



Reregistration Eligibility Decision (RED) Methylisothiazolinone



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, methylisothiazolinone which includes the active ingredients 5-chloro-2-methyl-3(2H)-isothiazolone and 2-methyl-3(2H)-isothiazolone. The enclosed Reregistration Eligibility Decision (RED), which was approved on **April 03, 1996** contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Barbara Briscoe at (703) 308-8177. Address any questions on required generic data to the Special Review and Reregistration Division representative, Deanna Scher at (703) 308-7043.

Sincerely yours,

Lois Rossi, Division Director
Special Review

Enclosures

and Reregistration Division

**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

Methylisothiazolinone

LIST C

CASE 3092

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

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METHYLISOTHIAZOLINONE REREGISTRATION ELIGIBILITY DECISION TEAM

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

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
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 has completed its reregistration eligibility decision for the pesticide case methylisothiazolinone, which includes the active ingredients 5-chloro-2-methyl-3(2H)-isothiazolone and 2-methyl-4-isothiazolin-3-one. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. 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. To mitigate risks of potential inhalation and dermal toxicity to workers the Agency is requiring, among other changes, the use of personal protective equipment. Additional data for hydrolysis for 5-chloro-2-methyl-3(2H)-isothiazolone are required to be submitted to confirm the Agency's assessment and conclusions.

Use Patterns

Methylisothiazolinone is an antimicrobial used to control slime-forming bacteria, fungi, and algae in cooling water systems, fuel storage tanks, pulp and paper mill water systems, oil extraction systems, and other industrial settings. It is also used to control the growth of mold, mildew, and sapstain on wood products.

Human Health Assessment

From its review of the mammalian toxicology data, the Agency determined that methylisothiazolinone is highly to very highly toxic, especially corrosive, by acute routes of exposure. In subchronic studies with oral and inhalation dosing of rats, the most significant toxicological effect was microscopic lesions in the nasal turbinates from inhalation exposure (NOEL of 0.34 $\mu\text{g}/\text{l}$), which is a typical physiological response to a respiratory irritant. Developmental and chronic/carcinogenicity studies resulted in no significant effects, with the Agency classifying methylisothiazolinone as a group D carcinogen. Results from mutagenicity studies were equivocal.

The Agency selected the respiratory effect from the subchronic inhalation study as the toxicological endpoint for risk assessment of short-term and intermediate occupational exposures. The Agency concluded that the risks to workers in most situations are not of concern and short-term risks of corrosivity can be adequately managed, as necessary. The Agency further believes risks from secondary occupational exposures, residential exposures, and post-application exposures are comparatively less and also not of concern.

Environmental Assessment

Methylisothiazolinone is moderately toxic to practically non-toxic to birds, and highly toxic to freshwater and estuarine/marine organisms. While the hazard to aquatic organisms from methylisothiazolinone has been characterized, a quantitative risk assessment has not been conducted because the risks to aquatic environments from these uses are regulated under the NPDES permitting program of EPA's Office of Water.

Product Reregistration

Before reregistering the products containing methylisothiazolinone, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. In addition, registrants must comply with the generic data requirements as outlined in Section V of this document. These data include the upgrading of an existing hydrolysis study. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products that contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

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

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

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of methylisothiazolinone. The document consists of six sections. Section I is the introduction. Section II describes methylisothiazolinone, 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 methylisothiazolinone. Section V discusses the reregistration requirements for methylisothiazolinone. 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

This Reregistration Eligibility Decision covers the two active ingredients 5-chloro-2-methyl-3(2H)-isothiazolone and 2-methyl-3(2H)-isothiazolone. These two active ingredients occur together in the currently registered products in approximately a 3:1 ratio, respectively, and are commonly referred to as methylisothiazolinone. The Agency has permitted most generic studies to be conducted on the formulation intermediate or on end-use products which contain both active ingredients in equilibrium (~3:1 ratio).

! Chemical Names: 5-Chloro-2-methyl-3(2H)-isothiazolone
2-Methyl-3(2H)-isothiazolone

! **Chemical Family:** Thiazole, heterocyclic aromatic compound

! **Trade and Other Names:** Kathon®

! **Basic Manufacturer:** Rohm and Haas Company

1. 5-Chloro-2-methyl-3(2H)-isothiazolone

! **CAS Registry Number:** 26172-55-4

! **OPP Chemical Code:** 107103

! **Empirical Formula:** C₄H₄ClNOS

2. 2-Methyl-3(2H)-isothiazolone

! **CAS Registry Number:** 2682-20-4

! **OPP Chemical Code:** 107104

! **Empirical Formula:** C₄H₅NOS

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods.

For Methylisothiazolinone:

(5-chloro-2-methyl-3(2H)-isothiazolone and 2-methyl-3(2H)-isothiazolone)

Type of Pesticide: Microbiocide/Microbiostat (slime-forming bacteria, fungi, and algae), Fungicide (mold and mildew, sapstain)

Use Sites:

TERRESTRIAL NON-FOOD SITES:

Wood Protection Treatment To Forest Products (Seasoned)

Wood Pressure Treatment To Forest Products

Oil Recovery Drilling Muds/Packer Fluids*

AQUATIC NON-FOOD INDUSTRIAL:

Air Washer Water Systems
Commercial/Industrial Water Cooling Systems
Evaporative condenser Water Systems
Heat Exchanger Water Systems
Industrial Processing Water
Industrial Scrubbing System
Oil Recovery Drilling Muds/Packer Fluids*
Pulp/Paper Mill Water Systems
Secondary Oil Recovery Injection Water

AQUATIC NON-FOOD OUTDOOR:

Wood Protection Treatment (unspecified)**

INDOOR FOOD

Adhesives and Coatings intended for Food Packaging
(regulated by FDA)

INDOOR NON-FOOD:

Adhesives, Industrial
Coatings, Industrial
Emulsions, Resin/Latex/Polymer
Fuels/Oil Storage Tank Bottom Water Additive
Metalworking Cutting Fluids
Oil Recovery Drilling Muds/Packer Fluids*
Paints, Latex (In-Can)
Pasteurizer/Warmer/Cannery Cooling Water Systems
Specialty Industrial Products
(e.g., cleaning fluids, hydraulic fluids, polishes, air fresheners,
carpet shampoos, detergents, waxes, photo plate processing
chemicals, conveyor lubricants)

* Registrants must specify on labels, as per Section V of this document, whether the product is used on off-shore and/or terrestrial sites.

** One label has use directions for treatment to pilings. The registrant has agreed to clarify their label to specify that these treated woods are not to be used in aquatic environments. For further details, see Section V.

* Registrants must specify on labels, as per Section V of this document, whether the product is used on off-shore and/or terrestrial sites.

Textiles/Textile Fibers/Cordage
Wet-End Additives/Industrial Processing Chemicals

Target Pests: Slime-forming bacteria, fungi, and algae; sulfate-reducing bacteria

Formulation Types Registered:

TYPE: End use, Manufacturing use

FORM: Soluble concentrate/liquid, Soluble concentrate/solid

Method and Rates of Application:

Types of Treatment - Industrial preservative treatment, Preservative treatment, Water treatment, Water treatment (recirculating system), Water treatment (unspecified)**, Wood protection treatment by pressure, Dip treatment, Non-soil contact non-fumigation

Equipment - Chemical pump, Metering pump, Automatic dispensing equipment, Dip tank, Sprayer, Not specified (Registrant must specify on labeling).

Use Rate -

Use Rates for 5-Chloro-2-methyl-3(2H)-isothiazolone:

Terrestrial Non-Food Crop

Microbiocide for oil recovery drilling muds and packer fluids - 0.34 to 34 ppm active ingredient.

Fungicide (mold and mildew) for wood products - 1.7 to 37 ppm active ingredient.

Fungicide (sapstain) for wood products - not able to calculate dosage.

Aquatic Non-Food Industrial

0.11 to 36 ppm active ingredient.

Aquatic Non-Food Outdoor

** See Section V for revisions to clarify this use site.

1.7 to 37 ppm active ingredient.

Indoor Non-Food

0.29 to 115 ppm active ingredient.

Use Rates for 2-Methyl-3(2H)-isothiazolone:

Terrestrial Non-Food Crop

Microbiocide for oil recovery drilling muds and packer fluids - 0.1 to 10 ppm active ingredient.

Fungicide (mold and mildew) for wood products - 0.52 to 11 ppm active ingredient. (wood protection treatment)

Fungicide (sapstain) for wood products - not able to calculate dosage. (wood protection treatment)

Aquatic Non-Food Industrial

0.034 to 11 ppm active ingredient.

Aquatic Non-Food Outdoor

0.52 to 11 ppm active ingredient.

Indoor Non-Food

0.088 to 12 ppm active ingredient.

Timing - During manufacture, Continuous feed (initial), Continuous feed (subsequent), Initial, Subsequent/maintenance, Intermittent (slug)(initial), Intermittent (slug)(subsequent), Shock/slug, When needed, Not specified (Registrant must specify on labeling).

Use Practice Limitations:

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

C. Data Requirements

The Agency applied the data requirements specified in 40 CFR Section 158 and the Phase II Requirements to active ingredients in this chemical case. Studies were generated and submitted to the Agency. The data from these studies along with other available information form the basis for the Agency's scientific assessment and regulatory decisions. Appendix B includes all data requirements needed to support reregistration of currently registered uses.

D. Regulatory History

5-Chloro-2 methyl-3(2H)-isothiazolone and 2-methyl-3(2H)-isothiazolone were registered in the United States as early as 1977 as active ingredients. Currently, 85 products are registered for uses for incorporation into products such as adhesives, coatings, fuels, metal working fluids, resin emulsions, paints and various other speciality industrial products (as a preservative); and, as a microbiocide in pulp/paper mills, cooling water systems, oil field operations, industrial process waters and air washers systems. The compound is also used to treat wood products (seasoned/unseasoned forest products and various finished wood products).

Two Data Call-Ins have been issued: The Antimicrobial Data Call-In of March 4, 1987 and a Reregistration Phase 4 Data Call-In dated November 3, 1992 requiring additional toxicity and environmental fate data.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

For methylisothiazolinone (5-chloro-2-methyl-3(2H)-isothiazolone and 2-methyl-3(2H)-isothiazolone at 3:1 ratio):

Color:	golden yellow at 25°C
Physical State:	clear liquid at 25°C
Odor:	pungent aromatic
Boiling Point:	101.1 ± 0.2°C at standard room pressure
Bulk Density:	1.296 g/ml at 25°C
pH:	1.90 at 23.8 °C
Vapor Pressure:	

For 5-chloro-2-methyl-3(2H)-isothiazolone - 1.8x10⁻² torr.

For 2-methyl-3(2H)-isothiazolone

- 6.2×10^{-4} torr.

Solubility:

For 5-chloro-2-methyl-3(2H)-isothiazolone

<u>Solvent</u>	<u>Solubility g/100ml Solvent</u>
Water	Infinite
Ethyl Acetate	≥ 4.31
Methanol	≥ 4.40
Toluene	≥ 4.07
Hexane	≥ 0.28

For 2-methyl-3(2H)-isothiazolone

<u>Solvent</u>	<u>Solubility g/100ml Solvent</u>
Water	Infinite
Ethyl Acetate	≥ 0.19
Methanol	≥ 1.52
Toluene	≥ 0.08
Hexane	≥ 0.03

Dissociation Constant: Does not dissociate into ions

Octanol/Water Partition Coefficient:

For 5-chloro-2-methyl-3(2H)-isothiazolone

$$K_{ow} = 0.401 \text{ at } 24^\circ\text{C in log P or } 2.519$$

For 2-methyl-3(2H)-isothiazolone

$$K_{ow} = 0.486 \text{ at } 24^\circ\text{C in log P or } 0.326$$

Stability:

For 5-chloro-2-methyl-3(2H)-isothiazolone

<u>Conditions</u>	<u>Duration</u>	<u>% of Active Ingredient Remaining</u>
54°C	1 week	98.0
	2 weeks	96.0
Metal (Mild steel)	1 week	97.0
	1 week	85.0
Sunlight	24 hours	99.0
	48 hours	99.0
	72 hours	99.0

For 2-methyl-3(2H)-isothiazolone

<u>Conditions</u>	<u>Duration</u>	<u>% of Active Ingredient Remaining</u>
54°C	1 week	99.0
	2 weeks	98.0
Metal (Mild steel)	1 week	100.0
	1 week	90.0
Sunlight	24 hours	100.0
	48 hours	100.0
	72 hours	100.0

B. Human Health Assessment

1. Toxicology Assessment

At present, the toxicology data base for methylisothiazolinone meets the requirements for antimicrobials. The data are adequate and will support a reregistration eligibility determination for the currently registered non-food uses. All food use of methylisothiazolinone is regulated by the U.S. Food and Drug Administration. All data have been generated on a formulation intermediate or on an end-use product. The formulation intermediate and all currently registered end-use products are a combination of 5-chloro-2-methyl-3(2H)-isothiazolone and 2-methyl-3(2H)-isothiazolone in an equilibrium ratio of approximately 3:1.

a. Acute Toxicity

The acute toxicity values and categories for Kathon 886, a formulation intermediate, are summarized in Table 1.

Table 1 - Acute Toxicity Data for Methylisothiazolinone

GDLN #	Test	Results	Category	MRID #
81-1	Oral LD ₅₀ --rat	105 mg/kg	II	86091
81-2	Dermal LD ₅₀ --rabbit	200 mg/kg	I	86092
81-3	Inhalation LC ₅₀ --rat	0.33 mg/L	II	41963501 42360901 42360902
81-4	Eye irritation--rabbit ¹	corrosive	I	86092
81-5	Dermal irritation-- rabbit ¹	severely irritating	I	86092
81-6	Dermal sensitization--guinea pig ¹	sensitizer	--	144880

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

b. Subchronic Toxicity

Exposure of Charles River COBS CD(SD)BR rats to methylisothiazolinone (15.5% a.i.) via the drinking water at dose levels of 25, 75, or 225 ppm (males 2.4, 6.3, or 16.3 mg/kg/day; females 4.1, 10.8, or 24.7 mg/kg/day) for three months resulted in a slight decrease (96% of control) in body weight in the high-dose males during weeks 1 and 2 and decreases in body-weight gain in both sexes (males 82-89% and females 82-85% of control) at the high-dose level during the first two weeks of the study. The mid- (90-91% of control) and low-dose (86-88% of control) females also displayed decreases in body-weight gains compared to the controls during weeks 1 and 2, but there was no dose response.

A dose-related decrease in food consumption was observed in males during weeks 1 through 3, which was statistically significant at all dose levels during weeks 1 and 3. Females displayed a dose-related decrease in food consumption during the first two weeks, which was statistically significant at the high dose during week 1 and at the mid- and high-dose levels during week 2. There was a dose-related decrease in water consumption throughout most of the study at all dose levels in males and females at the high-dose level. Females at all dose levels displayed a significant decrease in water consumption during the first week. This decrease in water consumption may have been due to a palatability problem.

No adverse effects were observed on hepatic mixed function oxidase activity in either sex. Although differences in several parameters were observed (decreased cholesterol in females, increased SGOT in females, decreased BUN, foci of erosion and focal blunting of the superficial epithelium of the glandular mucosa of the stomach in both sexes), there were no toxicologically significant effects observed in either sex. The NOEL is 75 ppm (males 6.3 mg/kg/day; females 10.8 mg/kg/day). The LOEL is 225 ppm (males 16.3 mg/kg/day; females 24.7 mg/kg/day), based on microscopic findings (focal blunting) in the stomach in both sexes. Although there were no toxicologically significant effects observed in either sex, the corrosive properties of methylisothiazolinone impose limitations on the dose levels tested for any duration (GDLN 82-1; MRID #42810101).

In a subchronic inhalation toxicity study, the exposure of 16 Crl:CD(SD)BR rats/sex/group to methylisothiazolinone (14% a.i.) at dose levels of 0.34, 1.15, or 2.64 mg/m³ via inhalation for 90 days resulted in decreased body weight in the high-dose males (~90% of control) and decreased body-weight gains in both sexes (males ~84%; females ~89%) at the high-dose level. There were no treatment-related deaths, and no effects were observed in the hematology, clinical chemistry, ophthalmoscopic, and gross pathology parameters monitored that could be attributed to treatment.

Treatment-related lesions in the nasal turbinate were observed at the mid- and high-dose levels, which consisted of eosinophilic droplets in the anterior respiratory mucosa (2.64 mg/m³) and rhinitis in the lining of the anterior portion of the nasal cavity (1.15 and 2.64 mg/m³). These are consistent with a normal physiological response to a respiratory irritant.

The NOEL is 0.34 µg/l. The LOEL is 1.15 µg/l, based on microscopic lesions in the nasal turbinates (rhinitis). With the exception of decreased body-weight gain, there were no toxicologically significant effects observed in either sex, but the corrosive properties of methylisothiazolinone imposed limitations on the dose levels tested for any duration (GDLN 82-4; MRID #148418).

c. Chronic Toxicity and Carcinogenicity

Although chronic data are not typically required for indoor non-food use patterns, these data were submitted. A discussion of the results is included here.

Exposure of 90 male and 80 female Crl:CD®BR rats per group to methylisothiazolinone (14.2% a.i.) via the drinking water at dose levels of 30

(males 2.0 mg/kg; females 3.1 mg/kg), 100 (males 6.6 mg/kg; females 9.8 mg/kg), or 300 ppm (males 17.2 mg/kg; females 25.7 mg/kg), or to tap water or 0.5% salt solution [MgCl_2 and $\text{Mg}(\text{NO}_3)_2$] vehicles for 24 months resulted in a dose-related decrease in drinking water consumption at all dose levels in both sexes throughout the study.

Decreased body weight (95-98% of control) and body weight gain (87% of control at week one, from 91-98% thereafter) were observed in the high-dose males, although statistical significance was not always attained. Females displayed an equivocal decrease in body weight throughout the study, with the mid- (93-96% of control) and high-dose (87-96% of control) groups showing comparable decreases that were not always dose-related.

During the second year, body-weight gains of the high-dose females were significantly decreased (83-88% of control). High-dose males displayed a significant decrease (91-98% of control) in food consumption compared to the control groups throughout most of the study, and females at all dose levels displayed significant decreases in food intake but a dose response was not always evident.

Hematology and clinical chemistry parameters were comparable among the groups of both sexes, as were the organ weights and eyes. During the first six months of the study, the specific gravity of the urine was increased in both sexes, which may be attributed to the decrease in water consumption.

With the exception of the stomach, none of the gross and non-neoplastic lesions observed could be attributed to treatment. An increased incidence in hyperplasia and hyperkeratosis of the squamous mucosa of the stomach was observed at the mid- and high-dose levels in both sexes, which correlated with the finding of prominence of the limiting ridge and/or thickened non-glandular mucosa of the forestomach on gross examination. Additionally, there was an increased incidence of necrosis of the glandular mucosa in the mid-dose females and in both sexes at the high-dose level.

There was no treatment-related increase in the incidence of any tumor in either sex. The corrosive properties of methylisothiazolinone imposed limitations on the dose levels tested. The NOEL is 30 ppm (males 2.0 mg/kg/day; females 3.1 mg/kg/day). The LOEL is 100 ppm (males 6.6 mg/kg/day; females 9.8 mg/kg/day), based on microscopic lesions (hyperplasia/hyperkeratosis in both sexes, necrosis of glandular mucosa in females) in the stomach (GDLN 83-1(a), 83-5; MRID #43140701).

Based on the results of the chronic drinking water study in rats and considering the corrosive nature and lethality of the test material in addition to the absence of another carcinogenicity study in a second species, the Office of Pesticide Program's Health Effects Division RfD Peer Review Committee determined that methylisothiazolinone should be classified as a Group D, not classifiable as to human carcinogenicity. This is further discussed below in subsection f., Toxicological Endpoints for Risk Assessment.

d. Developmental Toxicity

Exposure of Sprague-Dawley CR[®] rats (25 dams/group) to methylisothiazolinone (14% a.i.) via gavage (days 6-15 of gestation) at dose levels of 0 (distilled H₂O), 10, 30, or 100 mg/kg/day resulted in a dose-related decrease in maternal body-weight gains (62% of control at mid-dose and 41% of control at high-dose level) during treatment and a dose-related increase in maternal death (control 0/25, low 1/25, mid 2/25, high 3/25).

There were no effects on pregnancy rate, numbers of corpora lutea, implantations, resorptions, and/or live fetuses; pup weights, sex ratios, and crown-rump length were comparable among the groups. There were no adverse findings from the visceral or skeletal examinations of the fetuses that could be attributed to treatment.

Methylisothiazolinone was not found to be fetotoxic, embryotoxic, or teratogenic in rats. The maternal toxicity NOEL is 10 mg/kg/day. The maternal LOEL is 30 mg/kg/day, based on decreased body-weight gains, with support from the dose-related increase in deaths. The NOEL for developmental toxicity was 100 mg/kg/day, the highest dose tested (GDLN 83-3(a); MRID #78831).

In a second developmental toxicity study, dose levels of 0.5, 2, 8, or 20 mg methylisothiazolinone (13.4% a.i.)/kg body weight per day to presumed-pregnant New Zealand white rabbits (16/group) during days 7 through 19 of gestation resulted in: (1) death and gross pathological lesions of the stomach at the highest dose (all animals either died or were sacrificed moribund by day 15 of gestation); (2) scant or no feces and diarrhea at the 8 and 20 mg/kg/day dose levels; and (3) decreased overall body-weight gain (70% of control), corrected body weight (92% of control), and food consumption at the 8 mg/kg/day dose level.

The numbers of implantations, live fetuses, resorptions, dead implants, and dead fetuses per doe were comparable among the groups, and fetal body weight (combined and per sex) was comparable among the groups. Although there were no statistically significant differences in the incidence of any fetal alteration (external, visceral or skeletal malformations, variations, or

retarded development), there was a tendency for these to occur to a greater degree at the 8 mg/kg/day dose level than in the control or other treatment groups. The maternal toxicity NOEL is 2 mg/kg/day.

The maternal toxicity LOEL is 8 mg/kg/day, based on decreased body-weight gain, corrected body weight, food consumption, and scant/no feces and diarrhea. The developmental toxicity NOEL is 2 mg/kg/day. The developmental toxicity LOEL is 8 mg/kg/day, based on the slight increase in fetal alterations (GDLN 83-3(b); MRID #42311701).

e. Mutagenicity

Methylisothiazolinone (14% a.i.) was positive in the Ames assay in TA100 at concentrations as low as 0.0005 µl/plate without metabolic activation. TA100 with activation and all other strains with and without metabolic activation were negative (GDLN 84-2(a); MRID #78827, 96692).

In a second Ames assay using methylisothiazolinone manufactured by a different process than in the previous study, methylisothiazolinone was positive in TA100 without metabolic activation at concentrations as low as 0.0005 µl/plate. TA100 with activation and all other strains with and without metabolic activation were negative (GDLN 84-2; MRID #105044).

Methylisothiazolinone was positive in the mouse lymphoma gene mutation assay at dose levels as low as 1 nl/ml without metabolic activation and at 1.22 nl/ml with metabolic activation (GDLN 84-2(a); MRID #96693).

Negative results were observed in the *Drosophila* sex-linked recessive lethal assay up to the highest dose tested (dose levels 86 µg ai/ml oral; 258 µg ai/ml injection) (GDLN 84-4; MRID #130751).

Methylisothiazolinone did not cause a significant increase in the frequency of structural chromosome aberrations in mouse bone marrow cells at oral doses of 3, 15, or 30 mg ai/kg, which were considered sufficiently high dose levels (GDLN 84-2; MRID #42538001).

Methylisothiazolinone did not induce unscheduled DNA synthesis in primary rat hepatocytes at dose levels that were sufficiently high to adequately assess the mutagenic potential of the test material (GDLN 84-4; MRID #41875502).

f. Toxicological Endpoints for Risk Assessment

(1) Reference Dose

An RfD was not established for this chemical because it is currently registered for non-food use applications only, outside the FDA regulated uses in paper and adhesives which may contact food. Also, chemicals such as methylisothiazolinone, used as disinfectants, microbiocides, microbiostats, and sanitizer have not been reviewed by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR).

(2) Carcinogenicity Classification

The Agency's Office of Pesticide Program Health Effects Division RfD Peer Review Committee classified methylisothiazolinone as a Group D carcinogen. The Committee concluded that the effects observed in the studies on methylisothiazolinone result from a contact phenomenon, and observed that doses adequate to produce systemic toxicity are not possible because of its corrosive nature. In addition, the results of the mutagenicity studies are equivocal.

(3) Other Toxicological Endpoints

Based on the review of the toxicology database and information on the use patterns for methylisothiazolinone, the Agency's Office of Pesticide Program Health Effects Division Toxicity Endpoint Selection Committee established endpoints to be used in the occupational and residential risk characterization; they are listed in Table 2.

Table 2 - Toxicological Endpoints for Methylisothiazolinone

Type of Exposure	Endpoint and Dose
Acute Dietary	Because there is no anticipated dietary exposure, this endpoint is not required for this active ingredient.
Dermal Absorption	Not available, because methylisothiazolinone is corrosive and a human skin sensitizer.
Short term Occupational or Residential Exposure (one to seven days)	<u>Dermal Exposure</u> . The primary concern is acute exposure as this chemical is corrosive. There is no systemic toxicological endpoint for risk characterization.
Intermediate Term Occupational or Residential Exposure (one week to several months)	<u>Inhalation Exposure</u> . The toxicological endpoint is the NOEL of 0.34 $\mu\text{g}/\text{l}$ based on microscopic lesions in nasal turbinates observed in the 90-day rat inhalation study (MRID 00148418).
Chronic (noncancer)	Not applicable.

The Committee concluded that for methylisothiazolinone, occupational and residential risk should be characterized via the inhalation route of exposure. Occupational and/or residential exposure to methylisothiazolinone would occur over weeks or months (i.e., intermediate-term). Dermal exposure would tend to occur only in the short-term (i.e., acute) as methylisothiazolinone is corrosive. Thus, the inhalation route is appropriate for intermediate term risk characterization.

The Committee did not identify a chronic toxicological endpoint because methylisothiazolinone is so corrosive that an adequately high dose cannot be administered to observe systemic effects.

2. Exposure Assessment

a. Occupational/Residential Exposure

An occupational and/or residential exposure assessment is required for an active ingredient if there are applicable toxicological endpoints and if there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete, or to persons in residential settings. The Agency has identified short-term and intermediate-term toxicological endpoints (inhalation effects) for methylisothiazolinone and recognizes that there is occupational and residential exposure from the use of methylisothiazolinone products. Therefore, an exposure assessment is appropriate.

In addition to methylisothiazolinone, the Agency had concerns that individuals may be exposed to formaldehyde as this pesticide is a putative formaldehyde generator based on its chemical structure. However, hydrolysis studies do not suggest that formaldehyde will be formed.

The following exposure and risk characterization addresses both primary and secondary exposure for occupational and residential methylisothiazolinone application and post-application scenarios. As noted earlier, the risk for methylisothiazolinone is characterized via the inhalation route.

Exposure to the registered end-use products of methylisothiazolinone is considered primary exposure and it may occur to handlers during application or post-application. Primary application exposure scenarios include those where persons handle the methylisothiazolinone end-use

products; for example, exposures which occur as the handler pours end-use product into a vat. During handling, workers may experience both acute (dermal and inhalation) and intermediate (inhalation) effects.

Primary post-application exposure scenarios include those where persons are in or near areas where methylisothiazolinone end-use products are being or have recently been applied; for example, exposures to a handler working near a vat containing water treated with methylisothiazolinone. Because methylisothiazolinone is an industrial pesticide, primary exposures will only occur in an occupational setting; no primary residential exposure is expected.

Exposure to a product that is not a pesticide but happens to contain one is considered secondary exposure and again, it may occur during application or post-application. Secondary application scenarios include those where persons, either people in a residential setting or handlers in an occupational setting, handle products such as paints and adhesives to which methylisothiazolinone has been added. Secondary post-application exposure scenarios include those where persons are in or near areas where products such as methylisothiazolinone-treated paints or adhesives are being used or have recently been used. Because methylisothiazolinone-containing products may be used in either industrial-use or residential-use products, secondary exposure is possible in both occupational and residential settings.

(1) Application Exposure Scenarios

Primary Exposures to Occupational Handlers

Primary occupational handler exposure scenarios include open-pouring the soluble liquid or the soluble solid formulation product into receiving vessels, applications of the soluble liquid by metering pumps, automatic dispensers, dip tanks, and spraying.

Of these scenarios, the Agency considers the open-pouring of a soluble concentrate liquid formulation to represent a reasonable worst-case inhalation exposure scenario for primary occupational handlers. Provided in Table 3 are exposure estimates based on for five open-pour liquid applications (oil well injection fluid, cooling tower, paint manufacturing, metal-working fluid, and pulp and papermill) and one open-mixing solid application (drilling mud). These estimates were derived from the Pesticide Handlers Exposure Database, Agency knowledge of industry practice, and pesticide labels.

Table 3 -Inhalation Exposure Estimates and Risks to Workers for Methylisothiazolinone Application Scenarios

Application Site/Product	Calculation of Pounds A.I. Used Per Day			Calculations of Worker Exposure and MOE				
	Product Used Per Vol. Treated ¹	Volume Treated Per Day ²	lb ai used/day ³	UE (µg/lb ai) ⁴	A.I. Inhaled ⁵ (µg/day)	ADE (mg/kg/day) ⁶	MOE ⁷	
Primary Exposure Scenarios (Open-Pouring Applications)								
Oil Well Injection Fluid /Liquid	<u>1010.5 lbs</u> 42,000 gal	1000 barrels (42,000 gal)	15.1	1.2	18.12	2.6x10 ⁻⁴	189	
Cooling Tower /Liquid	<u>7.46 lbs</u> 1000 gal	20,000 gal	2.24		2.69	3.84x10 ⁻⁵	1,300	
Paint Manufacturing /Liquid	<u>1.65 lb</u> 1000 lb (119 gal)	100 gal (833.7 lbs)	0.02		0.025	3.5x10 ⁻⁷	139,000	
Metal Fluid /Liquid	<u>9.94 lbs</u> 1000 gal	300 gal	0.04		0.049	7.0x10 ⁻⁷	70,000	
Pulp and Papermill /Liquid	<u>1.5 lbs</u> ton	100 tons	2.25		2.73	3.9x10 ⁻⁵	1,300	
Drilling Mud /Solid	<u>17.5 lbs</u> 1000 barrels	1000 barrels	1.22	1.7	2.074	3.0x10 ⁻⁵	1,655	
Secondary Exposure Scenarios								
Paint Application	Occupational	<u>1675 ppm</u>	5 gal	0.0013	570	0.741	1.1x10 ⁻⁵	4,896
	Residential	1 gal paint	1 gal	0.00025		0.143	2.0x10 ⁻⁶	24,480

¹ Product Used Per Vol. Treated = The use rate of methylisothiazolinone. The concentration of the product, for all settings is 1.5% a.i. (except Drilling Mud @ 6.98 % a.i.) This was obtained from the following pesticide labels: EPA Reg. Nos. 10445-66, 10707-13, 1577-73, 1448-348, and 1757-79.

² Volume Treated Per Day = EPA assumption based on knowledge of industrial practices.

³ lb ai used/day = Product Used per Vol. Treated x volume treated/day x % ai. For paint, 1 gallon of paint = 10 lbs.

⁴ UE = Unit Exposure, which was derived from Pesticide Handlers Exposure Database (Version 1.1, 1995), based on 29 l/min as an inhalation rate.

⁵ Amount Inhaled (µg/day) = UE x lb ai used/day.

⁶ ADE = Actual Daily Exposure (by the inhalation route). Calculated as: ADE (mg/kg/day) = (Amount Inhaled/BW)/1000; where BW = 70 kg.

⁷ MOE = NOEL/ADE (inhalation dose), where NOEL = 0.00034 mg/L (0.049 mg/kg/day) with a daily inhalation rate of 10 m³.

Secondary Exposures to Occupational Handlers

Secondary occupational handler exposure scenarios include exposures while handling methylisothiazolinone-containing paint, adhesives, wood/forestry products, and metalworking fluids.

The Agency considers exposures while handling methylisothiazolinone-containing paint to represent a reasonable worst-case inhalation exposure scenario for secondary occupational handlers. Exposures to handlers from methylisothiazolinone in paints, adhesives, wood products, and textiles are expected to be smaller than

those for primary handlers, since the dilution rate is usually far greater than one percent. Provided in Table 3 (as Paint Application) is the exposure estimate for this scenario.

For exposure to methylisothiazolinone-containing metal working fluids, the assessment of occupational exposure addresses only the potential exposures to pesticide handlers who are loading methylisothiazolinone products as an active ingredient into metal working fluids. The Agency continues to discuss with Occupational Safety and Health Administration (OSHA) and National Institute for Occupational Safety Health (NIOSH) the roles and responsibilities of regulating the uses of metalworking fluids, paints and other products in the industrial setting. Because OSHA is responsible for regulating machinists' safety and exposure, these exposures will not be addressed in detail in this document.

Primary Exposures to Residential Handlers

Because methylisothiazolinone products are currently intended for occupational use, there are no primary residential scenarios.

Secondary Exposures to Residential Handlers

Secondary residential handler exposure scenarios include exposures while handling methylisothiazolinone-treated paint, adhesives, paper products, wood products, and fabrics.

The Agency believes that exposures from handling methylisothiazolinone-containing paint represent a reasonable worst-case inhalation exposure scenario for secondary residential handlers. The Table 3 - Paint Application provides the exposure estimate for this scenario.

(2) Post-Application Exposure Scenarios

There are no data available to estimate the exposures from these types of post-application scenarios described above. However, the Agency assumes that the application exposures from primary and secondary scenarios are much higher than post-application exposures. The Agency believes that the concentration in a methylisothiazolinone-treated product, such as paint or wood products, is significantly reduced from that concentration an individual would be exposed to during application of the end-use product.

b. Dietary Exposure

Administrative guidelines are established for methylisothiazolinone uses (in adhesives and as slimicides) in food contact through food packaging. These uses of methylisothiazolinone in the manufacture of paper, paperboard (21 CFR §176.170 and 21 CFR §175.300) and adhesives (21 CFR §175.105) which may contact food are regulated under the jurisdiction of the United States Food and Drug Administration. These guidelines are not directly regulated by EPA. There are no other registered food uses of methylisothiazolinone.

3. Risk Characterization

a. Occupational and Residential

(1) Application Exposure Scenarios

Intermediate-Term Risks

Based on the Agency's assessment of the available toxicity data and described exposure scenarios for methylisothiazolinone, the Agency has determined that quantitative risk characterizations are appropriate for occupational and residential handlers. Because of the selected toxicity endpoint from the 90-day inhalation study for methylisothiazolinone, the Agency is characterizing the intermediate-term risks by margins of exposure (MOE), that is, by the ratio of the NOEL to the exposure estimates.

Provided in Table 3 are the MOEs for the methylisothiazolinone application scenarios. For methylisothiazolinone, all the application exposure MOEs are greater than 100. The occupational scenario MOEs range from nearly 200 for open-pouring oil well injection fluid to 139,000 for open-pouring during paint manufacturing; the residential scenario (painting) MOE is ~25,000. The Agency generally is not concerned about the risk if MOEs are greater than 100.

Acute Risks

However, even though the MOEs for intermediate term exposure are not of concern, EPA is concerned with potential adverse effects resulting from acute dermal and inhalation exposures to methylisothiazolinone for the following reasons:

Technical methylisothiazolinone is corrosive and a skin sensitizer. In acute toxicity tests, methylisothiazolinone (14% a.i.) was shown to be in Toxicity Category I for: dermal toxicity with rabbits, dermal irritation with rabbits and primary eye irritation with rabbits. In a dermal sensitization study in guinea pigs, methylisothiazolinone produced delayed contact hypersensitivity. In an acute inhalation study with rats, methylisothiazolinone showed Category II toxicity. Finally, methylisothiazolinone is volatile.

Methylisothiazolinone may be used indoors as well as outdoors and is often applied to systems by open pouring. For example, handlers may openly pour methylisothiazolinone into cooling towers, vats of paint during the manufacturing process, and into metal cutting fluids. During such operations the pesticide may volatilize and cause inhalation irritation or it may splash onto skin, causing dermal irritation. Even under closed-metering conditions, workers may experience acute dermal and inhalation exposure during coupling operations. Indoor use may result in greater acute inhalation exposure than outdoor use as the pesticide most likely would not dissipate from the vicinity of the workers as quickly as it would outdoors.

(2) Post-Application Exposure Scenarios

As previously discussed, the Agency does not have data to directly assess post-application exposure to methylisothiazolinone in occupational or residential settings. However, the Agency believes that exposures following application are likely to be less than exposures during application, and therefore risks will be less (i.e., higher MOE values). Further, the Agency believes that post-application dermal risks will be minimal because the concentrations that individuals would be exposed to would be much lower than the amount of methylisothiazolinone workers are exposed to during application. Thus, a quantified characterization of the dermal post-application exposure risks is unnecessary.

The Agency has also considered the potential formaldehyde exposure from products containing methylisothiazolinone (based on methylisothiazolinone's chemical structure). Supported by hydrolysis studies, EPA believes that exposure to formaldehyde from methylisothiazolinone is unlikely (no formaldehyde release was observed). Even if some formaldehyde were generated, the post-

application exposure in the workplace would be governed by the Occupational Safety and Health Administration (OSHA).

In May 1992 OSHA published a comprehensive workplace standard for the protection of workers in the industrial setting due to formaldehyde-release in the workplace. The standard set a permissible exposure level (PEL) of 0.75 ppm and prescribes that certain actions should be taken if monitoring shows levels of 0.50 ppm. Further, it requires monitoring before workers enter the premises following use of formaldehyde or when potential ambient formaldehyde is generated from other chemicals.

b. Dietary

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

C. Environmental Assessment

1. Ecological Toxicity Data

Ecological effects toxicity testing was performed using a formulation intermediate (Kathon[®] 886F, 14.17%), or end-use formulations (Kathon[®] WT, Kathon[®] OM, or Kathon[®] WT, 1.5%). Testing of the formulation intermediate and end-use products is sufficient to fulfill guideline data requirements where ecological effects testing of the technical grade is indicated, due to the inherent instability of the active ingredients at higher percentages.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute Toxicity

In order to establish the acute toxicity of methylisothiazolinone to birds, the following test is required using the technical grade material: one avian single-dose oral (LD₅₀) study on one species of waterfowl or upland game bird (preferably mallard duck or bobwhite quail).

In an acute oral toxicity study conducted using bobwhite quail, methylisothiazolinone (14.17% a.i.) gave an LD₅₀ of 62.7 mg/kg. This is sufficient information to characterize methylisothiazolinone as moderately toxic to avian species on an acute oral basis. The guideline requirement is fulfilled. (MRID #41719501)

(2) Birds, Subacute Toxicity

In order to establish the subacute toxicity of methylisothiazolinone to birds, the following test is required using the technical grade material: one subacute dietary study (LC₅₀) on one species of waterfowl or upland game bird (preferably the mallard duck or bobwhite quail).

TABLE 4 - Avian Subacute Dietary Toxicity Findings

Species	% A.I.	LC ₅₀ ppm	MRID No.	Toxicity Category
Mallard ¹	14.17%	717	41719503	moderately toxic
Bobwhite Quail ¹	14.17%	2200	41719502	practically non-toxic

¹ Study is considered to be supplemental because the analytical methodology may not have followed GLP procedures.

There is sufficient information to characterize methylisothiazolinone as moderately toxic to practically non-toxic to avian species on an subacute dietary basis (Table 4). Both avian subacute dietary toxicity studies are considered to be supplemental because GLP compliance was not evident. However, the guideline requirement is considered fulfilled. (MRID #41719502 and #41719503)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish, Acute Toxicity

In order to establish the toxicity of methylisothiazolinone to freshwater fish, the minimum data required on the technical grade of the active ingredient is a single 96-hour LC₅₀ fish toxicity study using either a warmwater fish (preferably bluegill sunfish) or a coldwater fish (preferably rainbow trout).

TABLE 5 - Freshwater Fish Acute Toxicity Findings

Species	% A.I.	LC ₅₀ ppm	MRID	Toxicity Category
Rainbow trout	14.17%	0.19	41718802	Highly toxic
Rainbow trout ¹	14.17%	0.07	41963503	Highly toxic
Bluegill sunfish	14.17%	0.30	41718801	Highly toxic

¹ Study is considered to be supplemental because the results were based on a 14-day exposure period.

There is sufficient information to characterize methylisothiazolinone as highly toxic to both cold and warmwater fish (Table 5). The guideline requirements for freshwater fish acute toxicity are fulfilled. (MRIDs #41718802 and #41718801, respectively)

(2) Freshwater Fish, Chronic Toxicity

In order to establish the chronic toxicity of methylisothiazolinone to freshwater fish, the minimum data required on the technical grade of the active ingredient is a single fish early life stage study using the technical material.

In a chronic toxicity study conducted using fathead minnows, methylisothiazolinone (14.17% a.i.) gave an Maximum Allowable Toxicant Concentration (MATC) of 0.035 ppm. The MATC (the geometric mean of the NOEL and LOEL), based on significantly reduced weight at 0.06 mg a.i./L, was >0.02 and <0.06 ppm. The guideline requirement for freshwater fish chronic toxicity is fulfilled. (MRID #42012201)

(3) Freshwater Invertebrates, Acute Toxicity

The minimum testing required to assess the acute toxicity of methylisothiazolinone to freshwater invertebrates is a single 48-hour LC₅₀ test. Two studies were reviewed.

Table 6 - Freshwater Invertebrate Acute Toxicity Findings

Species	% A.I.	LC ₅₀ ppm	MRID #	Toxicity Category
Daphnid <i>Ceriodaphnia</i>	1.5% ¹	0.20	42358701	highly toxic
Daphnid <i>Daphnia</i>	14.17%	0.18	41718803	highly toxic

¹Adjusted to 100% a.i.

There is sufficient information to characterize methylisothiazolinone as highly toxic to freshwater invertebrates (Table 6). The guideline requirement for freshwater invertebrate acute toxicity is fulfilled. (MRIDs #42358701 and #41718803)

(4) Freshwater Invertebrates, Chronic Toxicity

In order to establish the chronic toxicity of methylisothiazolinone to freshwater invertebrates, the minimum data required on the technical grade of the active ingredient is an invertebrate life cycle study using the technical material.

In a freshwater invertebrate chronic toxicity study conducted using *Daphnia*, methylisothiazolinone (14.17% a.i.) gave an MATC of 0.13 ppm. The MATC, based on survival, was >0.10 and <0.18 ppm. The guideline requirement for freshwater invertebrate chronic toxicity is fulfilled. (MRID #41963502)

(5) Estuarine and Marine Animals, Acute Toxicity

The minimum data required to evaluate acute toxicity to estuarine/marine species are a fish 96-hour LC₅₀ test using either a marine or estuarine species, a mollusc 96-hour EC₅₀ shell deposition study or 48-hour EC₅₀ on oyster embryo/larvae, and a shrimp 96-hour LC₅₀ test using either a marine or estuarine species.

Table 7 - Estuarine/Marine Acute Toxicity Findings

Species	% A.I.	LC ₅₀ /EC ₅₀ (ppm)	MRID #	Toxicity Category
Sheepshead Minnow	13.9%	0.36	00042556	highly toxic
Marine copepod <i>Acartia tonsa</i> ¹	unspecified purity	0.056	42840301	highly toxic
Pink Shrimp	13.9%	2.3	00042559	moderately toxic
Fiddler Crab <i>Uca pugilator</i> ¹	13.9%	59.0	00042557	moderately toxic
Eastern Oyster Embryo-larvae	13.9%	0.028	00042558	highly toxic

¹Study is considered to be supplemental because a test organism was used that is not recommended.

There is sufficient information to characterize methylisothiazolinone as moderately toxic to highly toxic to estuarine/marine species (Table 7). Certain studies are considered to be supplemental because test organisms were used that are not recommended, nevertheless, these studies are considered to have satisfied the guideline requirements. The guideline requirements for estuarine/marine acute toxicity are fulfilled. (MRID #00042556, #42840301, #00042559, #00042557, and #00042558)

2. Environmental Fate

a. Environmental Fate Assessment

Although only hydrolysis and aqueous availability data were required for both chemicals, the registrant also submitted aerobic soil metabolism and leaching-adsorption/desorption studies for 5-chloro-2-methyl-3(2H)-isothiazolone. The additional studies were reviewed in order to gain a better understanding of the fate of methylisothiazolinone in the environment.

5-Chloro-2-methyl-3(2H)-isothiazolone is susceptible to hydrolysis at alkaline pH (half-life=22 days) but stable at acidic and neutral pHs. Methyl-3(2H)-isothiazolone is not susceptible to hydrolysis at acidic, neutral, and alkaline pHs.

5-Chloro-2-methyl-3(2H)-isothiazolone was found to be readily degradable in a sandy loam soil (pH 4.9) under aerobic conditions (half-life=5 hours). Because of the low adsorption coefficient ($K_{ads}=0.1-4.9$; or $K_{oc}=30-310$), the chemical is expected to be very mobile in soil. No information is

available on the metabolism and mobility of methyl-3(2H)-isothiazolone in soil.

Both chemicals are very volatile: the vapor pressure for 5-chloro-2-methyl-3(2H)-isothiazolone is 1.8×10^{-2} torr and the vapor pressure for methyl-3(2H)-isothiazolone is 6.2×10^{-4} torr.

Because of the low octanol/water partition coefficients ($K_{ow}=0.4$ for 5-chloro-2-methyl-3(2H)-isothiazolone and $K_{ow}=0.5$ for methyl-3(2H)-isothiazolone), the chemicals are unlikely to accumulate in fish at a significant level upon exposure.

An aqueous availability study was required because of the wood preservation uses of methylisothiazolinone. The results from the aqueous availability study indicate that both chemicals are readily released from the treated wood to the aqueous environment. Approximately 84% of the chemicals leached out of the treated woods within 28 days under non-stirred conditions. Of the amount leached, 55% leached out within first 5 days.

b. Environmental Fate and Transport

(1) Degradation: Hydrolysis

(a) 5-Chloro-2-Methyl-3(2H)-Isothiazolone

The submitted study on the hydrolysis of 5-chloro-2-methyl-3(2H)-isothiazolone is unacceptable because degradates detected in the pH 9 solution were not identified. The study must be upgraded by providing information on the identity of the degradates.

In this hydrolysis study, ring-labeled $[4,5-^{14}\text{C}][5\text{-chloro-2-methyl-3(2H)-isothiazolone}]$, at 10.9-11.4 ppm, did not hydrolyze in sterile pH 5 and 7 aqueous buffered solutions that were incubated in the dark at $25.0^\circ \pm 0.5^\circ\text{C}$ for 30 days. The 5-chloro-2-methyl-3(2H)-isothiazolone degraded with a half-life of 22 days in pH 9 buffered solutions when incubated under similar conditions. The parent compound comprised 97.0-97.7% of the applied at 0 day posttreatment, 53.6-60.8% at 10 days, 46.9-48.4% at 18 days, and 26.8-51.8% at 30 days. Three degradates, "A" (maximum of 46.4% of the applied), "B" (maximum of 10.6%), and "other" (maximum of 23.8%) were detected in the pH 9 solution. They were only partially identified. None these degradates were, however,

formaldehyde. During the study, material balances ranged from 100.2-107.7%. (MRID #42681301)

(b) Methyl-3(2H)-Isothiazolone

The submitted study on the hydrolysis of methyl-3(2H)-isothiazolone is acceptable. No additional data are required.

The following summarizes the results of the hydrolysis study. Ring-labeled [4,5-¹⁴C][methyl-3(2H)-isothiazolone], at 9.9-13.3 ppm, that were incubated in the dark at 24-25 C for 30 days were stable in sterile aqueous buffered solutions (pH 5, 7, and 9). Throughout the study, methyl-3(2H)-isothiazolone comprised 87.1-108.3% of the applied radioactivity in the pH 5 buffered solution, 88.2-103.3% in the pH 7 buffered solution, and 96.8-101.6% in the pH 9 buffered solution. The material balances ranged from 90.6-108.3%. (MRID #42578401)

(2) Degradation: Metabolism

(a) Aerobic Soil Metabolism

The submitted study on the metabolism of 5-chloro-2-methyl-3(2H)-isothiazolone in soil under aerobic conditions is acceptable.

The following summarizes the results of the aerobic soil metabolism study. At 1 ppm, [¹⁴C][5-chloro-2-methyl-3(2H)-isothiazolone], ring-labeled at the 4 and 5 carbons, degraded with a half-life of 5.4 hours in sandy loam soil that was incubated in the dark at 24°-26°C for 64 days, and 75% of field moisture capacity. The parent was the only compound extracted from the soil, and averaged 107.4% of the applied radioactivity immediately posttreatment, 81.0% at 1 hour, 102.1% at 2 hours, 46.3% at 4 hours, 55.1% at 6 hours, 10.9% at 48 hours, and 4.8% at 64 days. Unextracted soil residues increased from an average of 1.6% of the applied immediately posttreatment to a maximum of 76.5% at 48 hours, and was 58.7-59.1% at 30 and 64 days. At 64 days, 12.4-12.6% of the applied radioactivity was in the humin fraction, 17.3-17.7% was humic acid, and 28.4-29.0% was

fulvic acid. The only volatile compound was CO₂, which increased from 0.8-1.7% of the applied at 4-6 hours to 9.9-12.8% at 48 hours, 16.7-17.7% at 30 days, and 27.0-27.3% at 64 days. Material balances ranged from 91-113%. (MRID #42086901)

(3) Mobility/Leachability

(a) Leaching-Adsorption/Desorption

The submitted study on the adsorption and desorption of 5-chloro-2-methyl-3(2H)-isothiazolone in soil is acceptable.

In an aerobic soil metabolism study, ring-labeled [4,5-¹⁴C][5-chloro-2-methyl-3(2H)-isothiazolone] was very mobile in sandy loam, silt loam, clay loam, and sand soils with Freundlich K_{ads} values of 0.1-1.5, and in sandy loam sediment with a Freundlich K_{ads} value of 4.9. K_{oc} values were 30-144 for the soils and 310 for the sediment. No degradation of the parent compound was noted during the course of the experiment. Material balances were greater than 99%. (MRID #42086902)

(b) Aqueous Availability

The registrant has submitted a study in which the aqueous availability of 5-chloro-2-methyl-3(2H)-isothiazolone and methyl 3(2H)-isothiazolone from pressure-treated wood was evaluated. This study is acceptable. No additional data are required.

The following summarizes the results of the study. The active ingredients, 5-chloro-2-methyl-3(2H)-isothiazolone and methyl-3(2H)-isothiazolone, leached from the pressure-treated Southern yellow pine wood blocks when incubated in artificial sea water; deionized water; and pH 5, 7, and 9 aqueous buffered solutions at room temperature under non-stirred conditions. Approximately 84% of the chemicals in the wood leached out of the treated woods within 28 days. Of the amount leached, about 55% leached out within first 5 days of the study.

The degradation profile observed in the aqueous availability study is similar to the one observed in the hydrolysis. The released 5-chloro-2-methyl-3(2H)-isothiazolone and methyl-3(2H)-isothiazolone appear to be stable at acidic and neutral pHs, 5-chloro-2-methyl-3(2H)-isothiazolone is susceptible to hydrolysis at alkaline pH. The recovery of the parent compounds, based on the analysis of treated wood and solutions at the end of the study, ranged from 100-135% for deionized water, sea water, and pH 5 and 7 buffer solutions. However, the recovery was only 23% in the pH 9 solution. The low recovery in the pH 9 buffer solution was apparently caused by the hydrolysis of 5-chloro-2-methyl-3(2H)-isothiazolone. (MRID #43478401)

3. Exposure and Risk Characterization

Methylisothiazolinone is moderately toxic to practically nontoxic to avian species, but highly toxic to freshwater fish and invertebrates and moderately toxic to highly toxic to marine/estuarine species.

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

The jet fuel use (indoor non-food) of methylisothiazolinone may be associated with periodic releases into the environment from the purging of storage tanks. This terrestrial use is expected to result in minimal to no exposure. The oil-related aquatic uses (oil recovery drilling muds/packer fluids, secondary oil recovery injection water) are expected to result in minimal to no exposure if proper procedures are employed in the disposal of the contaminated materials.

Based on the environmental fate assessment, wildlife are not expected to be significantly exposed to methylisothiazolinone from its wood preservative uses, therefore, there is little likelihood of adverse effects occurring to wildlife.

Although the aqueous availability study shows that these two chemicals are readily released from the treated wood under laboratory conditions, their potential for exposure to aquatic or terrestrial organisms under actual use conditions is relatively low. This is because:

- (1) 5-chloro-2-methyl-3(2H)-isothiazolone and methyl-3(2H)-isothiazolone are highly volatile and expected to dissipate from the wood surface quickly;
- (2) The major active ingredient, 5-chloro-2-methyl-3(2H)-isothiazolone, hydrolyzes at pH 9 and degrades very rapidly in soil under aerobic conditions;

- (3) The areas where the treated wood is used are relatively small, and mainly in residential areas;
- (4) It is not anticipated that methylisothiazolinone will be applied to wood that will be placed in aquatic environments because the label specifies that it be applied to soft woods only (such as pine) and the wood preservation protection will last 12 weeks; and
- (5) The use of water repellents and sealers on treated wood further decreases the leachability of the chemicals from the wood. As a result, the risk of exposure would likely be reduced.

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 methylisothiazolinone 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 methylisothiazolinone. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of methylisothiazolinone, 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 methylisothiazolinone and to determine that methylisothiazolinone can be used as specified in this document without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing methylisothiazolinone 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 methylisothiazolinone 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 methylisothiazolinone, 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 ingredients in the case methylisothiazolinone, the Agency has sufficient information on the health effects of methylisothiazolinone and on its potential for causing adverse effects in fish, wildlife, and the environment. The Agency has determined that methylisothiazolinone products, labeled and used as specified in this Document, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing methylisothiazolinone for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

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

C. Regulatory Position

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

1. Endangered Species Statement

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

2. Labeling Rationale/Risk Mitigation

During reregistration, the Agency considers handler safety requirements for occupational and residential uses. The Agency establishes handler safety requirements

when risk assessments or general concerns suggest such requirements are appropriate. If the Agency determines that no specific handler requirements are warranted based on the potential acute or other adverse effects of the active ingredient, the handler safety requirements will be based on the acute toxicity characteristics of the end-use product.

a. Occupational-Use Products

Primary Occupational Handlers. The Agency has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for methylisothiazolinone.

Even though the estimated risks for intermediate-term inhalation exposures are considered low to very low (MOEs well above 100), the Agency is concerned with short-term inhalation exposure to methylisothiazolinone because the material is volatile, corrosive, and used primarily indoors. Hence, the Agency believes that there may be some circumstances in the industrial/commercial setting where risks from inhalation exposures may be of concern. Respirator requirements based on the end-use product toxicity and vapor pressure are being required to mitigate these risks.

Acute dermal and eye irritation risks from end-use products containing methylisothiazolinone will be addressed based on the acute inhalation toxicity of the end-use products.

Secondary Occupational Handlers. At this time, the Agency believes that risks from inhalation exposures and skin/eye corrosivity would be not of concern for secondary occupational handlers, since the methylisothiazolinone in such products as paint, adhesives, metal-working fluids, wood products, and textiles is very diluted, usually far less than one percent.

b. Homeowner-Use Products

Primary Homeowner Handlers. All methylisothiazolinone end-use pesticide products are intended primarily for occupational use. There are no primary homeowner uses of methylisothiazolinone that would result in homeowner primary exposure.

Secondary Homeowner Handlers. At this time, the Agency believes that risks from inhalation exposures and skin/eye corrosivity would be acceptable for secondary occupational handlers, since the

methylisothiazolinone in such products as paint, adhesives, metal-cutting fluids, wood products, and textiles is very diluted.

c. Post-Application Safety Requirements

Primary Occupational Post-Application Workers. The Agency is not establishing entry restrictions based on the corrosivity concerns about methylisothiazolinone because the anticipated frequency, duration, and degree of dermal/eye exposure following occupational applications do not warrant special risk mitigation measures at this time.

Secondary Occupational Post-Application Workers. The Agency has determined that no regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for secondary occupational post-application workers must be taken for methylisothiazolinone, since the anticipated frequency, duration, and degree of exposure following secondary occupational applications do not warrant special risk mitigation measures at this time.

d. Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing methylisothiazolinone. For the specific labeling statements, refer to Section V of this document.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Additional Data Requirements

Generic Data Requirements: The generic data base supporting the reregistration of methylisothiazolinone for the above eligible uses has been reviewed and determined to be substantially complete, with the exception of the hydrolysis study. Additional data to characterize the hydrolysis at pH 9 for 5-chloro-2-methyl-3(2H)-isothiazolone are required by November 16, 1998 to upgrade the existing study.

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.

B. Labeling Requirements

The following chart summarizes the label changes that must be made on all manufacturing and end-use products.

Table 8: Summary of Labeling Requirements for Methylisothiazolinone

Description	Required Labeling	Placement on Label
Manufacturing Use		
The following language must be added to MP labeling to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into a microbiocide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
The following language may be added to an MP label at the discretion of an MP registrant to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:	<p>"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)."</p> <p>"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)."</p>	
Environmental Hazards Statements	"This chemical is toxic to terrestrial and aquatic plants, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	Precautionary Statements: Hazards to Humans and Domestic Animals
End Use Products Intended for Occupational Use ¹		
Baseline PPE requirements: The following language must be placed on each product:	<p>"Mixers, loaders, and others exposed to methylisothiazolinone products must wear:</p> <ul style="list-style-type: none"> - long-sleeve shirt and long pants - chemical-resistant gloves² - shoes plus socks." 	Precautionary Statements: Hazards to Humans and Domestic Animals

¹ For **sole-active-ingredient** end-use products that contain methylisothiazolinone, the product labeling must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed. For **multiple-active-ingredient** end-use products that contain methylisothiazolinone, the handler personal protective equipment set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained.

² For the glove statement, use the statement established through the instructions in Supplement Three of PR Notice 93-7. In addition, the corrosiveness and penetration of methylisothiazolinone itself must be considered and appropriate chemical-resistant materials must be listed on the product labeling.

<p>Additional PPE requirements: The PPE established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling.</p>	<p>“Protective eyewear” must be added to the above list if the end-use product is classified as Toxicity Category I or II for eye irritation potential.</p> <p>“Chemical-resistant apron” must be added if the end-use product is classified as toxicity category I or II for acute dermal toxicity or skin irritation potential.</p> <p>A respirator requirement must be added if the end-use product is classified as toxicity category I or II for acute inhalation toxicity. The type of respirator must be specified in the statement and is based on the acute toxicity category and the vapor pressure. EPA will assist registrants in determining the appropriate type of respirator during the end-use product phase of reregistration.</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>User Safety Requirements</p>	<p>The following wording is required on all products intended primarily for occupational use.</p> <p>“Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them. Follow manufacturer’s instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements</p>
<p>Application Restrictions</p>	<p>The following wording is required on all products intended primarily for occupational use.</p> <p>“Do not apply this product in a way that will contact workers or other persons.”</p>	<p>Directions for Use</p>
<p>User safety Recommendations</p>	<p>The following wording is required on all products intended primarily for occupational use.</p> <p>“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.”</p> <p>“Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”</p> <p>“Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly.”</p>	<p>Precautionary Statement: Hazards to Humans and Domestic Animals</p>
<p>Skin Sensitizer Statement</p>	<p>“This product may cause skin sensitization reactions in some people.”</p>	<p>Precautionary Statement: Hazards to Humans and Domestic Animals</p>
<p>Environmental Hazards</p>	<p>"This chemical is toxic to terrestrial and aquatic plants, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."</p>	<p>Precautionary Statements under Environmental Hazards</p>

C. Labeling Clarifications

The following clarifications must be made on all end-use products labels, where applicable.

1. Use Profile Clarifications

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

2. Use on Pilings

Methylisothiazolinone is to be used only on terrestrial-use pilings not aquatic-use pilings. The phrase “terrestrial-use pilings” must be used when referring to any type of piling.

3. Water Treatment Systems

All use of products containing methylisothiazolinone in water treatment systems must clearly specify recirculating water treatment systems. The word “recirculating” must be added before all references to water treatment systems (e.g., water treatment, cooling towers, etc.).

4. Clarification of Oil Drilling Mud Use

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

"For use in terrestrial wells only."

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

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

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

"For use in offshore wells only."

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

"This product may be used for terrestrial and off-shore oil drilling muds and packer fluids."

D. 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 methylisothiazolinone 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

GUIDE TO APPENDIX B

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

REQUIREMENT	USE PATTERN	CITATION(S)
<u>PRODUCT CHEMISTRY</u>		
61-1	Chemical Identity	All 41741401
61-2A	Start. Mat. & Mnfg. Process	All 41741401
61-2B	Formation of Impurities	All 41741401
62-1	Preliminary Analysis	All 41741401
62-3	Analytical Method	All 41741401
63-2	Color	All 41741401
63-3	Physical State	All 41741401
63-4	Odor	All 41741401
63-6	Boiling Point	All 41741401
63-7	Density	All 41741401
63-8	Solubility	All 41741401
63-9	Vapor Pressure	All 41741401
63-11	Octanol/Water Partition	All 41741401
63-12	pH	All 41741401
63-13	Stability	All 41741401
<u>ECOLOGICAL EFFECTS</u>		
71-1A	Acute Avian Oral - Quail/Duck	C,E,F 41719501
71-2A	Avian Dietary - Quail	C,E,F 41719502
71-2B	Avian Dietary - Duck	C,E,F 41719503
72-1A	Fish Toxicity Bluegill	C,E,F 41718801
72-1C	Fish Toxicity Rainbow Trout	C,E,F 41718802, 41963503
72-2A	Invertebrate Toxicity	C,E,F 41718803, 42358701
72-3A	Estuarine/Marine Toxicity - Fish	C,E,F 00042556

Data Supporting Guideline Requirements for the Reregistration of Methylothiazolinone

REQUIREMENT	USE PATTERN	CITATION(S)
72-3B	Estuarine/Marine Toxicity - Mollusk	C,E,F 00042558
72-3C	Estuarine/Marine Toxicity - Shrimp	C,E,F 00042559, 00042557
72-4A	Early Life Stage Fish	C,E,F 42012201
72-4B	Life Cycle Invertebrate	C,E,F 41963502
<u>TOXICOLOGY</u>		
81-1	Acute Oral Toxicity - Rat	All 00086091
81-2	Acute Dermal Toxicity - Rabbit/Rat	All 00086092
81-3	Acute Inhalation Toxicity - Rat	All 41963501, 42360901, 42360902
81-4	Primary Eye Irritation - Rabbit	All 00086092
81-5	Primary Dermal Irritation - Rabbit	All 00086092
81-6	Dermal Sensitization - Guinea Pig	All 00144880
82-1A	90-Day Feeding - Rodent	All 42810101
82-4	90-Day Inhalation - Rat	All 00148418
83-1A	Chronic Feeding Toxicity - Rodent	All 43140701
83-3A	Developmental Toxicity - Rat	All 00078831
83-3B	Developmental Toxicity - Rabbit	All 42311701
83-5	Combined Chronic Toxicity / Carcinogenicity	All 43140701
84-2A	Gene Mutation (Ames Test)	All 00078827, 00096692, 00096693, 00105044
84-2B	Structural Chromosomal Aberration	All 42538001

**Data Supporting Guideline Requirements for the Reregistration of
Methylisothiazolinone**

REQUIREMENT	USE PATTERN	CITATION(S)
84-4 Other Genotoxic Effects	All	00130751, 41875502
<u>ENVIRONMENTAL FATE</u>		
160-5 Chemical Identity	All	41741401
161-1 Hydrolysis	All	42578401, 42681301
162-1 Aerobic Soil Metabolism	C	42086901
163-1 Leaching/Adsorption/Desorption	C,E,F	42086902
168-1-SS Aqueous Availability	C,E	43478401

GUIDE TO APPENDIX C

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
 - b. **Document date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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- 00042556 Heitmuller, T. (1980) Acute Toxicity of Kathon WT to Sheepshead Minnows, *Cyprinodon variegatus*: Report No. BP-80-3-53. (Unpublished study received Aug 28, 1980 under 707-128; prepared by EG&G, Bionomics, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:243239-A)
- 00042557 Heitmuller, T. (1980) Acute Toxicity of Kathon WT to Fiddler Crabs, *Uca pugilator*: Report No. BP-80-3-52. (Unpublished study received Aug 28, 1980 under 707-128; prepared by EG&G, Bionomics, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 243238-A)
- 00042558 Hollister, T.A. (1980) Acute Toxicity of Kathon WT to Embryo Larvae of Eastern Oysters, *Crassostrea virginica*: Report No. BP-80-5-85. (Unpublished study received Aug 28, 1980 under 707-128; prepared by EG&G, Bionomics, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:243237-A)
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- 00078827 Scribner, H.E.; Melly, J.G.; Lohse, K.L. (1981) Kathon 886 MW; Microbial Mutagen Test: Report No. 81R-96. (Unpublished study received Jul 8, 1981 under 707-166; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:245555-C)
- 00078831 Weatherholtz, W.M.; Hoberman, A.; Durloo, R.S. (1980) Teratogenicity Study in Rats: Kathon 886: Project No. 417-399. Final rept. (Unpublished study received Jul 8, 1981 under 707-166; prepared by Hazleton Laboratories America, Inc., submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:245555-G)
- 00086091 Rohm and Haas Company (1977) Toxicity Data: Kathon 886 All-magnesium Formulation: Report No. 77-38. (Unpublished study received on unknown date under 707-129; CDL:233075-B)
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- 00096692 Scribner, H.E.; Melly, J.G.; Lohse, K.L. (1981) Kathon 886 MW; Microbial Mutagen Test: Report No. 81R-96. (Unpublished study received Mar 17, 1982 under 707-166; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:247017-C)
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- 00105044 Scribner, H.E.; Melly, J.G.; Lohse, K.L. (1981) Kathon 886 NAR Process; Microbial Mutagen Test: Report No. 81R-97. (Unpublished study received Mar 17, 1982 under 707-166; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:247017-D)
- 00130751 Valencia, R. (1983) Drosophila Sex-linked Recessive Lethal Test on Kathon Biocide: Laboratory Project No. 100; Rohm & Haas Project No. 82P-152. Final rept. (Unpublished study received Aug 23, 1983 under 707-130; prepared by Univ. of Wisconsin, Zoology Dept., submitted by Rohm & Haas Co., Philadelphia, PA; CDL: 251100-A)
- 00144880 Parsons, R. (1982) Delayed Contact Hypersensitivity Test of RH-573 and RH-886 in Guinea Pigs: Report No. 79R-195. Unpublished study prepared by Rohm and Haas Co. 52 p.
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- 41718801 Ward, T.; Boeri, R. (1990) Acute Flow Through Toxicity of Kathon 886 F Biocide to the Bluegill Sunfish, *Lepomis macrochirus*: Lab Project Number: 9002-RH: 89RC-0342. Unpublished study prepared by Resource Analysts Inc., Envirosystems Div. 287 p.
- 41718802 Ward, T.; Boeri, R. (1990) Acute Flow Through of Kathon 886 Biocide to the Rainbow Trout, *Oncorhynchus mykiss*: Lab Project Number: 9003-RH: 89RC-0343. Unpublished study prepared by Resource Analysts Inc., Envirosystems Div. 250 p.
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- 41719501 Pedersen, C. (1990) Kathon 886 Biocide: 21-Day Acute Oral LD50 Study in Bobwhite Quail: Lab Project Number: 90 QD148: 89RC-0339 Unpublished study prepared by Bio-Life Associates, Ltd. 45 p.
- 41719502 Pedersen, C. (1990) Kathon 886 Biocide: 8-Day Acute Oral LC50 Study in Bobwhite Quail: Lab Project Number: 90 QC148: 89RC- 0340. Unpublished study prepared by Bio-life Associates, Ltd. 45 p.
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- 41963501 Wanner, F.; Hagan, J. (1991) Kathon 886F Biocide: Acute Inhalation Toxicity Study in Rats: Lab Project Number: 91R-018: PROTOCOL No. 91P-018. Unpublished study prepared by Rohm and Haas Co. 85 p.
- 41963502 Ward, T.; Boeri, R. (1991) Chronic Toxicity of Kathon 886 Biocide to the Daphnid, *Daphnia magna*: Lab Project Number: 9005-RH: 89RC-0346. Unpublished study prepared by Resource Analysts, Inc. 507 p.
- 41963503 Ward, T.; Boeri, R. (1991) Acute Flow Through Toxicity of Kathon 886 Biocide to the Rainbow Trout, *Oncorhynchus mykiss*--14 Day Prolonged Test: Lab Project Number: 9006-RH: 89RC-0348. Unpublished study prepared by Resource Analysts, Inc. 306 p.
- 42086902 Wang, W. (1991) Adsorption and Desorption of carbon 14*-RH-651 in Four Soils and One Sediment: Lab Project Number: XBL 90024: RPT 0046: RH TECH. 34-91-09. Unpublished study prepared by XenoBiotics Labs, Inc. 86 p.

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- 42358701 Jop, K. (1992) Kathon WT 1.5 Percent Biocide--Acute Toxicity to Ceriodaphnia dubia under Static Conditions: Final Report: Lab Project Number: 92-404209: 91RC-0196: 86.0392-6152.132. Unpublished study prepared by Springborn Labs, Inc. 36 p.
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- 42360902 Bernacki, H.; Hagan, J. (1992) Kathon 886F Biocide Acute Inhalation Toxicity Study in Rats: A Supplement: Lab Project Number: 91R-018B. Unpublished study prepared by Rohm and Haas Co. 5 p.
- 42538001 Gudi, R. (1992) Acute Test for Chemical Induction of Chromosome Aberration in Mouse Bone Marrow Cells in Vivo: Kathon 886 MW Biocide: Lab Project Number: 0202-1541: 92RC-0054. Unpublished study prepared by SITEK Research Lab. 65 p.
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- 42681301 Jalali-Araghi, K.; Shepler, K. (1993) Hydrolysis of (carbon 14)-RH-651 (the major component of RH-886) at pH 5, 7 and 9: Lab Project Number: 225W-1: 225W: 34P-90-06: 34-93-07. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory-West. 134 p.
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- 42840301 Weideborg, M. (1993) Toxicity Test Results with Acartia tonsa for the chemical Kathon OM: Lab Project Number: 0-93007: 93-028: 93RC-1011. Unpublished study prepared by Aquateam-Norwegian Water Technology Centre A/S. 27 p.

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- 43478401 Doshi, D. (1994) Aqueous Availability of Kathon WT from Treated Southern Yellow Pine: Lab Project Number: 3122.00. Unpublished study prepared by Rohm and Haas Co. and Hickson Corp. 325 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 03-31-99).

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

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

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

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

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

as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of

extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

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

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

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails

to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

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

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

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

- a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."
- b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.
- c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both

available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

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

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

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois A. Rossi, 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

METHYLISOTHIAZOLINONE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 methylisothiazolinone. 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 Methylisothiazolinone 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 methylisothiazolinone are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on methylisothiazolinone 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 methylisothiazolinone 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 Barbara Briscoe at (703) 308-8177.

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

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

RE: **Methylisothiazolinone**

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

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

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

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

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

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

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

Compensation Requirements" form (EPA Form 8570-29) and (2) two completed and signed copies of the Confidential Statement of Formula (EPA Form 8570-4).

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

Items 10-13. Self-explanatory.

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

EPA'S BATCHING OF METHYLISOTHIAZOLINONE (5-Chloro-2-methyl-3(2H)-isothiazolone and 2-Methyl-3(2H)-isothiazolone) 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 methylisothiazolinone (approximately a 3:1 ratio of 5-Chloro-2-methyl-3(2H)-isothiazolone and 2-Methyl-3(2H)-isothiazolone, respectively) 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. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product, should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so 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 are generated or existing data are 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 (DCI) 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.

Eighty-three (83) products were found which contain methylisothiazolinone (5-Chloro-2-methyl-3(2H)-isothiazolone and 2-Methyl-3(2H)-isothiazolone) as the active ingredient, plus two (2) products which contain only 2-Methyl-3(2H)-isothiazolone as the active ingredient. These products have been placed into eighteen batches in accordance with the active and inert ingredients and type of formulation.

Results from studies available to the Agency indicate that products containing (a wide range of percentages) of methylisothiazolinone as the active ingredient produce irreversible destruction of ocular tissue or corneal involvement/irritation lasting for more than 21 days. Therefore, all products containing this active ingredient will be classified as Toxicity Category I. However, if the registrant does not agree with this classification, new studies must be submitted/cited to fulfill the primary eye irritation data requirement.

Studies assessing skin sensitization are not required, because the existing data for the Technical (SF-886 Technical Industrial Microbicide) indicate that the active ingredients are skin sensitizers, and therefore, all products (including the End Use Products) would be considered positive for skin sensitization. However, if the registrant does not agree with this classification, new studies must be submitted/cited to fulfill the skin sensitization data requirement.

The following summarizes acute data requirements by batch:

- The registrant with the product in Batch 1 must cite/submit all acute data (except for the primary eye irritation and the skin sensitization data).
- The products in Batch 1a may be supported by citing/submitting the acute data from Batch 1. Data from EPA Reg. No. 707-256 may not be used to support EPA Reg. No. 707-255.

I. The registrants with products in Batch 2 need to cite/submit all acute data (except for the primary eye irritation and skin sensitization data) on one of the subject products.

II. The registrants with products in Batch 3 need to cite/submit all acute data (except for the primary eye irritation and skin sensitization data) on one of the subject products.

III. The registrants with products in Batch 3a may cite/submit all acute data (except for the primary eye irritation and skin sensitization data) on one of the subject products. Products in Batch 3a may also be supported by data from products in Batch 3.

IV. The registrants with products in Batch 4 need to cite/submit all acute data (except for the primary eye irritation and skin sensitization data) on one of the subject products.

V. The registrants with products in Batch 4a may cite/submit all acute data (except for the primary eye irritation and skin sensitization data) on one of the subject products. Products in Batch 4a may be supported by data from products in Batch 4.

VI. The registrants with products in Batch 5 need to cite/submit all acute data (except for the primary eye irritation and skin sensitization data).

- The registrants with products in Batch 5a may cite/submit all acute data (except for the primary eye irritation and skin sensitization data) on one of the subject products. Products in Batch 5a may be supported by data from products in Batch 5.

VII. The registrant with the product in Batch 6 needs to cite/submit all acute data (except for the primary eye irritation and skin sensitization data).

VIII. The registrant with the product in Batch 7 needs to cite/submit all acute data (except for the primary eye irritation and skin sensitization data). The product in Batch 7 may also be supported by data from the products in Batch 4.

IX. The registrants with products in Batch 8 need to cite/submit all acute data (except for the primary eye irritation and skin sensitization data) on one of the subject products.

X. The registrants with products in Batch 9 need to cite/submit all acute data (except for the primary eye irritation and skin sensitization data) on one of the subject products.

XI. The registrant with the product in Batch 10 needs to cite/submit all acute data (except for the primary eye irritation and skin sensitization data).

XII. The registrants with products in Batch 10a need to cite/submit all acute data (except for the primary eye irritation and skin sensitization data). EPA Reg. No. 68708-9 may be supported by data from EPA Reg. No. 67071-16.

XIII. The registrant with the product in Batch 11 needs to cite/submit all acute data (except for the primary eye irritation and skin sensitization data).

XIV. The registrants with products in Batch 12 need to cite/submit all acute data (except for the primary eye irritation and skin sensitization data). EPA Reg. No. 1448-398 may be supported by data from EPA Reg. No. 1448-397.

XV. The registrant with the product in Batch 13 needs to cite/submit all acute data (except for the primary eye irritation and skin sensitization data).

XVI. The Registrant with the product in Batch 14 needs to cite/submit all acute data (except for the primary eye irritation and skin sensitization data).

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

[Under “% Active Ingredient”, the 5-Chloro-2-methyl-3(2H)-isothiazolone is listed as “5-Chloro-2-methyl”, and the 2-Methyl-3(2H)-isothiazolone is listed as “2-Methyl”.]

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	707-234	70.1% 5-Chloro-2-methyl 26.0% 2-Methyl	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1a	707-255	93.8% 2-Methyl	Liquid
	707-256	50.0% 2-Methyl	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	707-128	10.4% 5-Chloro-2-methyl 3.7% 2-Methyl	Liquid
	707-129	10.4% 5-Chloro-2-methyl 3.7% 2-Methyl	Liquid
	707-130	10.4% 5-Chloro-2-methyl 3.7% 2-Methyl	Liquid
	707-132	10.4% 5-Chloro-2-methyl 3.7% 2-Methyl	Liquid
	707-194	10.4% 5-Chloro-2-methyl 3.7% 2-Methyl	Liquid
	707-217	10.4% 5-Chloro-2-methyl 3.7% 2-Methyl	Liquid
	6836-238	10.8% 5-Chloro-2-methyl 3.83% 2-Methyl	Liquid
	6836-239	10.8% 5-Chloro-2-methyl 3.83% 2-Methyl	Liquid
	6836-240	10.8% 5-Chloro-2-methyl 3.83% 2-Methyl	Liquid
	49403-24	8.6% 5-Chloro-2-methyl 2.6% 2-Methyl	Liquid
	67071-5	10.2% 5-Chloro-2-methyl 4.0% 2-Methyl	Liquid
	67071-9	10.2% 5-Chloro-2-methyl 4.0% 2-Methyl	Liquid
Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
3	707-220	2.69% 5-Chloro-2-methyl 0.81% 2-Methyl	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	1706-170	3.11% 5-Chloro-2-methyl 0.94% 2-Methyl	Liquid
	6836-257	3.69% 5-Chloro-2-methyl 1.31% 2-Methyl	Liquid
	45017-42	2.8% 5-Chloro-2-methyl 1.0% 2-Methyl	Liquid
	45017-44	2.30% 5-Chloro-2-methyl 0.70% 2-Methyl	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
3a	707-171	4.3% 5-Chloro-2-methyl 1.3% 2-Methyl	Solid
	10707-44	5.36% 5-Chloro-2-methyl 1.62% 2-Methyl	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
4	527-105	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	707-133	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	707-134	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	707-196	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	707-209	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	707-216	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	707-219	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	707-260	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	1448-348	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	1553-126	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	1706-153	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	1706-158	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	1706-183	1.12% 5-Chloro-2-methyl 0.40% 2-Methyl	Liquid
	1757-67	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid

4

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	1757-79	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	3635-271	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	3876-143	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	3876-156	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	3931-7	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	6836-258	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	6836-259	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	8540-23	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	8591-34	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	9386-38	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	10445-66	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	10445-69	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	10707-38	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	11529-12	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	15300-24	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	33355-12	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	45017-34	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	48301-9	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	49403-25	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	67071-01	1.1% 5-Chloro-2-methyl 0.4% 2-Methyl	Liquid
	67071-08	1.1% 5-Chloro-2-methyl 0.4% 2-Methyl	Liquid
4	67071-10	1.11% 5-Chloro-2-methyl 0.44% 2-Methyl	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	67071-11	1.11% 5-Chloro-2-methyl 0.44% 2-Methyl	Liquid
	67071-12	1.11% 5-Chloro-2-methyl 0.44% 2-Methyl	Liquid
	67071-13	1.11% 5-Chloro-2-methyl 0.44% 2-Methyl	Liquid
	67071-14	1.11% 5-Chloro-2-methyl 0.44% 2-Methyl	Liquid
	68329-17	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	68708-1	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
4a	707-166	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	707-218	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid
	6836-241	1.18% 5-Chloro-2-methyl 0.40% 2-Methyl	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
5	707-168	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	10707-13	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
5a	707-167	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid
	101-169	1.15% 5-Chloro-2-methyl 0.35% 2-Methyl	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
6	707-198	1.11% 5-Chloro-2-methyl 0.39% 2-Methyl	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
7	1757-74	0.575% 5-Chloro-2-methyl 0.175% 2-Methyl	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
8	48301-16	0.7% 5-Chloro-2-methyl 0.2% 2-Methyl	Liquid
	69838-1	0.8% 5-Chloro-2-methyl 0.3% 2-Methyl	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
9	60061-78	0.06% 5-Chloro-2-methyl 0.02% 2-Methyl 64.34% Didecyl Dimethyl Ammonium Chloride 7.55% 3-Iodo-2-Propynyl Butyl Carbamate	Liquid
	60061-93	0.06% 5-Chloro-2-methyl 0.02% 2-Methyl 31.94% Didecyl Dimethyl Ammonium Chloride 3.75% 3-Iodo-2-Propynyl Butyl Carbamate	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
10	3876-151	1.6% 5-Chloro-2-methyl 0.5% 2-Methyl 5.3% 2-Bromo-2-nitropropane-1,3-diol	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
10a	67071-16	0.84% 5-Chloro-2-methyl 0.33% 2-Methyl 8.80% 2-Bromo-2-nitropropane-1,3-diol	Liquid
	68708-9	0.28% 5-Chloro-2-methyl 0.10% 2-Methyl 8.80% 2-Bromo-2-nitropropane-1,3-diol	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
11	1448-396	1.04% 5-Chloro-2-methyl 0.37% 2-Methyl 1.0% 2-Bromo-2-nitropropane-1,3-diol 12.0% Poly[oxyethylene (dimethyliminio) ethylene(dimethyliminio)ethylene] dichloride	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
12	1448-397	1.04% 5-Chloro-2-methyl 0.37% 2-Methyl 12.0% Poly[oxyethylene (dimethyliminio) ethylene(dimethyliminio)ethylene] dichloride	Liquid
	1448-398	0.52% 5-Chloro-2-methyl 0.18% 2-Methyl 6.0% Poly[oxyethylene (dimethyliminio) ethylene(dimethyliminio)ethylene] dichloride	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
13	3876-157	1.41% 5-Chloro-2-methyl 0.47% 2-Methyl 7.5% Glutaraldehyde	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
14	10445-89	0.059% 5-Chloro-2-methyl 0.018% 2-Methyl 23.725% 1,2-dibromo-2,4-dicyanobutane	Liquid

Cost Share, Data Compensation Forms, Confidential Statement of Formula Form and Instructions

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

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



United States Environmental Protection Agency
Washington, D.C. 20460

**Certification of Offer to Cost
Share in the Development of Data**

Form Approved
OMB No. 2070-0106,
2070-0057
Approval Expires
3-31-99

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

Please fill in blanks below:

Company Name	Company Number
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Product Name	EPA Reg. No.
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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 firms on the following date(s):

Name of Firm(s)	Date of Offer
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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
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Name and Title (Please Type or Print)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Active Ingredient(s) and/or representative test compound(s)	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it 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	Date	Typed or Printed Name and Title
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date		EPA Reg No./File Symbol			Page of
Applicant's/Registrant's Name & Address		Product			
Ingredient					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Signature			Name and Title		Date

INSTRUCTIONS FOR DATA MATRIX

INSTRUCTIONS: Identify all data submitted or cited and all submitters from whom permission has been received or to whom offers to pay have been sent by entering sufficient information in the attached matrix (photocopy and attach additional pages as necessary). Complete all columns; omission of essential information will delay approval of the registration/reregistration. On each page enter the date, Applicant's/Registrant's name, EPA Registration Number or application file symbol of the product, ingredient, page number, and total number of pages.

The Data Compensation Form entitled "Certification with Respect to Citation of Data" and the Data Matrix will be publicly available, except for the Guideline Reference Number, Guideline Study Name, and MRID Number columns after the registration/reregistration of this product has been granted or once this form is received in response to a Data-Call-In Notice. However, the information in the Guideline Reference Number, Guideline Study Name, and MRID Number columns is available through the Freedom of Information Act in association with the EPA Registration Number.

Ingredient: Identify the active ingredient(s) in this product for which data are cited. The active ingredient(s) are to be identified by entering the chemical name and the CAS registry number. Begin a new page for each separate active ingredient for which data are cited. If bridging data from a related chemical or representative test compound are cited, enter the identity of that chemical/representative test compound including the EPA Registration Number/File Symbol if appropriate.

If the cite-all method is used for all data supporting this particular ingredient, enter "CITE-ALL" in the Guideline Reference Number column and leave the Guideline Study Name column blank. If the cite-all method is used for a particular Guideline Reference Number enter "CITE-ALL" in the MRID Number column on the line for that Guideline Reference Number. In either case, enter all submitters to whom offers to pay have been sent on subsequent lines. [Note: if the selective method of support is used and written authorization (letter of permission) is provided, the individual Guideline Reference Number, Guideline Study Name, and MRID Number columns must still be completed.] Otherwise:

Guideline Reference Number: Enter on separate lines in numerical order the Guideline Reference Numbers from 40 CFR Part 158 for all studies cited to support the registration/reregistration for this ingredient.

Guideline Study Name: For each Guideline Reference Number cited, enter the corresponding Guideline Study Name.

MRID Number: For each individual study cited in support of a Guideline Reference Number and Guideline Study Name, enter the Master Record Identification (MRID) Number listed in the Pesticide Document Management System (PDMS). Enter only one MRID Number on each line. Note that more than one MRID Number may be required per Guideline Reference Number. Note: Occasionally a study required to maintain a registration/reregistration is not associated with a Guideline Reference Number and Guideline Study Name. In such case, enter the MRID Number(s) for the study(ies).

Submitter: Using the most recent Data Submitters List, identify the Original Data Submitter with their current address for each study cited. The EPA assigned company number or other abbreviation may be used. Clearly explain any variations (alternate addresses, data owners not on the Data Submitters List, etc.) in footnotes to this table.

Status: Enter one of the following codes for each study cited, as appropriate:

OWN: I am the Original Data Submitter for this study.

EXC: I have obtained written permission of the Original Data Submitter to cite this exclusive-use study in support of this application.

PER: I have obtained the permission of the Original Data Submitter to use this study in support of this application.

OLD: The study was submitted more than 15 years ago and all periods of compensation have expired.

PL: The study is in the public literature.

PAY: I have notified in writing the Original Data Submitter or, if the cite-all method is used, all companies listed in the most current Data Submitters List for this ingredient, and have offered (a) to pay compensation in accordance with FIFRA sections 3(c)(1)(F) and/or 3(c)(2)(B), and (b) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study(ies).

GAP: This Guideline data requirement is a data gap as defined in 40 CFR sections 152.83(a) and 152.96.

FOR: I am taking the formulator's exemption for this ingredient only. Other columns of this line should be marked "NA". However, if this product is to be registered/reregistered for additional uses for which the purchased EPA registered ingredient is not supported, additional data must be submitted or cited here to support those uses.

Note: If additional explanation is needed, enter a footnote number in this column and attach the corresponding explanation.

United States Environmental Protection Agency
Washington, DC 20460



Form Approved
OMB No. 2070-0107,
2070-0057
Approval Expires
3-31-99

**CERTIFICATION WITH RESPECT TO
DATA COMPENSATION REQUIREMENTS**

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief, Regulatory Information Division, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Signature	Date
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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
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Name and Title (Please Type or Print)

List of Available Related Documents

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

Electronic

File format: Portable Document Format (.PDF) requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet using WWW (World Wide Web) on WWW.EPA.GOV., or contact Venus Eagle at (703)-308-8045.

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 methylisothiazolinone.

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