Murli, H. [1987] "Mutagenicity Test on HPMTS in an **In Vitro** Sister Chromatid Exchange (SCE) Assay Measuring Sister Chromatid Exchange Frequencies in Chinese Hamster Ovary (CHO) Cells", [HLA 9973-0-438]; Hazleton Laboratories America, Inc., Kensington, MD; [HED Doc. No. 006594].

40420202 Cifone, M.A. [1987] "Mutagenicity Test on HPMTS in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay", [HLA 9973-0-447]; Hazleton Laboratories America, Inc., Kensington, MD; [HED Doc. No. 006594].

40747101 Rodwell, D.E. [1988] "Pilot Teratology Study in Rats with HPMTS", [SLS 3138.10]]; Springborn Life Sciences, Inc.; Spencerville, OH; [HED Doc. No. 006920].

40747102 Siglin, J.C. [1988] "Two-Week Dermal Toxicity Study in Rats with HPMTS", [SLS 3138.8]; Springborn Life Sciences, Inc., Spencerville, OH; [HED Doc. No. 006920].

40974701 Siglin, J.C., [1988] "91-Day Dermal Toxicity Study in Rats with HPMTS", [SLS 3138.9]; Springborn Life Sciences, Inc., Spencerville, OH; [HED Doc. No. 007483].

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41010401 Rodwell, D.E. [1988] "Teratology Study in Rabbits with HPMTS", [SLS 3138.13]; Springborn Life Sciences, Inc., Spencerville, OH; [HED Doc. No. 007453].

41010501 Rodwell, D.E. [1988] "Pilot Teratology Study in Rabbits with HPMTS", [SLS 3138.12], Springborn Life Sciences, Inc., Spencerville, OH; [HED Doc. No. 006984].

41010501 Rodwell, D.E. [1988] "Teratology Study in Rats with HPMTS", [SLS 3138.11]; Springborn Life Sciences, Inc., Spencerville, OH; [HED Doc. No. 007453].

41632401 Glaza, S. M. [1990] "Acute Dermal Toxicity of HPMTS in Rabbits", [HLA 0060-5-263]; Hazleton Laboratories America, Inc., Madison, WI; [HED Doc. No. 010670].

41634701 Glaza, S. M. [1990] "Acute Oral Toxicity of HPMTS in Rats" [HLA 0060-5-262]; Hazleton Laboratories America, Inc., Madison, WI; [HED Doc. No. 010670].

41733201 Ward, G. (1990) 2-Hydrocypropyl methanethiolsulfonate (HPMTS): Acute Toxicity to Bluegill, Lepomis macrochirus, Under Flow-through Test Conditions: Lab Project Number: J9007018C. Unpublished study prepared by Toxikon Environmental Sciences. 37 p.

41733202 Ward, G. (1990) 2-Hydroxypropyl methanethiolsulfonate (HPMTS): Acute Toxicity to the Water Flea, Daphnia magna, under Flow-through Test Conditions: Lab Project Number: J9007018B. Unpublished study prepared by Toxikon Environmental Sciences. 38 p.

41733203 Ward, G. (1990) 2-Hydroxypropyl methanethiolsulfonate (HPMTS): Acute Toxicity to Rainbow Trout, Oncorhynchus mykiss, under Flowthrough Test Conditions: Lab Project Number: J9007018D. Unpublished study prepared by Toxikon Environmental Sciences. 38 p.

42349201 Karcher, R., Siglin, J.C. and Becci, P.C. [1986] "Delayed Contact Hypersensitivity Study in Guinea Pigs with HPMTS", [SIB 3138.7]; Springborn Institute for Bioresearch, Inc., Spencerville, OH; [HED Doc. No. 009690].

42771801 Mao, J. (1993) HPMTS--Determination of Aqueous Hydrolysis Rate Constants and Half-Lives: Lab Project Number: 995.0292.6138.715: 93-3-4668. Unpublished study prepared by Springborn Labs, Inc. 76 p.

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- -	Doyle, E. [1995] "Less than Lifetime/Peer Review Report of [S-(2-hydroxypropyl)thiomethane sulfonate]", Internal U.S. EPA memorandum, [Doyle to Aikens].
- -	Ghali, G.Z. [1995] "RfD/Peer Review Report of Busan 74 [S-(2-hydroxypropyl)thiomethane sulfonate]", Internal U.S. EPA memorandum, [Ghali to Swindell, 2/15/95].
- -	Whalan, J.E., "Policy on Acute Inhalation Toxicity Data Waivers", Internal U.S. EPA memo, Nov. 27, 1991 [Fenner-Crisp to Lindsay], 12/8/91.

DRAFT:EPA:OPP:HED:RCAB:AMAikens: 8/18/95: Revised (TOX 81-3) 8/22/95: Revised (TOX CATEGORY 81-4 and 81-5; addition of OREB provisional statements/ contractor) 8/29/95: Edited/RCAB 8/31/95: Final for OD review 9/5/95: Edited 9/15/95: Edited to include OREB/S. McDonald comments received this date 9/19/95: Revised 9/22/95.

BIBLIOGRAPHY

MRID **CITATION**

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.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited

to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

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

HYDROXYPROPYL METHANETHIOSULFONATE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Hydroxypropyl methanethiosulfonate are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Hydroxypropyl methanethiosulfonate 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 Hydroxypropyl methanethiosulfonate 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 Moana Appleyard at (703) 308-8175.

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

Moana Appleyard
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: **Hydroxypropyl methanethiosulfonate**

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

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

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

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

Items 8-11. Self-explanatory.

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

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

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

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

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

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

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is

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

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "**Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two

completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

EPA'S BATCHING OF HYDROXPROPYLMETHANE THIOSULFONATE (HPMTS) PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing HPMTS as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's

data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Nine products were found which contain HPMTS as the active ingredient. The products have been placed into three batches and a "no batch" category in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the batched products. Table 2 lists 1 product that was considered not to be similar to any other product and has been placed in the "no batch" category.

Table 1

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	1448-31	80.0	Liquid
	1448-36	80.0	Liquid
2	1448-76	25.0	Liquid
	1448-77	15.0	Liquid
	1448-78	10.0	Liquid
	1448-79	5.0	Liquid
3	1448-27	32.0	Liquid
	1448-30	14.6	Liquid

Table 2 (No Batch)

EPA Reg. No.	% Active Ingredient	Formulation Type
1448-90	10.0	Liquid

The products in Batch 1 are considered technicals and have been reviewed in the RED Toxicology Chapter. Data are sufficient to label these products and no additional data needs to be submitted. In addition, as the active ingredient is considered to be a dermal sensitizer, all products containing this active ingredient should be labeled for dermal sensitization. No additional dermal sensitization studies need be submitted. Inhalation toxicity has been waived for all products also, because the use pattern precludes inhalation exposure.

There is sufficient information on acute toxicity to label the products in Batch 2 with the following exceptions:

A primary dermal irritation study is needed for 1448-76 and 1448-77. A category III result from 1448-76 could be bridged to 1448-77.

A primary eye irritation study is needed for 1448-79.

For Batch 3, an acute oral and dermal toxicity study is needed for 1448-27. Primary dermal and eye irritation studies are needed for both 1449-27 and 1448-30.

There is sufficient information on acute toxicity to label 1448-90 with the exception of the acute oral toxicity study. The study on file is inconclusive with regard to the LD_{50} in female animals. The study must be repeated.

ATTENTION CRM::: PLEASE NOTE:::
REMOVE THIS PAGE AND INSERT THE LIST OF REGISTRANTS RECEIVING THIS DCI

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.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

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

21. Date

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

EPA	United States Environmental Protection Agency Washington, DC 20460 **CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA**	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date

Name and Title (Please Type or Print)

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

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents for Hydroxypropyl methanethiosulfonate that my 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 Moana Appleyard at (703)-308-8175.

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 Hydroxypropyl methanethiosulfonate.

The following documents are part of the Administrative Record for Hydroxypropyl methanethiosulfonate 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