United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA 738-R-96-001 December 1995

Reregistration Eligibility Decision (RED)

Hydroxyethyl octyl sulfide

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 hydroxyethyl octyl sulfide which includes the active ingredient hydroxyethyl octyl sulfide-2-(octylthio) ethanol. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration.

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 Jean Holmes (703) 308-8008. Address any questions on generic data to the Special Review and Reregistration Division representative Ron Kendall at (703) 308-8068.

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

2-Hydroxyethyl octyl sulfide

LIST C

CASE 3103

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

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2-HYDROXYETHYL OCTYL SULFIDE REREGISTRATION ELIGIBILITY TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

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Gabe Patrick	Biological Analysis Branch
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Risk Management

Ron Kendall	Accelerated Reregistration Branch
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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
NPDES	National Pollutant Discharge Elimination System

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
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 © of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (referred to as "the Agency") has completed its reregistration eligibility decision of 2-hydroxyethyl octyl sulfide hereafter referred to as hydroxyethyl octyl sulfide. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. Hydroxyethyl octyl sulfide is an insect repellent used in recreational areas, refuse/solid waste containers (garbage cans), compost/compost piles, household/domestic dwellings, and pet living/sleeping quarters. The Agency has concluded that all uses as prescribed in this document, will not cause unreasonable risks to humans or the environment and therefore, all products are 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 hydroxyethyl octyl sulfide. The document consists of six sections. Section I is the introduction. Section II describes hydroxyethyl octyl sulfide, 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 hydroxyethyl octyl sulfide. Section V discusses the reregistration requirements for hydroxyethyl octyl sulfide. 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:** Hydroxyethyl octyl sulfide
- **Chemical Name:** 2-Hydroxyethyl octyl sulfide
  2(Octylthio) ethanol
- **Trade Names:** MGK R-874
- **CAS Registry Number:** 3547-33-9
- **OPP Chemical Code:** 46301
- **Empirical Formula:** $C_{10}H_{22}OS$
- **Molecular Weight:** 190
- **Basic Manufacturer:** McLaughlin Gormley King Co.

B. Use Profile

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

TYPE OF PESTICIDE: Insect repellent/feeding depressant

MODE OF ACTION: Repellent-moderately negative effect on insect nervous system.

USE SITES: Terrestrial nonfood crop:

Recreational areas, refuse/solid waste containers (garbage cans).

Outdoor residential:

Ornamental and/or shade trees, compost/compost piles, household/domestic dwellings outdoor premises, refuse/solid waste containers (garbage cans)

Indoor residential:

Household/domestic dwellings, household/domestic dwellings indoor premises, pet living/sleeping quarters.

Indoor Food:

Household/domestic dwellings indoor food handling areas. The Agency considers this a non-food use for hydroxyethyl octyl sulfide as long as the following precautionary labeling requirements are included on the labels:

"Do not use in commercial food processing, storage preparation or serving areas. In the home, all food processing surfaces and utensils should be covered or removed during treatment and thoroughly washed before use. Cover and remove food before treatment."

PESTS: Ants, ticks, centipedes, flying moths, roaches, crickets, fleas, flies, gnats, mosquitoes, silverfish, waterbugs, spiders, and wasps.

FORMULATION TYPES: Emulsifiable concentrate--5-9.1% and up to four other AIs
Pressurized liquid--0.1-1.5% and up to four other AIs
Formulation not identified--10-100% and up to four other AIs
Formulation not identified/liquid--25% and two other AIs

METHODS AND RATES OF APPLICATION: Pressurized liquid--Apply spot, contact, surface, and fog treatments by spraying with aerosol can.

Emulsifiable concentrate--Apply with automatic or ordinary sprayer at 0.25 gal product/gal spray.

EQUIPMENT: Aerosol can and Ready-to-Use Fogger.

TIMING: Evening to late evening, nighttime, or as needed.

USE LIMITATIONS: The following limitations apply for outdoor uses. Keep out of lakes streams and ponds. Do not apply directly to water or wetlands, swamps, bogs, marshes and potholes. Spray from center when not breezy. Spray with wind if breeze is blowing.

C. Regulatory History

Hydroxyethyl octyl sulfide was first registered in the United States in 1962 for use as an insect repellent. There are currently 26 pesticide products registered primarily for homeowner use which contain hydroxyethyl octyl sulfide as an active ingredient. In September 1992, EPA issued a Data Call-In under reregistration Phase 4 requiring the registrant to provide appropriate chemistry, toxicology and environmental fate data on this active ingredient. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Data Call-In.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Color: Clear, colorless to faint yellow

Physical State: Semi-viscous liquid at 25°C

Odor: Mild sweet odor

Boiling Point: 288°C at 760 mm Hg

Density: 0.935 g/mL at 20°C

Solubility: Soluble in most organic solvents such as acetone, methanol, isopropanol, and petroleum ether. Also soluble in water at 0.0968 g/L

Vapor Pressure: 5.94×10^{-4} Torr at 25°C

Octanol/Water Partition Coefficient: K_{ow} is 4,367 at 25°C

Stability: Stable under normal storage conditions

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on hydroxyethyl octyl sulfide, as a non-food use pesticide, is adequate and will support a reregistration decision.

a. Acute Toxicity

Results of the acute toxicity studies conducted with technical grade hydroxyethyl octyl sulfide (96.1%) are summarized below in Table 1:

Table 1. Acute Toxicity Values of hydroxyethyl octyl sulfide

Route	Species	Results	Toxicity Category
Oral	Rat	LD_{50} = > 5000 mg/kg	IV
Dermal	Rabbit	LD_{50} = > 2000 mg/kg	III
Inhalation	Rat	LC_{50} = > 6.12 mg/L	IV
Eye Irritation*	Rabbit	Moderate irritant	II
Skin Irritation*	Rabbit	Slight irritant	III
Dermal Sensitization*	Guinea Pig	Non-sensitizer	NA

* This study is a requirement for manufacturing-use and end-use products (40 CFR 158). The hydroxyethyl octyl sulfide data have been generated on the TGAI and are presented here for informational purposes.

In an acute oral toxicity study, a group of young adult Sprague-Dawley rats (5/sex) was administered a single oral dose of undiluted technical hydroxyethyl octyl sulfide (96.1%) at 5000 mg/kg (Limit Dose). One female was found dead on Day 2. Clinical signs observed in both sexes were ruffled fur, diarrhea, dark stained muzzle, and anogenital staining. By Day 6, all rats recovered from the above conditions and appeared active and healthy for the remainder of the 14 day observation period. No treatment-related gross pathology was observed at termination. The acute oral LD_{50} was greater than 5000 mg/kg for both sexes. This suggests hydroxyethyl octyl sulfide is practically non-toxic via the oral route in rats and places it in Toxicity Category IV for acute oral toxicity (MRID 41772801).

In an acute dermal toxicity study, technical hydroxyethyl octyl sulfide (96.1%) was applied to the intact skin of New Zealand white rabbits (5/sex) at 2000 mg/kg (Limit Dose) for a period of 24 hours. The test material produced well defined erythema with severe edema and eschar at 4 days. Body weight loss was seen in 4/5 males and 4/5 females on Day 7, and in 2/5 males and 4/5 females on Day 14. Decreases in body weight gain were seen in 2/5 males and 4/5 females during the 14 day period. While no clinical signs were seen in males, 1-4 females exhibited tremors, lethargy, signs of diarrhea, no feces or thin appearance on Days 6 through 14. Gross necropsy revealed a lower gastrointestinal tract full of gas, mucus and dark liquid in two males and three females. The results of this study determined that the acute dermal LD_{50} was greater than 2000 mg/kg for both sexes. This suggests that hydroxyethyl octyl sulfide is slightly toxic via the dermal route in rabbits and places it in Toxicity Category III for acute dermal toxicity (MRID 41772802).

In an acute inhalation toxicity study, groups of Sprague-Dawley rats (5/sex) were exposed to aerosol concentrations of undiluted technical hydroxyethyl octyl sulfide (96.1%) at a mean analytical concentration of 6.12 ± 0.16 mg/L (slightly excessive of the Limit-Dose) with a mass median aerodynamic diameter (MMAD) particle size distribution of 2.0 ± 0.03 µM for 4-hours. The results of this study determined that the acute inhalation LC_{50} was greater than 6.12 mg/L (above the Limit-Dose) for both sexes. This suggests that hydroxyethyl octyl sulfide is practically non-toxic via the inhalation route in rats and places it in Toxicity Category IV for acute inhalation toxicity (MRID 41772803).

In a primary eye irritation study, 0.1 mL of technical hydroxyethyl octyl sulfide (96.1%) was instilled into the conjunctival sac of New Zealand white rabbits (3/sex). Hydroxyethyl octyl sulfide produced mucus discharge in one, hazy cornea in four, and conjunctival irritation in all rabbits. Although no visible corneal opacity or iritis was noted, the positive reading noted in five rabbits during fluorescein dye examination indicated damage to the corneal epithelium. No ocular effects were seen by Day 14. Since conjunctival irritation was seen in all animals and fluorescein readings did indicate damage to corneal epithelium which was not visible to the naked eye, the test material is considered to be a moderate eye irritant. The results of this study determined that hydroxyethyl octyl sulfide is a moderate eye irritant in rabbits, places it in Toxicity Category II for eye irritation (MRID 41772804).

In a primary dermal irritation study, New Zealand white rabbits (3/sex) received 0.5 mL of technical hydroxyethyl octyl sulfide (96.1%) on the intact skin under 4-hour semi-occluded conditions. Treatment-related

dermal reactions were erythema, edema and eschar formation; the average of the 4-, 24-, 48-, and 72-hour scores was 3.63. The results of this study determined that hydroxyethyl octyl sulfide was a slight irritant, places it in Toxicity Category III for dermal irritation (MRID 41772805).

In a study to evaluate the dermal sensitization potential of technical hydroxyethyl octyl sulfide (96.1%), 12 Hartley guinea pigs received dermal applications of 0.5 mL of the test material as a 1% v/v mixture in white mineral oil to the pre-assigned, delineated test site 3 times/week during a 3-week induction phase (total of 9 applications). Following a two-week resting period, the animals were challenged at the same concentration. None of the treated or naive control animals exhibited any irritation when challenged; the average skin reaction score for the virgin site was 0.0. A non-irritating dose (0.5 mL) of the positive control (0.1% 2-DNCB in 50% ethanol:saline solution) produced sensitization response (erythema and edema). Under the conditions of this study, hydroxyethyl octyl sulfide was shown to be a non-sensitizer in guinea pigs (MRID 41772806).

b. Subchronic Toxicity

In a 21-day dermal toxicity study, New Zealand white rabbits (5/sex/dose) were given repeated dermal applications of technical hydroxyethyl octyl sulfide (100%) in corn oil at doses of 50, 100 or 200 mg/kg, 6 hours/day, 7 days/week for 21 days; the vehicle control group (5/sex) received corn oil only on the same regimen. Treatment had no adverse effect on survival, clinical signs, mean body weights, body weight gain, food consumption, hematology, clinical chemistry, organ weights or gross histopathology. Treatment-related skin reactions were confined mainly to a proportion of animals receiving 100 or 200 mg/kg/day. Dermal reactions included: skin wrinkling in 1 male at 200 mg/kg/day; desquamation in 1 female at the vehicle control, 1 male and 1 female at 50 mg/kg/day, in 3 males and 2 females at 100 mg/kg/day, and in 5 males and 4 females at 200 mg/kg/day; and moderate to severe erythema usually in combination with moderate edema in 1 male and 1 female at the vehicle control and at 50 mg/kg/day, in 4 males and 0 females at 100 mg/kg/day and in 4 males and 2 females at 200 mg/kg/day. Based on these results, for dermal irritation the NOEL was 50 mg/kg/day and the LOEL was 100 mg/kg/day. For systemic toxicity the NOEL was > 200 mg/kg/day (HDT); a LOEL was not established (MRID 43123301).

c. Developmental Toxicity

In a developmental toxicity study, Sprague-Dawley Crl:CD BR rats (24/group) were orally administered technical hydroxyethyl octyl sulfide

(96.5%) at 0, 100, 300 or 1000 mg/kg/day (Limit-Dose) during Days 6 through 15 of gestation. No maternal toxicity was seen. The slight decrease in food consumption seen during gestation Days 9-11 in dams treated at 1000 mg/kg/day was not considered to be toxicologically significant due to the size of the standard deviations, range of food consumed, and because there were no corresponding decreases in either mean body weight or weight gain. Treatment had no effect on any of the cesarean parameters. Therefore, for maternal toxicity the NOEL was 1000 mg/kg/day (HDT); a LOEL was not established. No treatment-related fetal external or fetal soft tissue abnormalities were seen at any dose level. Treatment-related skeletal variations were limited to an increase, both in the number and percent of fetuses, as well as litters with 14th vestigial ribs at 1000 mg/kg/day when compared to controls. No treatment-related skeletal malformations were seen. Based on these results, the NOEL for developmental toxicity was 300 mg/kg/day and the LOEL was 1000 mg/kg/day. The LOEL was based on increased incidence of skeletal variations (MRID 42225802).

d. Mutagenicity

In a *Salmonella/*Mammalian microsome reverse mutation assay, when tested at concentrations of 0, 3, 10, 33 or 333 µg/plate in *S.typhimurium* strains TA98, TA100, TA1535 and TA1538, technical hydroxyethyl octyl sulfide (96.9%) was non-mutagenic in both the presence and absence of rat liver activation (MRID 41784003).

In a forward gene mutation assay, technical hydroxyethyl octyl sulfide (96.9%) gave negative results following exposure of Chinese hamster ovary cells at 0, 0.013, 0.025 or 0.05 µg/mL in the presence of metabolic activation and at concentrations of 0, 0.007, 0.013, 0.025 or 0.05 µg/mL in the absence of metabolic activation (MRID 41784002).

When tested in the L5178Y TK +/- mouse lymphoma assay, technical hydroxyethyl octyl sulfide (96.9%) was non-mutagenic both with (at concentrations ranging from 0.42 to 0.94 µL/mL) and without (at concentrations ranging from 0.01 to 0.05 µL/mL) metabolic activation (MRID 41784001).

In an *in vitro* primary rat hepatocyte UDS assay, technical hydroxyethyl octyl sulfide (96.9%) at concentrations of 0, 0.001, 0.003, 0.01, 0.03, 0.05, 0.075, or 0.1 µL/mL, did not cause a significant increase in the net nuclear grain counts of treated hepatocytes (MRID 41802101).

e. Other Toxicological Concerns

The Agency waived the requirement for a 90-Day inhalation study in rats with hydroxyethyl octyl sulfide because of its low acute inhalation toxicity and the lack of systemic toxicity in both the 21-day dermal study and the developmental toxicity study.

Based upon the Agency's review of the toxicology database for hydroxyethyl octyl sulfide, no short-term (1-7 days) or intermediate-term (7-90 days) occupational or residential exposure toxicological endpoints of concern were identified.

2. Exposure Assessment

a. Dietary Exposure

Based on the current use patterns and exposure profiles for hydroxyethyl octyl sulfide, residues in/on food and/or feed are not expected to occur. Because there is no expected dietary exposure to hydroxyethyl octyl sulfide, a dietary exposure assessment is not required.

b. Residential and Occupational Exposure

A residential and/or occupational exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete.

While products containing hydroxyethyl octyl sulfide are primarily for homeowner use, the Agency assumes there may be a potential for exposure to hydroxyethyl octyl sulfide in both residential and occupational settings under the current use-patterns associated with hydroxyethyl octyl sulfide products. The Agency identified the following two potential exposure scenarios:

- primary handler exposure -- persons handling end-use pesticide products containing hydroxyethyl octyl sulfide as an active ingredient;

- primary post-application exposures -- persons in and near areas where end-use pesticide products containing hydroxyethyl octyl sulfide as an active ingredient are being or have recently been applied.

3. Risk Assessment

a. Dietary

Based on the current use patterns and exposure profiles for hydroxyethyl octyl sulfide, residues in/on food and/or feed are not expected to occur. Therefore, a dietary risk assessment is not required.

b. Occupational and Residential

The Agency determined that the potential handler and post application exposure scenarios to hydroxyethyl octyl sulfide do not warrant a quantitative risk assessment because no toxicological endpoints of concern were identified in Section III. However, the Agency has determined that it is prudent to require consistent use precautions to afford product users increased protection from unnecessary exposure either during application or immediately following applications.

C. Environmental Assessment

1. Ecological Toxicity Data

The Agency has adequate data to assess the hazard of hydroxyethyl octyl sulfide to nontarget terrestrial organisms.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the acute and subacute toxicity of hydroxyethyl octyl sulfide to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); and two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail).

TABLE 2: Avian Acute Oral Toxicity Findings.			
Species	**% A.I.**	**LD_{50} mg/kg**	**Toxicity Category**
Northern Bobwhite	100	> 2,250	Practically nontoxic
Mallard	100	> 2,250	Practically nontoxic

TABLE 3: Avian Subacute Dietary Toxicity Findings.			
Species	**% A.I.**	**LC_{50} ppm**	**Toxicity Category**
Northern Bobwhite	100	> 6,554	Practically nontoxic
Mallard	100	> 6,554	Practically nontoxic

These results indicate that hydroxyethyl octyl sulfide is practically nontoxic to avian species on an acute oral (TABLE 2) and subacute dietary basis (TABLE 3). The guideline requirements are fulfilled. (MRIDs 41983001, 41983002, 41948001, and 41948002)

(2) Insects

A honey bee acute contact LD_{50} study is required if the proposed use will result in honey bee exposure. Based on the use pattern, which includes outdoor terrestrial uses, honey bee exposure to hydroxyethyl octyl sulfide is expected and therefore, acute testing is required.

TABLE 4: Nontarget Insect Toxicity Findings.			
Species	**% AI**	**LD_{50} μg/bee**	**Toxicity Category**
Honey Bee	96.3	56.9	Practically nontoxic

There is sufficient information to characterize hydroxyethyl octyl sulfide as practically nontoxic to bees (TABLE 4). The guideline requirement is fulfilled. (MRID 41982901)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of hydroxyethyl octyl sulfide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a cold water species (preferably the rainbow trout), and the other should use a warm water species (preferably the bluegill sunfish).

TABLE 5: Freshwater Fish Acute Toxicity Findings.

Species	% A.I.	LC_{50} ppm	Toxicity Category
Rainbow trout	96.5	2.9	Moderately toxic
Bluegill sunfish	96.5	2.8	Moderately toxic

The results of the acute toxicity studies indicate that hydroxyethyl octyl sulfide is moderately toxic to both cold and warm water fish (TABLE 5). The guideline requirements are fulfilled. (MRID 41910202 and 41910203)

(2) Freshwater Invertebrates

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

TABLE 6: Freshwater Invertebrate Toxicity Findings.

Species	% A.I.	EC_{50} ppm	Toxicity Category
Daphnia magna	96.5	0.37	Highly toxic

There is sufficient information to characterize hydroxyethyl octyl sulfide as highly toxic to aquatic invertebrates (TABLE 6). The guideline requirement is fulfilled. (MRID 41910204)

c. Toxicity to Plants.

Terrestrial and aquatic plant testing (seedling emergence and vegetative vigor) was not required for hydroxyethyl octyl sulfide.

2. Environmental Fate

a. Environmental Fate Assessment

All environmental fate data requirements are now satisfied for the outdoor, residential, terrestrial and non-food uses of hydroxyethyl octyl sulfide. Leaching and runoff are not likely to be significant based on the use patterns and lack of persistence in aerobic soil of both the parent compound and metabolites ($T_{1/2} < 2$ days), and the moderate mobility in soils with low organic material. Hydroxyethyl octyl sulfide is not expected to undergo direct photolysis, therefore, the Agency waived the aqueous photolysis data requirement. The Agency also waived the aged leaching-adsorption-desorption and terrestrial field dissipation data requirements for all uses because the parent compound and its metabolites degrade very rapidly in aerobic soil. Should hydroxyethyl octyl sulfide be applied using foggers in areas that are adjacent to surface waters, there would be some potential for surface water contamination due to drift.

b. Environmental Fate and Transport

The submitted studies are acceptable and give a consistent understanding of hydroxyethyl octyl sulfide dissipation in the environment. Hydroxyethyl octyl sulfide and its sulfoxide and sulfone degradates are not likely to persist for any significant amount of time, having half-lives of < 2 days in soil. Even though hydroxyethyl octyl sulfide residues are moderately mobile in soil and have a relatively high water solubility (97 ppm), ground and surface water contamination are not likely based on the lack of persistence in soil, the limited amount of use, and its outdoor application as a fog. However, hydroxyethyl octyl sulfide may persist if it is applied directly to water.

(1) Hydrolysis.

Hydroxyethyl octyl sulfide is an aliphatic compound that is stable to hydrolysis at pH 5, 7, and 9.(MRID 41982801)

(2) Aerobic Soil Metabolism.

The half-life in an aerobic sandy loam soil was 31 hours (1.3 days). Metabolites were the sulfone, sulfoxide, and alpha-hydroxylated sulfone and sulfoxide compounds, which degrade by beta oxidation to CO_2.

Uncharacterized residues in the soil extracts were 4.6 - 25.8% of the applied dose between 4 and 24 hours after treatment. No storage stability data are available.

Reanalysis of the soil extracts using another HPLC column and detector resulted in greater resolution of ^{14}C-hydroxyethyl octyl sulfide and its metabolites. Most of the previously uncharacterized radioactivity now appears to be from the parent compound, based on the results from the new methodology. The amount of parent compound increased from 53 to 81% for the 4-hour sampling interval, and from 37 to 58% for the 16-hour sampling interval. The half-life estimate for the parent compound increased slightly from 0.9 days (21.6 hours) to 1.3 days (31 hours). However, this is not a significant increase in persistence.

The proportions of metabolites also changed upon reanalysis of the soil extracts. The concentrations of the sulfoxide and sulfone metabolites (Metabolites 1 and 2) were higher in the early sampling intervals upon reanalysis, but Metabolites 3 and 4 (hydroxylated sulfoxide and sulfone) were actually lower upon reanalysis. Both the sulfoxide and sulfone metabolites reached maximum concentrations of approximately 25% by 36-96 hours, but degraded quickly with half-lives of < 1 day. The alpha-hydroxylated sulfoxide and sulfone metabolites never exceeded 3% of the applied compound. Total residues increased with the new analytical methodology, and the uncharacterized residues decreased from a maximum of 25% to a maximum of 2%. Soil extracts were found to be stable in storage for approximately 2 years, far longer than the study duration (30 days).

Hydroxyethyl octyl sulfide degraded with a calculated half-life of 31 hours (1.3 days) in sandy loam soil that had been dosed with 10 ppm of the parent compound and aerobically incubated at 25 ± 1 °C in darkness for up to 30 days. The identified metabolites were the sulfone, sulfoxide, and alpha-

hydroxylated sulfone and sulfoxide. Beta-oxidation and decarboxylation were the apparent degradation pathways of the aliphatic parent compound, based on the increase in soil-bound material and CO_2 in the volatility traps with increasing time (MRIDs 42459401 and 43005501).

(3) Unaged Leaching-Adsorption-Desorption.

Parent hydroxyethyl octyl sulfide is moderately mobile in Tiffany sand (North Dakota, 0.25% OC), Anthony sandy loam (Arizona, 0.35% OC), and Dundee clay loam (Mississippi, 0.65% OC) soils with Freundlich K_{ads} values of 1.5, 3.4, and 3.5, and K_{des} values of 1.2, 3.3, and 1.9. However, hydroxyethyl octyl sulfide was bound much more tightly in a Gardena silt loam soil (North Dakota, 2.1% OC) with Freundlich K_{ads} and K_{des} values of 14.7 and 13.7, respectively. This indicates that soil organic carbon may bind significant amounts of the hydroxyethyl octyl sulfide that reaches soil. K_{oc} values were 600, 538, 971, and 700 for adsorption, and K_{ocdes} values were 479, 292, 932, and 654. The 1/n (slope of regression isotherm) values were 1.02, 1.07, 1.02, and 0.89 for adsorption, and 0.91, 0.74, 1.18, and 1.12 for desorption.(MRID 42208201)

(4) Aqueous Photolysis.

This data requirement was waived because the current use patterns and label language prohibit direct application to water or were surface water is present.

(5) Aged Leaching-Adsorption-Desorption.

This data requirement was waived for the current use patterns because hydroxyethyl octyl sulfide and its metabolites degrade rapidly in aerobic soil with half-lives of < 2 days.

(6) Terrestrial Field Dissipation.

This data requirement was waived for the current use patterns because hydroxyethyl octyl sulfide and its metabolites degrade rapidly in aerobic soil with half-lives of < 2 days.

3. Exposure and Risk Characterization

a. Exposure and Risk to Nontarget Terrestrial Animals

(1) Birds

Based on the above studies this chemical is practically nontoxic to avian species on both an acute oral and subacute dietary basis. It is unlikely that birds will ingest any residue on avian food items (i.e. leaves, seed pods, insects) because hydroxyethyl octyl sulfide is quick to volatilize and, therefore, would not be available for uptake. In addition, based on the limited use pattern of hydroxyethyl octyl sulfide products and the lack of persistence in aerobic soil of both the parent compound and metabolites, it is unlikely that birds will be exposed through water. Therefore, nontarget avian species are not likely to be adversely impacted from the currently registered uses of hydroxyethyl octyl sulfide.

(3) Insects

Hydroxyethyl octyl sulfide is practically nontoxic to honeybees. However, its insecticidal use suggests that there is the potential for adverse affects to nontarget insects.

b. Exposure and Risk to Nontarget Aquatic Animals

Based on the above studies hydroxyethyl octyl sulfide displays moderate to high toxicity to most aquatic organisms tested to date. However, it is neither persistent nor mobile in the environment. Taking into account the relative immobility, the rapid dissipation in soils, and the use patterns, it is unlikely that hydroxyethyl octyl sulfide will leach into groundwater.

There is minimal potential for contamination of surface water by drift from the fogger application method should hydroxyethyl octyl sulfide be applied in close proximity to surface water. It is stable to hydrolysis, and may persist if applied directly to water. If aquatic organisms are exposed to hydroxyethyl octyl sulfide, they may be adversely impacted. However, the currently registered uses and existing label restrictions minimize the risk of surface water contamination.

c. Endangered Species

In order to lessen the exposure to endangered and/or threatened species from drift, use of hydroxyethyl octyl sulfide near water is restricted. Adherence to existing environmental hazards labeling should lessen the potential for exposure and risks to endangered and/or threatened species.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing hydroxyethyl octyl sulfide active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing hydroxyethyl octyl sulfide. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of hydroxyethyl octyl sulfide, 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 hydroxyethyl octyl sulfide and to determine that hydroxyethyl octyl sulfide, as specified in this document, can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing hydroxyethyl octyl sulfide as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc., and the data identified in Appendix B. Although the Agency has found that all uses of hydroxyethyl octyl sulfide, as specified in this document, are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing hydroxyethyl octyl sulfide, 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 hydroxyethyl octyl sulfide, the Agency has sufficient information on the health effects of hydroxyethyl octyl sulfide and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that hydroxyethyl octyl sulfide 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 hydroxyethyl octyl sulfide for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

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

C. Regulatory Position

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

1. Risk Mitigation Measures/Labeling Rationale

Worker Protection

At this time all registered uses of hydroxyethyl octyl sulfide are outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The Agency is not establishing any new entry restrictions at this time for occupational uses of hydroxyethyl octyl sulfide end-use products because no toxicological endpoints of concern were identified and no additional risk mitigation measures are warranted. However, the Agency has concluded that it is prudent to require a continuation of current minimal label precautions to afford product users protection from unnecessary exposure. These label requirements are specified below in Section V and must be retained and/or added since there may be potential for application and post application exposure.

Personal Protective Equipment/Engineering Controls for Handlers

1. If the Agency determines that regulatory action on an active ingredient must be taken as a result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects:

* In the RED for that active ingredient, the Agency may establish minimum or baseline handler PPE requirements that pertain to all or most end-use products containing the 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, etc.) must be placed on the label of the end-use product.

2. If the Agency determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent Agency guidelines.

The Agency has identified no toxicological endpoints of concern for hydroxyethyl octyl sulfide that would require the establishment of personal protective equipment (PPE) or engineering controls based on the toxicity of the technical hydoxyethyl octyl sulfide. Therefore, as stated above PPE for pesticide handlers will be based on the acute toxicity of the end-use products. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent Agency guidelines.

Aquatic Risk Mitigation/Labeling Rationale

From its assessment of the environmental fate and ecotoxicology data for hydroxyethyl octyl sulfide and in consideration of the outdoor fogging use, the Agency concludes that a continuation of labeling precautions and restrictions against surface water contamination is prudent.

Other Labeling Requirements

Other use and safety information is being required for labeling of end-use products to afford users a greater degree of protection. Refer to Section V for these label requirements.

V. ACTIONS REQUIRED BY REGISTRANTS

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

A. Manufacturing-Use Products

1. Generic Data Requirements

The generic data base supporting the reregistration of hydroxyethyl octyl sulfide for the above eligible uses has been reviewed and determined to be complete. No additional generic data are required at this time.

2. Labeling Requirements for Manufacturing-Use Products

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

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

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under

> "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

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

(b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or

grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

B. End-Use Products

To remain in compliance with FIFRA, end-use product (EP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies.

1. Additional Product-Specific Data Requirements

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

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

2. Labeling Requirements for End-Use Products

a. PPE/Engineering Control Requirements for Pesticide Handlers

Any necessary PPE for each hydroxyethyl octyl sulfide end-use product will be established on the basis of the end-use product's acute toxicity. The more protective handler PPE/engineering control requirement's must be retained. For guidance on which requirements are considered more protective, as well as the format, the language, and the requirements location on the end-use product label, see PR Notice 93-7.

b. Application Restrictions

For all end-use products:

"Do not apply this product in a way that will contact any unprotected person, either directly or through drift. Keep people and pets out of area during application."

For end-use products formulated as foggers:

"Not for indoor use."

c. User Safety Requirements

For multiple active ingredient end-use products that contain hydroxyethyl octyl sulfide, the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled." The Agency is requiring the following minimum user safety requirements for end-use products containing hydroxyethyl octyl sulfide.

For end-use product formulated as foggers:

"Allow spray to disperse for several minutes before allowing people or pets to enter the treated area."

For all indoor end-use products:

"Do not use in commercial food processing, storage preparation or serving areas. In the home, all food processing surfaces and utensils should be covered or removed during treatment and thoroughly washed before use. Cover and remove food before treatment."

For all other end-use products:

"Do not allow people or pets to touch treated surfaces until the sprays have dried."

d. User Safety Recommendations

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"If pesticide gets inside clothing, remove clothing immediately, wash thoroughly and put on clean clothing."

e. Use Limitations

"Do not apply directly to water or wetlands, swamps, bogs, marshes and potholes, or areas where surface water is present or to intertidal areas below the mean high water mark. Keep out of lakes streams and ponds. Do not apply on food crops. Do not apply on household pets."

"The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas)."

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 hydroxyethyl octyl sulfide 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 REPORT

Case 3103[2-(Octylthio)ethanol] **Chemical 046301[2-Hydroxyethyl octyl sulfide]**

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop 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													
FOOD/FEED USES													
HOUSEHOLD/DOMESTIC DWELLINGS INDOOR FOOD HANDLING AREAS				Use Group: INDOOR FOOD									
Indoor general surface treatment, When needed, Aerosol can	PRL	NA		UC	* NS	NS	NS	NS	AN	NS			
	PRL	NA		UC	* NS	NS	NS	NS	NS	NS			
NON-FOOD/NON-FEED													
COMPOST/COMPOST PILES				Use Group: OUTDOOR RESIDENTIAL									
Spot treatment, When needed, Aerosol can	PRL	NA		UC	* NS	NS	NS	NS	AN	NS			
Spray, When needed, Aerosol can	PRL	NA		UC	* NS	NS	NS	NS	AN	NS			
HOUSEHOLD/DOMESTIC DWELLINGS				Use Group: INDOOR RESIDENTIAL									
Indoor general surface treatment, When needed, Aerosol can	PRL	NA		UC	* NS	NS	NS	NS	NS	NS			
HOUSEHOLD/DOMESTIC DWELLINGS INDOOR PREMISES				Use Group: INDOOR RESIDENTIAL									
Indoor general surface treatment, When needed, Aerosol can	PRL	NA		UC	* NS	NS	NS	NS	AN	NS			
	PRL	NA		UC	* NS	NS	NS	NS	NS	NS			
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES				Use Group: OUTDOOR RESIDENTIAL									
Contact and/or surface treatment, Evening, Aerosol can	PRL	NA		UC	* NS	NS	NS	NS	AN	NS			
	PRL	NA		UC	* NS	NS	NS	NS	NS	NS			C92, C94
Contact and/or surface treatment, Late evening, Aerosol can	PRL	NA		UC	* NS	NS	NS	NS	AN	NS			

APPENDIX A REPORT

Case 3103[2-(Octylthio)ethanol] Chemical 046301[2-Hydroxyethyl octyl sulfide]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop 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 (con't)													
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES (con't)				Use Group: OUTDOOR RESIDENTIAL (con't)									
Contact and/or surface treatment, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Directed spray, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Fog, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Outdoor general surface spray, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
Outdoor premise treatment, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
Spot treatment, Nighttime, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		
Spot treatment, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Spray, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
ORNAMENTAL AND/OR SHADE TREES				Use Group: OUTDOOR RESIDENTIAL									
Spray, Foliar, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		

APPENDIX A REPORT

Case 3103[2-(Octylthio)ethanol] Chemical 046301[2-Hydroxyethyl octyl sulfide]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop 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 (con't)													
ORNAMENTAL GROUND COVER				Use Group: OUTDOOR RESIDENTIAL									
Directed spray, Evening, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Directed spray, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Spray, Foliar, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
ORNAMENTAL HERBACEOUS PLANTS				Use Group: OUTDOOR RESIDENTIAL									
Directed spray, Evening, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Directed spray, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
ORNAMENTAL LAWNS AND TURF				Use Group: OUTDOOR RESIDENTIAL									
Directed spray, Evening, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Directed spray, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
ORNAMENTAL NONFLOWERING PLANTS				Use Group: OUTDOOR RESIDENTIAL									
Directed spray, Evening, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Directed spray, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
ORNAMENTAL WOODY SHRUBS AND VINES				Use Group: OUTDOOR RESIDENTIAL									
Directed spray, Evening, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Directed spray, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Spray, Foliar, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
PATHS/PATIOS				Use Group: OUTDOOR RESIDENTIAL									
Contact and/or surface treatment, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		

APPENDIX A REPORT

Case 3103[2-(Octylthio)ethanol] Chemical 046301[2-Hydroxyethyl octyl sulfide]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
PATHS/PATIOS (con't)				Use Group: OUTDOOR RESIDENTIAL (con't)									
Fog, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		
Outdoor premise treatment, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
Spot treatment, Nighttime, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		
Spot treatment, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		
PET LIVING/SLEEPING QUARTERS				Use Group: INDOOR RESIDENTIAL									
Spot treatment, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
RECREATIONAL AREAS				Use Group: TERRESTRIAL NON-FOOD CROP									
Contact and/or surface treatment, Evening, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Contact and/or surface treatment, Late evening, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
Contact and/or surface treatment, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Fog, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94

APPENDIX A REPORT

Case 3103[2-(Octylthio)ethanol] Chemical 046301[2-Hydroxyethyl octyl sulfide]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop 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 (con't)													
RECREATIONAL AREAS (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)									
Outdoor premise treatment, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
Spot treatment, Nighttime, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		
Spot treatment, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		
	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
REFUSE/SOLID WASTE SITES (OUTDOOR)				Use Group: TERRESTRIAL NON-FOOD CROP									
Directed spray, Evening, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Directed spray, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	NS	NS		C92, C94
Outdoor general surface spray, When needed, Aerosol can	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		

APPENDIX A REPORT

Case 3103[2-(Octylthio)ethanol] Chemical 046301[2-Hydroxyethyl octyl sulfide]

LEGEND

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

PRL	: PRESSURIZED 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

C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

APPENDIX A REPORT

Case 3103[2-(Octylthio)ethanol] Chemical 046301[2-Hydroxyethyl octyl sulfide]

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USE LIMITATIONS CODES (Cont.)

C94 : Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas.

* 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 hydroxyetheyl octyl sulfide covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to hydroxyetheyl octyl sulfide 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 Hydroxyethyl octyl sulfide

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	all	**MRID 41972201**
61-2A	**Start. Mat. & Mnfg. Process**	all	**MRID 41972201**
61-2B	**Formation of Impurities**	all	**MRID 41972201**
62-1	**Preliminary Analysis**	all	**MRID 41972202**
62-2	**Certification of limits**	all	**MRID 41972202**
62-3	**Analytical Method**	all	**MRID 41972202**
63-2	**Color**	all	**MRID 41972203**
63-3	**Physical State**	all	**MRID 41972203**
63-4	**Odor**	all	**MRID 41972203**
63-6	**Boiling Point**	all	**MRID 41972203**
63-7	**Density**	all	**MRID 41972203**
63-8	**Solubility**	all	**MRIDs 41972203, 41983003**
63-9	**Vapor Pressure**	all	**MRIDs 41972203, 41982802**
63-10	**Dissociation Constant**	all	**waived**
63-11	**Octanol/Water Partition**	all	**MRIDs 41972203, 41983004**
63-12	**pH**	all	**waived**
63-13	**Stability**	all	**MRIDs 41972203, 42060001**
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	CKM	**MRIDs 41983001, 41983002**

Data Supporting Guideline Requirements for the Reregistration of Hydroxyethyl octyl sulfide

REQUIREMENT		USE PATTERN	CITATION(S)
71-2A	**Avian Dietary - Quail**	CKM	**MRID 41948001**
71-2B	**Avian Dietary - Duck**	CKM	**MRID 41948002**
72-1A	**Fish Toxicity Bluegill**	CKM	**MRID 41910202**
72-1C	**Fish Toxicity Rainbow Trout**	CKM	**MRID 41910203**
72-2A	**Invertebrate Toxicity**	CKM	**MRID 41910204**
141-1	**Honey Bee Acute**	CKM	**MRID 41982901**
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	CKM	**MRID 41772801**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	CKM	**MRID 41772802**
81-3	**Acute Inhalation Toxicity - Rat**	CKM	**MRID 41772803**
81-4	**Primary Eye Irritation - Rabbit**	CKM	**MRID 41772804**
81-5	**Primary Dermal Irritation - Rabbit**	CKM	**MRID 41772805**
81-6	**Dermal Sensitization - Guinea Pig**	CKM	**MRID 41772806**
82-2	**21-Day Dermal - Rabbit/Rat**	CKM	**MRID 43123301**
83-3A	**Developmental Toxicity - Rat**	CKM	**MRID 42225802**
84-2A	**Gene Mutation (Ames Test)**	CKM	**MRIDs 42658801, 42658802, 42658803**
84-2B	**Structural Chromosomal Aberration**	CKM	**MRIDs 42658801, 42658802**
84-4	**Other Genotoxic Effects**	CKM	**MRID 42658804**
ENVIRONMENTAL FATE			

Data Supporting Guideline Requirements for the Reregistration of Hydroxyethyl octyl sulfide

REQUIREMENT		USE PATTERN	CITATION(S)
160-5	**Chemical Identity**	C	**MRID 41972201**
161-1	**Hydrolysis**	C	**MRID 41982801**
162-1	**Aerobic Soil Metabolism**	C	**MRIDs 42459401, 43005501**
163-1	**Leaching/Adsorption/Desorption**	C	**MRID 42208201**
164-1	**Terrestrial Field Dissipation**	C	**WAIVED**

GUIDE TO APPENDIX C

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

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

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

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

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

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

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

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

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

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

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

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

BIBLIOGRAPHY

MRID	CITATION
41772801	Gabriel, D. (1990) MGK Repellent 874 Code No. 673-90: Acute Oral Toxicity, Single Level-Rats: Lab Project Number: 90-7122A. Un-published study prepared by Biosearch Inc. 10 p.
41772802	Gabriel, D. (1990) MGK Repellent 874 Code No. 673-90: Acute Dermal Toxicity, Single Level-Rabbits: Lab Project Number: 90-7122A. Unpublished study prepared by Biosearch Inc. 13 p.
41772803	Hershman, R. (1990) MGK Repellent 874 Code No. 673-90: Acute Inhalation Toxicity, Single Level, 4-Hour Exposure-Rats: Lab Project Number: 90-7122A. Unpublished study prepared by Biosearch Inc. 26 p.
41772804	Bielucke, J. (1990) MGK Repellent 874 Code No. 673-90: Primary Eye Irritation-Rabbits: Lab Project Number: 90-7122A. Unpublished study prepared by Biosearch Inc. 14 p.
41772805	Romanelli, P. (1990) MGK Repellent 874 Code No. 673-90: Primary Skin Irritation-Rabbits: Lab Project Number: 90-7122A. Unpublished study prepared by Biosearch Inc. 10 p.
41772806	Romanelli, P. (1990) MGK Repellent 874 Code No. 673-90: Guinea Pig Dermal Sensitization-Modified Buehler Method: Lab Project Number: 90-7122A. Unpublished study prepared by Biosearch Inc. 20p.
41910202	Bowman, J.; Bucksath, J. (1991) Acute Flow-through Toxicity of MGK Repellant 874 to Bluegill (Lepomis macrochirus): Lab Project Number: 39202. Unpublished study prepared by ABC Labs, Inc. 320 p.
41910203	Bowman, J.; Bucksath, J. (1991) Acute Flow-through Toxicity of MGK Repellent 874 to Rainbow Trout (Oncorhynchus mykiss): Lab Project No. 39203. Unpublished study prepared by ABC Labs, Inc. 316 p.
41910204	Blasberg, J.; Butzlaff, T.; Bucksath, J. (1991) Acute Toxicity of MGK Repellant 874 to Daphnia magna under Flow-through Conditions: Lab Project Number: 39204. Unpublished study prepared by ABC Labs, Inc. 334 p.
41948001	Grimes, J.; Lynn, S.; Smith, G. (1991) MGK Repellent 874: A Dietary LC50 Study in the Northern Bobwhite: Lab Project Number: 163-118 Unpublished study prepared by Wildlife International Ltd. 22p.
41948002	Grimes, J.; Lynn, S.; Smith, G. (1991) MGK Repellent 874: A Dietary LC50 Study with the Mallard: Lab Project Number: 163-119. Unpublished study prepared by Wildlife International Ltd. 22 p.
41972201	Meinen, V.; Sundquist, D. (1991) Product Identity and Composition of MGK Repellent 874: Lab Project Number: GLP-249/61. Unpublished study prepared by McLaughlin Gormley King Co. 140 p.
41972202	Meinen, V.; Sundquist, D. (1991) Analysis and Certification of Product Ingredients for MGK Repellent 874. Unpublished study prepared by McLaughlin Gormley King Co. 49 p.
41972203	Sundquist, D.; Meinen, V. (1991) Product Chemistry of MGK Repellent 874: Physical and Chemical Characteristics: Lab Project Number: GLP-250/225. Unpublished study prepared by McLaughlin Gormley King Co. 33 p.

BIBLIOGRAPHY

MRID	CITATION
41982801	Gorman, M. (1991) Hydrolysis of MGK 874 as a Function of PH at 25C: Lab Project Number: 39311. Unpublished study prepared by ABC Laboratories, Inc. 41 p.
41982802	Laster, W. (1991) Vapor Pressure at 25C of MGK 874: Lab Project Number: 39312. Unpublished study prepared by ABC Laboratories, Inc. 210 p.
41982901	Blasberg, J. and T. Butzlaff. 1991. Final report for LX119-02 (Repellent 874) acute contact toxicity study on honey bees in Georgia. Southern Agricultural Research, Inc., PO Box 5126, 3025 Madison Highway, Valdosta, GA 31603-5126. LANDIS protocol number 1411-91-19-02-21F-01. Submitted by McLaughlin Gormley King Co., 8810 Tenth Avenue N, Minneapolis, Minn. 55427.
41983001	Campell, S.; Lynn, S.; Smith, G. (1991) MGK Repellent 874: An Acute Oral Toxicity Study with the Northern Bobwhite: Lab Project Number: 163-120. Unpublished study prepared by Wildlife International Ltd. 28 p.
41983002	Campell, S.; Lynn, S.; Smith, G. (1991) MGK Repellent 874: An Acute Oral Toxicity Study with the Mallard: Lab Project Number: 163-121. Unpublished study prepared by Wildlife International Ltd. 27 p.
41983003	Pesselman, R. (1991) Water Solubility Determination of MGK Repellent 874: Lab Project Number: HWI 6001-718. Unpublished study prepared by Hazleton Wisconsin, Inc. 33 p.
41983004	Pesselman, R. (1991) Octanol/Water Partition Coefficient Determination of MGK Repellent 874: Lab Project Number: HWI 6001-708. Unpublished study prepared by Hazleton Wisconsin, Inc. 39 p.
42060001	Meinen, V. (1991) Product Chemistry of MGK Repellent 874: Physical and Chemical Characteristics: Supplemental Information: Lab Project Number: GLP-225. Unpublished study prepared by McLaughlin Gormley King Co. 20 p.
42208201	Williams, M.; White-Berghaus, L. (1992) Soil/Sediment Adsorption-Desorption of MGK Repellent 874: Lab Project Number: 39435. Unpublished study prepared by ABC Labs., Inc. 51 p.
42225802	Irvine, L. (1992) MGK Repellent 874 (R874): Rat Development Toxicity (Teratology) Study: Lab Project Number: MCA/4/R. Unpublished study prepared by Toxicol Labs., Ltd. 175 p.
42459401	Williams, M. (1992) Aerobic Soil Metabolism of MGK Repellent 874: Lab Project Number: 39431. Unpublished study prepared by ABC Laboratories, Inc. 44 p.
42658801	Meinen, V. (1991) Analysis of Ethanol Dilutions Regarding L5178Y TK+/-Mouse Lymphoma Mutagenesis Assay: Final Report: Lab Project Number: GLP-279. Unpublished study prepared by MGK Co. 10 p.
42658802	Meinen, V. (1991) Analysis of Ethanol dilutions Regarding Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells: Final Report: Lab Project Number: GLP-279. Unpublished study prepared by MGK Co. 10 p.

BIBLIOGRAPHY

MRID	CITATION
42658803	Meinen, V. (1991) Analysis of Ethanol Dilutions Regarding Salmonella/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames Test): Final Report: Lab Project Number: GLP-279. Unpublished study prepared by MGK Co. 11 p.
42658804	Meinen, V. (1991) Analysis of Ethanol Dilutions Regarding Unscheduled DNA Synthesis in Rat Primary Hepatocytes: Final Report: Lab Project Number: GLP-279. Unpublished study prepared by MGK Co. 10 p.
43005501	Williams, M. (1993) Aerobic Soil Metabolism of MGK Repellent 874-Supplemental Report: Lab Project Number: 394311: N/163/1. Unpublished study prepared by ABC Laboratories, Inc. 61 p.
43123301	Husband, R. (1994) MGK Repellent 874: 21 Day Dermal Toxicity Study in the Rabbit: Lab Project Number: MCA/21/C: MCA/21/93. Unpublished study prepared by Toxicol Laboratories, Ltd. 182 p.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

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

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

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information

is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-96).

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or © 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 CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or 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

HYDROXYETHYL OCTYL SULFIDE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 hydroxyethyl octyl sulfide. 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 hydroxyethyl octyl sulfide 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 hydroxyethyl octyl sulfide are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on hydroxyetheyl octyl sulfide 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 hydroxyethyl octyl sulfide 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 Jean Holmes at (703) 308-8008.

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

Jean Holmes
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: **hydroxyethyl octyl sulfide**

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 <u>only one</u> of the following response codes <u>for each data requirement</u> 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 2-HYDROXYETHYL OCTYL SULFIDE 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 2-Hydroxyethyl octyl sulfide 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. Not with-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.

Twenty six products were found which contain 2-hydroxyethyl octyl sulfide as an active ingredient. The products have been placed into 5 batches in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the products in each batch. Table 2 identifies the products that could not be batched.

Table 1

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	499-342	2-hydroxyethyl octyl Sulfide 1.00 Permethrin 0.265	Pressurized Liquid
	11715-27	2-Hydroxyethyl octyl Sulfide 1.00 Permethrin 0.284	" "
	432-526	2-hydroxyethyl octyl Sulfide 1.00 Permethrin 0.28	" "
2	4822-161	2-hydroxyethyl octyl sulfide 1.00d-Trans Allethrin 0.223 Resmethrin 0.188	" "
	4822-99	2-hydroxyethyl octyl Sulfide 1.00 d-Trans Allethrin 0.222 Resmethrin 0.188	" "
	432-617	2-hydroxyethyl octyl sulfide 1.00 d-Trans Allethrin 2.00 Resmethrin 0.0750	" "
3	4822-82	2-hydroxyethyl octyl sulfide 1.00 Methoxychlor 1.00 Piperonyl Butoxide 1.00 Pyrethrins 0.020	" "
	4822-56	" " " " "	" "
4	4822-184	2-hydroxyethyl octyl sulfide 1.00 d-trans allethrin 0.223 Sumithrin 0.084	" "
	4822-185	" " " " "	" "
5	3282-68	2-Hydroxyethyl octyl Sulfide 1.50 Trans Allethrin 1.08 MGK Synergist 0.500	Pressurized Liquid
	3282-17	2-Hydroxyethyl octyl Sulfide 1.00 Piperonyl Butoxide 0.150 MGK Synergist 265 0.250 Pyrethrins 0.075	" "

Table 2

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	1021-676	2-hydroxyethyl octyl Sulfide 94.37	Liquid
	1021-851	2-Hydroxyethyl octyl Sulfide 50.00 MGK Synergist 12.50 Piperonyl Butoxide 7.50	" "
	1021-1241	1-Hydroxyethyl octyl Sulfide 27.4 Piperonyl Butoxide 27.4 Esbiol concentrate 3.49 other isomers 0.275	" "
	1021-1495	2-Hydroxyethyl octyl Sulfide 25.00 d-cis-trans Allethrin 5.0 Multicide pynamin forte 1.88	" "
	1021-1541	2-Hydroxyethyl octyl Sulfide 20.0 MGK 264 synergist 10.0 Piperonyl Butoxide 6.0	" "
	1021-1026	2-Hydroxyethyl octyl Sulfide 10.0 d-Trans allethrin 2.23	" "
	1021-912	2-Hydroxyethyl octyl Sulfide 9.091 MGK 264 Synergist 2.275 Piperonyl butoxide 1.365 Premium Pyrocide 3.412	" "
	1021-1046	2-Hydroxyethyl octyl Sulfide 10.00 Piperonyl Butoxide 3.31 d-Trans Allethrin 0.74 Methoxychlor 13.34	" "
	3282-25 *	2-Hydroxyethyl Octyl Sulfide 1.50 Trans allethrin 0.1 Piperonyl Butoxide 0.05	Pressurized Liquid
	239-2421 *	2-Hydroxyethyl octyl Sulfide 1.00 Resmethrin 0.2840	" "
	9688-50 *	2-Hydroxyethyl octyl Sulfide 0.950 Piperonyl Butoxide 0.150 MGK Synergist 0.250 Pyrethrins 0.075	" "

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	478-80 *	2-Hydroxyethyl octyl Sulfide 0.950 Trans Allethrin 0.112 Resmethrin 0.375 Permethrin 0.575	" "
	4822-309 *	2-Hydroxyethyl octyl Sulfide 0.500 Trans Allethrin 0.1425 Permethrin 0.154	" "
	475-175	2-Hydroxyethyl octyl Sulfide 0.500 Resmethrin 0.2280	" "

* Data in category III or IV from EPA 3282-25 may be bridged to registrations marked with asterisk, but these registrations cannot be batched.

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

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

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

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

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

Signature	Date

Name and Title (Please Type or Print)

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

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents for hydroxyetheyl octyl sulfide 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 Jean Holmes at (703)-308-8008.

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 hydroxyethyl octyl sulfide.

The following documents are part of the Administrative Record for hydroxyethyl octyl sulfide 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