



Reregistration Eligibility Decision (RED) Methylene bis(thiocyanate)



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 methylene bis(thiocyanate). The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration.

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 date of this letter. The second set of required responses is due 8 months from receipt 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 Karen Jones (703) 308-8047. Address any questions regarding the RED to the Special Review and Reregistration Division representative Walter Waldrop at (703) 308-8062.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

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

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, 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

Methylene bis(thiocyanate)

LIST B

CASE 2415

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**METHYLENE BIS(THIOCYANATE) 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
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD ₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD ₁₀	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
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
RUP	Restricted Use Pesticide
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.
ug/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

ABSTRACT

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision of the pesticide methylene bis(thiocyanate). This decision includes a comprehensive reassessment of the required target data base and the use patterns of currently registered products. Additionally, the Agency has examined information concerning the exposure and susceptibility of infants and children to methylene bis(thiocyanate), and available information concerning aggregate exposure to methylene bis(thiocyanate) as well as the potential for cumulative effects from methylene bis(thiocyanate) and other substances that have a common mode of toxicity.

Methylene bis(thiocyanate) is an antimicrobial used as a microbiocide/microbiostat, fungicide/fungistat, and algicide in water cooling systems (recirculating), paint manufacturing, metalworking cutting fluids, pulp and paper mills, oil drilling/mud fluids, leather processing, wood pressure treatments (forest products), wood protection treatments to buildings/products, and latex paints (in-can). Methylene bis(thiocyanate) is also used in residential settings as a wood preservative stain to combat wood rot/decay.

The Agency is concerned about possible effects from inhalation exposure to methylene bis(thiocyanate) based on the only methylene bis(thiocyanate) inhalation data available, an acute study, which showed very high toxicity. Cyanide is a metabolite of methylene bis(thiocyanate) and both cyanide and formaldehyde are potential degradates of methylene bis(thiocyanate). It is possible that the thiocyanate ion would degrade to cyanide, but degradation data are lacking that would indicate whether this occurs in the working environment and, if so, under what conditions. However, notwithstanding these concerns, the Agency believes many uses of methylene bis(thiocyanate) are eligible for reregistration. The existing acute inhalation study is of very poor quality and can only be used for establishing a labeling toxicity category and not for risk assessment. Surrogate data for industrial biocide uses show that dermal exposure is 2 or 3 orders of magnitude greater than inhalation exposure and that inhalation exposure for some use scenarios is below the limit of detection. In addition, the Agency is requiring all methylene bis(thiocyanate) end-use product labels in Toxicity Category I or II to require the use of a respirator because of acute inhalation toxicity. The Agency is also requiring a subchronic inhalation study and air monitoring data that will quantitate amounts of cyanide and formaldehyde that might be present during application and post-application.

Generally, methylene bis(thiocyanate) uses that showed acceptable Margins of Exposure (MOE) from dermal exposure have been determined to be eligible for reregistration. The Agency could not make a decision for those uses for which there was neither dermal exposure data or a way to determine if these uses posed any worse exposure than uses where data are available. The Agency also determined that it could not make a decision on the use of paint and ready-to-use products that are applied with a paint brush, roller or compressed sprayer even though MOE's are very low for occupational handlers. Those uses for which a reregistration decision cannot be made are: Wood or wood structure protection treatments to both seasoned and unseasoned forest products; Wood or wood structure protection treatments; Wood protection treatment to buildings/products; Leather processing liquids; Leather/leather products; and Paints (in-can).

Before a decision can be made, additional data along with information on what types of paints contain methylene bis(thiocyanate) and what levels of post-application exposure (dermal and inhalation) result from painting and applications of ready-to-use products are necessary. The eligibility of specific uses is detailed in Part IV.

There were no developmental effects seen in two developmental toxicity studies and no adverse effects on offspring in a reproductive study, therefore, an additional uncertainty factor for estimating risk to infants and children is not warranted. The aggregate exposures from all non-occupational sources are not likely to be of concern, and the cumulative risks will be assessed when methodologies for determining common mode of toxicity and for performing cumulative risk assessment are finalized. The Agency does not anticipate any exposure of concern to fish, wildlife, and/or endangered species providing that all methylene bis(thiocyanate) products are handled and applied as specified in the product labeling and that discharges to the environment comply with all Federal disposal laws and NPDES.

Before reregistering the products containing methylene bis(thiocyanate), 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. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

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

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for 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.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances. Because methylene bis(thiocyanate) has no food uses, and therefore, no tolerances have been established, the specific considerations outlined in FQPA are not required for this chemical. Nevertheless, EPA believes that consideration of available data relating to the special sensitivity of infants and children, the potential for aggregate exposures and cumulative effects is prudent for methylene bis(thiocyanate).

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of methylene bis(thiocyanate). The document consists of six sections. Section I is the introduction. Section II describes methylene bis(thiocyanate), 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 methylene bis(thiocyanate). Section V discusses the reregistration requirements for methylene bis(thiocyanate). Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Methylene bis(thiocyanate)
Methylene dithiocyanate
Thiocyanic acid, methylene ester
- **Chemical Name:** Methylene bis(thiocyanate)
- **CAS Registry Number:** 6317-18-6
- **OPP Chemical Code:** 068102
- **Empirical Formula:** C₃H₂N₂S₂
- **Molecular Weight:** 130.2
- **Trade and Other Names:** Slimicide MC
Busan 110
Nalco D-1994
Antiblu 3737
Cyttox
- **Basic Manufacturers:** Buckman Laboratories International, Inc.
Albright and Wilson Ltd.
Akzo Chemicals, Inc.
AmeriBrom, Inc.

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of the uses of methylene bis(thiocyanate) is in Appendix A.

TYPE OF PESTICIDE

Pesticide Type Single Active Ingredient Products:

Fungicide; Microbiocide/Microbiostat (Slime-Forming Algae);
Microbiocide/Microbiostat (Slime-Forming Bacteria); Microbiocide/Microbiostat
(Slime-Forming Fungi)

Additional Pesticide Types for Multiple Active Ingredient Products:
Insecticide; Molluscicide and Tadpole Shrimp; Repellent/Feeding Depressant

USE SITES:

Terrestrial Non-Food Crop

Industrial preservatives with oil recovery drilling muds/packer fluids

Wood or wood structure protection treatments to both seasoned and unseasoned forest products.

Aquatic Non-Food Industrial

Aquatic Sites: Air washer water systems; commercial/industrial water cooling systems (recirculating); evaporative condenser water systems; heat exchanger water systems; industrial auxiliary water systems; industrial scrubbing system; industrial waste disposal systems; pulp/paper mill water systems; secondary oil recovery injection water; sewage systems

Industrial Preservatives: Oil recovery drilling muds/packer fluids

Outdoor Residential

Wood or wood structure protection treatments; Wood protection treatment to buildings/products

Indoor Non-Food

Aquatic Sites: Pasteurizer/warmer/cannery cooling water systems; reverse osmosis water systems

Industrial Preservatives: Industrial adhesives, industrial coatings, resin/latex/polymer emulsions, fuel/oil storage tank bottom water additive, leather processing liquids, leather/leather products, metalworking cutting fluids, paints (in-can), paper/paper products, speciality industrial products, wet-end additives/industrial processing chemicals.

Indoor Residential

Wood or wood structure protection treatments; wood protection treatment to buildings/products

TARGET PESTS:

Target pests for single active ingredient: Slime-forming bacteria, algae, and fungi; fungi associated with sapstain and dry rot; surface mold; spoilage microorganisms; sulfate-reducing bacteria; yeast; sulfide-producing bacteria.

FORMULATION TYPES REGISTERED:

TGAI Soluble Concentrate/solid	98%
Manufacturing-use Product	
Crystalline	99%
Soluble Concentrate/Liquid	98 to 99%
Soluble Concentrate/Solid	97 to 99%
End-use Product	
Liquid Ready-to-use	0.2 to 0.5%
Soluble Concentrate/Liquid	1.0 to 14.7%
Soluble Concentrate/Solid	4.9 to 7%

RATES OF APPLICATION:

Terrestrial Non-Food Crop

Industrial Preservatives: 6.5 to 1000 ppm active ingredient.

Wood Protection Treatment to Forest Products (seasoned):

Dip treatment-0.29 gal active ingredient in 100 gal of water.
Nonsoil contact nonfumigation-maximum of 0.05 lb active ingredient per 1000 sq.ft.

Soil contact nonfumigation-0.1 gal active ingredient in 19 gal of water.

Wood Protection Treatment to Forest Products (unseasoned):

Dip treatment-2.4 to 3.2 lb active ingredient in 100 gal of water.
0.29 gal active ingredient in 100 gal of water.

Spray-2.4 to 3.2 lb active ingredient in 100 gal of water.

Aquatic Non-Food Industrial

0.15 to 1000 ppm active ingredient.

Outdoor Residential

Wood Protection Treatment to Buildings/Products Outdoor:

Brush-on, Dip treatment, Spray-Maximum of 0.43 lb active ingredient per 1000 sq.ft.

Surface treatment- Maximum of 0.43 lb active ingredient per 1000 sq.ft.
Nonsoil contact nonfumigation- Maximum of 0.05 lb active ingredient per 1000 sq.ft. 0.1 gal active ingredient in 32.3 gal of water.

Soil contact nonfumigation- 0.1 gal active ingredient in 32.3 gal of water.

Indoor Non-Food

Aquatic Sites: 0.022 to 9.7 ppm active ingredient.

Industrial Preservatives: 0.47 to 20,000 ppm active ingredient.

Indoor Residential

Wood Protection Treatment to Buildings/Products Indoor:

Nonsoil contact nonfumigation-Maximum of 0.055 lb active ingredient per 1000 sq.ft.

Types of Treatment:

Additive treatment; brush-on; dip treatment; fresh hide treatment; hides and skins treatment; industrial preservative treatment; make-up fluids treatment; nonsoil contact nonfumigation; preservative treatment; soil contact nonfumigation; spray; surface treatment; water related surface treatment; water treatment; water treatment (recirculating system); wood chip treatment; wood surface treatment

Equipment:

Applicator rolls in paper production; brush; chemical pump; dip tank; drip-feed device; metering pump; paintbrush; roller; sprayer; sprinkler can; tank; not specified (registrant must specify on labeling see Section V)

Timing:

Continuous feed (initial); continuous feed (subsequent); curing manufacture; Initial; intermittent (slug)(initial); intermittent (slug)(subsequent); shock/slug; subsequent/maintenance; when needed; not specified (registrant must specify on labeling see Section V).

C. Regulatory History

Methylene bis(thiocyanate) was first registered in the United States in 1949 as an active ingredient. Currently, 59 products are registered for uses for incorporation into products such as adhesives, coatings, fuels, metalworking cutting fluids, plastic products, resin emulsions, paints, paper products and various other speciality industrial products primarily as a preservative and as a microbiocide in pulp/paper mills, cooling water systems (recirculating), oil field operations, leather processing and industrial water supply systems. The compound is also used to treat wood products (seasoned/unseasoned forest products and various finished wood products).

An Antimicrobial Data Call-In was issued in March 1987. A second Data Call-In was issued as part of the Phase 4 reregistration in June 1991. The Agency issued a third Data Call-In in June 1993 for additional environmental fate data on aquatic exposure. A fourth Data Call-In was issued in March 1997 for additional inhalation toxicity data. This Reregistration Eligibility Decision (RED) reflects a reassessment of all data which were submitted voluntarily by the registrants or in response to the above Data Call-Ins.

III. SCIENCE ASSESSMENT**A. Physical Chemistry Assessment**

Methylene bis(thiocyanate) is a methane group containing two thiocyanate groups. Technical methylene bis(thiocyanate) is a yellow granular solid with a sulphur like smell. It has a density of 0.820 g/mL and boils at 105.4° to 106.2° C. The vapor pressure is 1.22×10^{-4} torr at room temperature. It is more soluble in methanol compared to water and octanol. Its solubilities are 0.28, 0.35 and 5.1 g/mL for water, octanol and methanol, respectively.

B. Human Health Assessment**1. Toxicology Assessment**

The toxicological database for methylene bis(thiocyanate) is not complete for all current use patterns. The Agency is requiring additional data to further support the reregistration eligibility decisions set forth in this document. A hazard has been identified for inhalation exposure but data are insufficient to conduct a

quantitative risk assessment for this route of exposure. The Agency is requiring a 90-day inhalation study in order to quantify the level of hazard posed by exposure via the inhalation route. Although there are two supplementary metabolism studies, there is still a data gap for metabolism primarily due (but not limited) to inadequate metabolite identification. One study is potentially upgradable. The outstanding metabolism data is required as confirmatory data. Additionally, handler and post-application air monitoring studies for various use scenarios as described in this document are being required to confirm the registrants' assertions that there are no exposures to methylene bis(thiocyanate) as a result of the registered uses.

a. Acute Toxicity

Table 1 below summarizes the results of acute toxicity studies on methylene bis(thiocyanate) and the toxicity categories for the different routes of administration.

TABLE 1: ACUTE TOXICITY DATA FOR METHYLENE BIS(THIOCYANATE) (TGAI)

Test (MRID)	Result	Toxicity Category
Oral LD ₅₀ - rat (MRID 41592901)	LD ₅₀ (male) = 84.9(73.4 - 98.2) mg/kg LD ₅₀ (female) = 68.3(49.4 - 94.3) mg/kg	III
Dermal LD ₅₀ - rat (MRID 42873101)	LD ₅₀ > 2.0 g/kg	III
Inhalation LC ₅₀ (MRID 41201601)	LC ₅₀ = 0.0077(0.0061 - 0.011) mg/L	I
Eye Irritation* (study waived)	Corrosive	I
Dermal Irritation* (MRID 43699601)	Moderate to severe, corrosive in 1 male.	I
Dermal Sensitization* (MRID 00159567)	Positive skin sensitizer	N/A

* This study is a requirement for manufacturing-use and end-use products(40 CFR 158.340). The methylene bis(thiocyanate) data have been generated on the TGAI and are presented here for informational purposes.

In an acute oral study (GDLN 81-1) in CD (BR) rats, 5 animals/sex were administered concentrations of 60, 75, or 90 mg/kg test material to males and 40, 60, and 90 mg/kg to females. The LD₅₀ was 84.9 mg/kg for males and 68.3 mg/kg for females. The study satisfies the data requirements for GDLN 81-1. (MRID 41592901)

In an acute dermal study (GDLN 81-2) in Crl rats, 6 animals/sex were dermally exposed to 2.0 g/kg for 24 hours. The LD₅₀ is greater than 2.0 g/kg and the study satisfies the data requirements for GDLN 81-2. (MRID 42873101)

In an acute inhalation study (GDLN 81-3) in CD (Sprague-Dawley) rats, 20 animals/sex were exposed to nominal concentrations of 0, 14, 22,

36 or 53 mg/L test material for 4 hours. The LC₅₀ (95% confidence limits) were 0.0078 (males), 0.0077 (females) and 0.0077 (combined) for 4 hours. The study is of poor quality and would not usually be acceptable because (1) there were extreme differences in chamber concentration for measurements made at intervals for each and all exposures; (2) the mass median diameters of the particles were too large; (3) the relative humidity was too high suggesting that the airflow may have been inadequate; (4) the difference between the nominal and analytical values were 5000 fold; and (5) since this was whole body exposure, there could have been considerable oral exposure. However, a repeat of this study was not required for labeling purposes since the results place methylene bis(thiocyanate) in Toxicity Category I (highest toxicity category). (MRID 41201601)

A waiver was granted for the primary eye irritation data requirement (GDLN 81-4). Information was provided showing methylene bis(thiocyanate) is a severe eye irritant. Data on eye irritation is not required for this reregistration eligibility decision.

A primary dermal irritation study (GDLN 81-5) in adult male New Zealand White rabbits by the Draize method produced a Primary Irritation Index (PII) score of ≥ 2 and ≤ 5 which showed that methylene bis(thiocyanate) is a moderate to severe dermal irritant and is placed in Toxicity Category I for primary dermal irritation. (MRID 43699601)

In a dermal sensitization study (GDLN 81-6) with Hartley Albino guinea pigs, positive skin sensitization was observed. Therefore, methylene bis(thiocyanate) is classified as a skin sensitizer. (MRID 00159567)

b. Subchronic Toxicity

Oral Study in Rats: In a subchronic oral study (gavage), 6 week old F344/N rats (10/sex/groups) were administered 0, 1, 2, 4, 8 or 16 mg/kg/day of methylene bis(thiocyanate) (98% a.i.) 5 times per week for 13 weeks. Deaths occurred beginning in the 2 mg/kg/day group in males (as early as week 2) and in the 4 mg/kg/day group in females (week 5). The animals showed signs similar to cyanide poisoning, dyspnea, abnormal respiratory sounds, hunched posture and chromodacryorrhea. Anemia was observed in males in the 4, 8 and 16 mg/kg/day groups and in females in the 8 and 16 mg/kg/day groups. Hyperplasia and hyperkeratosis of the forestomach were increased in males and females in the 8 and 16 mg/kg/day groups. Hyperplasia was also observed in one female in the 4 mg/kg/day group. Ulceration of the forestomach was present in one male and one female in the 16 mg/kg/day group. An acute exudate and

epithelial necrosis of the nasal cavity and trachea were observed in males in the 8 and 16 mg/kg/day groups. An acute exudate and epithelial necrosis of the nasal cavity were also seen in one male in the 4 mg/kg/day group. Total protein was decreased in males and females in the 8 and 16 mg/kg/day groups accompanied by slight decreases in albumin in males in the 8 and 16 mg/kg/day group, an indication of dysproteinemia. Males in the 4 and 8 mg/kg/day groups exhibited a modest decrease in sperm motility. The LOEL is 2 mg/kg/day based on mortality. The NOEL is 1 mg/kg/day. (MRID 43420001)

Oral Study in Mice: In a subchronic oral study in mice, 6 week old B₆C₃F₁ mice (10/sex/groups) were administered 0, 1, 2, 4, 8 or 16 mg/kg/day of methylene bis(thiocyanate) (98% a.i.), 5 times per week for 13 weeks. Deaths occurred in males in the 8 (week 9) and 16 mg/kg/day groups and in females in the 16 mg/kg/day group (week 9). One male in the 16 mg/kg/day group exhibited hypothermia, dyspnea and hypoactivity at week 10. Pathology was limited to hyperplasia and/or hyperkeratosis of the forestomach in males and females in the 4, 8 and 16 mg/kg/day groups, and an acute exudate epithelial necrosis of the nasal cavity in a few animals in the 16 mg/kg/day group. Also an acute exudate and epithelial necrosis of the trachea was observed infrequently in females in the 16 mg/kg/day group. The LOEL is 4 mg/kg/day based on hyperplasia and hyperkeratosis of the forestomach in females. The NOEL is 2 mg/kg/day. (MRID 43420001)

Dermal Study in Rats: In a 3-week subchronic dermal toxicity study Crl:CD(SD)BR (5 rats/sex/group) were dermally administered 0, 10, 30 or 60 mg/kg/day methylene bis(thiocyanate) in 0.4% aqueous carboxymethyl cellulose. The rats were exposed for 6 hours/day, 4 or 5 days/week, for 3 weeks. No deaths occurred. There were no abnormal clinical signs and no effect on body weight gain, food consumption, clinical pathology values and organ weights. The systemic LOEL is greater than 60 mg/kg/day. The systemic NOEL is greater than or equal to 60 mg/kg/day. Dose-related signs of dermal irritation included erythema, edema, desquamation, fissuring, subcutaneous hemorrhage, necrotic appearance, atonia, eschar, exfoliation and pustules/papules. The LOEL for dermal effects is 10 mg/kg/day based on skin irritation. The NOEL for dermal effects is less than 10 mg/kg/day. (MRID 41111901)

Inhalation Study in Rats: There are no subchronic inhalation studies with methylene bis(thiocyanate). A subchronic inhalation study is required due to the high acute toxicity (LC₅₀ = 0.0077 mg/L toxicity category I) identified in the acute inhalation study and the potential for daily occupational/residential exposure. A hazard was identified by the

Toxicological Endpoint Selection Committee (TESC) based on the high toxicity (mortality) from this chemical to test animals by this route of exposure. Data were not readily available to further characterize or quantify the hazard due to inhalation exposure of methylene bis(thiocyanate).

c. Chronic Toxicity/Carcinogenicity

Oral Study in Rats: In a chronic (24 month) toxicity/oncogenicity study, methylene bis(thiocyanate) suspended in 0.5% carboxymethyl cellulose was administered once daily by gavage to groups of Sprague-Dawley rats (70/sex/groups) at 0, 0.4, 1.2, or 4.0 mg/kg/day. Twenty male and 20 female rats from each dose group were designated for a 52-week interim kill. An increase in the incidence of tracheal inflammation, thymic lymphocytolysis, breathing abnormalities, and an increase in mortality was observed in both males and females at 4.0 mg/kg/day. The mortality was 54% for males and 40% for females at the high dose (4.0 mg/kg/day) by week 70 at which time the high dose groups were terminated. Increased incidence of focal alveolitis was observed in males at all dose levels. These effects may be consequences of the dosing method that resulted from aspiration of the test material into the respiratory tract and the action of the material as an irritant on these tissues. However, these signs (including breathing abnormalities) are typical of cyanide poisoning and may not be solely due to the dosing method resulting in aspiration of the test material. There was an increase in benign and malignant (when combined) adrenal pheochromocytomas in males, but no statistically significant trend was seen. Exempting the probable effects associated with the gavage dosimetry, the NOEL for systemic effects in male and female rats was 1.2 mg/kg/day, and the LOEL was 4.0 mg/kg/day based on increased mortality. The Agency's Office of Pesticide Program's (OPP) RfD Committee (February 1, 1996) considered there to be a possible treatment related increase in adrenal pheochromocytomas in males. Although, there were fewer than 50% survivors in the high-dose group at 18 months of treatment, the mid-and low-dose groups were adequate to assess the carcinogenic potential of methylene bis(thiocyanate). This study is acceptable and satisfies the guideline requirements for a chronic toxicity study and oral oncogenicity study in rats. (MRID 42777601)

Oral Study in Mice: In a carcinogenicity study, methylene bis(thiocyanate) (99.3%) in 0.5% carboxymethyl cellulose was administered by gavage to CD-1 mice (50/sex/groups) at doses of 0, 0.4, 1.2, or 4/3 mg/kg/day for 78 weeks. The high dose of 4 mg/kg/day was reduced to 3 mg/kg/day during week 4 because of the death of six males;

five of the six deaths were due to dosing injury and not to treatment with the test material. The resulting time-weighted-average (TWA) dose was 3 mg/kg/day. No statistically and biologically significant effects occurred in male mice receiving methylene bis(thiocyanate) at doses of 0.4 or 1.2 mg/kg/day. The occurrence of lymphocytolysis in female mice was considered to be a result of dosing injury. No other significant effects were noted in female mice receiving 0.4 or 1.2 mg/kg/day. At 3 mg/kg/day, mean body weights were significantly reduced at various time points throughout the study in male (93-98% of control value) and female mice (89-97% of control value); net body weight gain showed a corresponding reduction (23% for males and 25% for females). No nonneoplastic lesions occurred with biologically and statistically significant increased incidence in mice receiving 3 mg/kg/day. The incidence of generalized and organ-specific amyloidosis was reduced in treated mice due to unknown causes. The mucosa of the stomach was not a target in the long-term study as indicated by the short-term range-finding studies. There was an increase in males in alveolar adenomas in the lung, with increasing dose, statistically significant at the mid dose only at $p < 0.05$. The LOEL for this study is 3 mg/kg/day (TWA dose) based on reduced body weight and body weight gain in both sexes. The NOEL is 1.2 mg/kg/day. The Agency's OPP RfD Committee (February 1, 1996) considered there to be a possible increase in alveolar adenomas in males. (MRID 42777301)

Oral Study in Dogs: In a chronic oral study, encapsulated methylene bis(thiocyanate) (99.4%) was administered once daily to Beagle dogs (4/sex/groups) at doses of 0, 0.5, 2.0 or 5.0 mg/kg/day for 52 consecutive weeks. Amounts administered were adjusted weekly based on individual body weights. Toxic effects were consistent with a mild local irritation of the stomach. There was a dose-related increase in emesis in treated animals, with 3-fold, 15-fold and 30-fold increases at the 0.5, 2.0 and 5.0 mg/kg/day dose levels, respectively, compared to the control group; in the 5.0 mg/kg/day dose group, fecal inconsistency and salivation were observed in a few animals. Hemoglobin, red blood cell count and hematocrit were marginally lower in the 5.0 mg/kg/day group. White blood cell counts were slightly elevated in all treated groups throughout the study. Reductions in albumin levels were statistically significant at 51 weeks at both the 2.0 and 5.0 mg/kg/day doses; marginal reductions in total protein and albumin/globulin ratios were also observed. In male dogs, a mild inflammatory cell infiltrate in the lamina propria of the stomach was dose related. In females the incidence was not dose related. Examination of the bone marrow revealed a statistically nonsignificant increased incidence of hematopoiesis in male dogs in the 5.0 mg/kg/day dose group (3 of 4 animals); one intermediate group animal was also affected. Incidence in the treated female groups (3/group) were mild and

were not dose related. The LOEL of 2.0 mg/kg/day was identified based on the marginal changes in blood chemistry and pathology findings in the stomach and bone marrow. The NOEL was 0.5 mg/kg/day. (MRID 41463201)

d. Developmental Toxicity

Oral Study in Rats: In a developmental toxicity study, 4 groups of 25 female Crl:CD BR rats were administered 0, 1, 3 or 6 mg/kg/day of methylene bis(thiocyanate) (99%) during gestation days 6-15. Due to an error in dosing only 14 control, 12 low dose, 11 mid dose and 17 high dose group dams were "fully dosed". Dams partially dosed (from gestation day (GD)) included 10, 12, 11 and 5 females from the control, low, mid and high dose groups, respectively. No maternal mortality was observed. When the data were analyzed regardless of the dosing error, maternal body weight, body weight gain, or feed consumption were slightly decreased at the 6 mg/kg/day dose level. The test material did not induce any gross pathological alterations. Pregnancy rate, average numbers of corpora lutea, implantations, percent of pre- and post-implantation loss, resorptions, fetuses/litter, viable number of fetuses/dam, fetal body weight, and percentage of male fetuses/litter were comparable between groups. The maternal LOEL is 6 mg/kg/day based on a slight decrease in maternal body weight gain and a small increase in the incidence of resorptions. The maternal NOEL is 3 mg/kg/day. The LOEL for developmental toxicity was greater than 6 mg/kg/day. The NOEL for developmental toxicity is greater than 6 mg/kg/day. (MRID 41171901)

Oral Study in Rabbits: In a second study the developmental toxicity potential of methylene bis(thiocyanate) (99%) was studied by dosing pregnant Hra:(NZW)SPF rabbits, (20/group) by stomach tube, with 0, 1, 3, 5(7) mg/kg/day. The highest dose tested caused 5 deaths (25% of total) and was reduced after the fifth death to 5 mg/kg/day. Five treatment-related deaths were observed in the high dose group following 1, 2, 3, 4 and 5 dosings at 7 mg/kg/day. All five dead rabbits were pregnant. The conceptuses of the three that died after 3-5 dosings appeared normal for their developmental age. The viability state of the *in utero* implantations of the two that died after 1-2 dosings could not be determined because of the early developmental stage. All four high-dose does that died after 2-5 dosings showed severe gastric ulceration and/or gastric mucosal sloughing and hemorrhage at necropsy. No further mortality was observed after the reduction of the high dose level. Clinical signs preceding the five deaths included respiratory difficulty, ataxia, decrease in motor activity, loss of righting reflex, tremors, convulsions and/or dry feces. After the high dose was reduced, two survivors in the group showed single incidence of tremor

(day 15 and day 17) and eight showed incidences of dry feces lasting 2-4 days, six of those during the period from day 8 to 12. Body weight gain and food consumption in the high dose group was significantly decreased, but only during the period when the high dose was at 7 mg/kg/day. The LOEL for maternal toxicity was 5 mg/kg/day based on mortality and decreased body weight gain. The NOEL was 3 mg/kg/day. Methylene bis(thiocyanate) at 1, 3, and 5/7 mg/kg/day did not affect pregnancy rate, average numbers of corpora lutea, implantations, early and late resorptions, fetuses/litter, viable number of fetuses/litter, fetal body weight, and percentage of male fetuses. These doses did not cause external, soft tissue, or skeletal malformations or variations in the fetuses, and incidences of fetal changes were not statistically significantly increased in any of the treated groups. The developmental LOEL for methylene bis(thiocyanate) in pregnant rabbits was greater than 5 mg/kg/day, and the developmental NOEL was 5 mg/kg/day. (MRID 41171902)

e. Reproductive Toxicity

Oral Study in Rats: The reproductive toxicity potential of methylene bis(thiocyanate) (99.3%), was studied by dosing SD (CD) (28/sex/group) rats by oral gavage, through two generations (F_0 - F_1 ; F_1 - F_2), with one mating period per generation. The doses used were 0, 1.0, 2.5, and initially 5.0 mg/kg/day. The initial high-dose caused four F_0 rats (1 male and 3 females) to be sacrificed *in extremis* within the first 16 days of dosing, and was reduced to 4.0 mg/kg/day (definitive high-dose) from dosing day 17 to the end of the study. The NOEL for parental systemic effects was 1.0 mg/kg/day and the LOEL was 2.5 mg/kg/day (mid-dose), based on one F_1 (female) mortality associated with necropsy findings of cecum distention with gas. The initial high dose (5 mg/kg/day) caused 4 deaths (see above), most of which were preceded by adverse clinical signs of breathing difficulty, piloerection, and swollen abdomen, and were associated with necropsy findings of gastrointestinal distention by gas. The definitive high-dose (4 mg/kg/day) was also associated with one F_1 (male) death. Some of the above described clinical signs were also observed in a few surviving mid-dose and high-dose F_0 rats. Methylene bis(thiocyanate) at 1-4 mg/kg/day did not adversely affect body weight, body weight gain, food consumption, or any reproductive parameter (precoital interval, oestrus state, male/female fertility indexes, duration of gestation, gestation index, number of implants/pregnancy, number of pups born dead or alive per dam) in either the F_0 or F_1 parental groups. Methylene bis(thiocyanate) at 1-4 mg/kg/day did not adversely affect any of the litter parameters (number of live pups/litter at lactation day 0, 4, 14, or 21, birth, live birth, viability, lactation, and overall survival indexes, male/female pup body weight, and litter weight during the entire lactation period) in either the F_1

or F₂ litter groups. The LOEL was greater than 4 mg/kg/day. The NOEL for reproductive effect was 4.0 mg/kg/day (high dose). (MRID 42028601)

f. Mutagenicity

The studies satisfy current mutagenicity initial testing battery guidelines. No further testing is required at this time.

S9-activated methylene bis(thiocyanate) was mutagenic in mouse lymphoma cells, but only at cytotoxic doses. The evidence of clastogenic activity in cultured mammalian cells, which occurred only at cytotoxic doses with or without S9 activation, was not confirmed. It was concluded, however, that requesting a repeat study would not add substantively to the overall database for methylene bis(thiocyanate). This decision is based on the similarity of the response between these two mammalian cell assays (i.e., positive results only at cytotoxic doses) in conjunction with the negative findings from the two acceptable whole animal somatic cell assays. Additionally, the suggestive evidence of test material/target cell interaction noted in one of the two micronucleus assays (MRID 41003702) provides some confidence that the lack of a response was likely not due to a failure of the test material to reach the bone marrow. Hence, while the *in vitro* data indicate that the test material is a mutagen and presumably a clastogen, the negative *in vivo* data suggests that methylene bis(thiocyanate) lacks *in vivo* mutagenic potential. This assumption is further supported by the findings that methylene bis(thiocyanate) did not cause significant reproductive or developmental toxicity attributable to a mutagenic mode of action (i.e., decreased total implants, increased resorptions). Based on the available toxicity data, it is concluded that methylene bis(thiocyanate) has intrinsic genotoxicity activity which is only expressed *in vitro*.

The mutagenic potential of methylene bis(thiocyanate)(99%) was studied in 5 histidine auxotrophs bacterial strains derived from *Salmonella typhimurium* (TA98, TA100, TA1535, TA1537, and TA1538), according to the reverse mutation test method of Ames. Positive controls were 2-aminoanthracene (2 µg/plate) for mutagenic testing with metabolic activation in all 5 strains, and sodium azide (1 µg/plate), 9-amino acridene (75 µg/plate), or 2-nitro fluorene (3 µg/plate), for mutagenic testing without metabolic activation, sodium azide in the TA100 and TA 1535 strains, 9-amino acridene in the TA1537 strain, and 2-nitro fluorene in the TA1538 and TA98 strains. Methylene bis(thiocyanate) at concentrations of 0.1-20 µg/plate in assays without metabolic activation or 0.3-50 µg/plate in assays with metabolic activation was negative in the Ames reverse mutation test with all 5 strains studied. The dosage ranges used were based on a range finding study with TA100, in which concentrations of methylene

bis(thiocyanate) $\geq 33 \mu\text{g}/\text{plate}$ (without metabolic activation) or $\geq 67 \mu\text{g}/\text{plate}$ (with metabolic activation) were 100% cytotoxic. The positive controls all induced positive reverse mutation in the bacterial strains studied. No positive mutagenic response was obtained under the conditions of this test. In a second Ames test methylene bis(thiocyanate) was tested at dose levels ranging from 0.005-5 $\mu\text{g}/\text{plate}$ with and without metabolic activation in strains TA98, TA100, TA1537 and TA1538. No positive mutagenic response was obtained under the conditions of the second test. (MRID 41003701, 00151925)

The mutagenic potential of methylene bis(thiocyanate)(99%) was studied using the mouse lymphoma mutation assay. Dose levels used ranges from 1-4 mg/mL with activation and 0.4-24 mg/ml without activation. Cytotoxic concentrations of methylene bis(thiocyanate) induced a positive mutagenic effect in the mouse lymphoma L5178Y tk⁺/tk⁻ cells line. In the presence of metabolic activation, concentrations of methylene bis(thiocyanate) of 2, 3, and 4 $\mu\text{g}/\text{mL}$ caused significant increases in both the mean tk⁺/tk⁻ mutant counts and the mean mutant fraction values (respective increases of mean mutant fraction were 1.6, 2, and 2.5 fold over controls). All 3 doses were greatly cytotoxic, causing respective decreases in cells survival (relative total growth) of 72, 90, and 99%. The positive mutagenic effect of methylene bis(thiocyanate) at 4 $\mu\text{g}/\text{mL}$ was confirmed in a repeat assay. In the absence of metabolic activation, dose-related significant increases in both the mean mutant count and the mean mutant fraction were observed with 1 and 1.5 $\mu\text{g}/\text{mL}$ (respective increases of mean mutant fraction were 2.3 and 15.2 folds over controls). These two doses caused 59 and 94% decreases in cells survival. Mutagenic effects in the absence of metabolic activation were not reproduced in the confirmatory trial with a dose range of 0.4-2.4 $\mu\text{g}/\text{ml}$. The mutant count of the vehicle cultures were within historical ranges. Both reference chemicals, EMS (without S9 mix) and 3-MC (with S9 mix), induced positive increases in both the mean mutant count and the mean mutant fraction values. A positive mutagenic response was obtained in the presence of S9. (MRID 41503802)

The mutagenic potential of methylene bis(thiocyanate)(99%) was studied using the chromosomal aberrations assay with Chinese hamster ovary (CHO) cells *in vitro*. Under the experimental conditions of the study no numerical chromosome aberrations were observed with methylene bis(thiocyanate) at any of the doses used (0.25, 0.5, 1.0, 2.0, and 4 $\mu\text{g}/\text{mL}$ culture medium). Non-cytotoxic concentrations of methylene bis(thiocyanate) ($\leq 1 \mu\text{g}/\text{mL}$) caused a dose-related positive increase in structural aberrations (mainly simple breaks and gaps), both with and without metabolic activation. This positive clastogenic effect is considered

a "presumptive" effect since it was not confirmed in a repeat (complete) assay. Cytotoxic concentrations of methylene bis(thiocyanate) (2 and 4 $\mu\text{g}/\text{mL}$) caused a dose-related positive increase in structural aberrations (mainly simple breaks and gaps), both with and without metabolic activation. This positive clastogenic effect is considered a "presumptive" effect since it was not confirmed in a repeat (complete) assay. The frequencies of chromosome aberrations in both vehicle and untreated control cultures were within the historical ranges. The reference chemicals CP, 2-AAF, and MMS all induced positive increases in structural chromosomal aberrations. Numerical chromosomal aberrations (number of cells with endoreplicated chromosomes) were increased by only 2-AAF. Although unconfirmed, a presumptively positive mutagenic response was observed. (MRID 41503801)

LACA mice were treated with 8.94, 17.89 or 35.78 mg/kg of methylene bis(thiocyanate) which represented 20, 40 and 80% of the LD_{50} dose, respectively. There were no significant increases in the number of micronucleated polychromatic erythrocytes in methylene bis(thiocyanate) treated mice when compared to the vehicle control. Thus, methylene bis(thiocyanate) did not show a mutagenic response. The mutagenic potential of methylene bis(thiocyanate)(99%) was tested in a second mouse micronucleus study. ICR mice of both sexes were injected IP with single doses of methylene bis(thiocyanate) (0.3, 1.3, or 2.6 mg/kg). The selection of this HDT was based on the results of a preliminary acute toxicity test showing that the LD_{50} was approximately 3.2 mg/kg. Vehicle controls were injected with 1% carboxy methyl cellulose and positive controls with triethylenelamine (TEM, 0.25 mg/kg). Five males and 5 females treated with TEM were sacrificed 24 hours after dosing. Five mice/sex in all the other groups were sacrificed each time at 24, 48 or 72 hours after dosing. Bone marrows from the animals' femurs were prepared for microscopy under oil immersion, and 1000 polychromatic erythrocytes (PE) per mouse were scored for incidence of micronucleated polychromatic erythrocytes (MPE). Slight declines in the PCE:NCE ratio in both sexes of the high dose group at the 24 hour sacrifice and high dose males at 48 hours suggests possible bone marrow cytotoxicity. Under the experimental conditions of the study, methylene bis(thiocyanate) did not exhibit any mutagenic potential in the mouse micronucleus assay, at any dose, and at any of the three observation times. In contrast, the reference chemical TEM exhibited a positive mutagenic effect at 24 hours. A negative mutagenic response was obtained. (MRID 00151926, 41003702)

The mutagenic potential of methylene bis(thiocyanate) (99%) was studied using the test of Unscheduled DNA Synthesis (UDS) in primary hepatocytes from male adult Fisher 344 rats. The primary hepatocytes (5

x 10⁵ viable cells/culture dish) were prepared according to the methods of Williams and Bradlaw. The following experimental groups (3 cultures/group) were incubated (37±1° C, humid atmosphere containing 5±1% CO₂) with ³H-thymidine (10 μCi/mL medium) for 18-20 hrs: medium control, vehicle control (with DMSO 10 μl/mL medium), test (with 10 levels of Methylene bis(thiocyanate) from 0.03-10 μg/mL medium), and positive control (DMBA 3 and 5 μg/mL medium). The methylene bis(thiocyanate) dose range selection was based on a preliminary test in which methylene bis(thiocyanate) 5 μg/mL medium was shown to cause a significant increase in the level of cytotoxic enzyme marker LDH in the incubation medium. Following the incubation period, the hepatocytes were treated for autoradiography, fixed, and stained. The incorporation of ³H-thymidine into the hepatocytes DNA (a measure of DNA repair) was measured by the number of net nuclear grains/cell nucleus. The number of cells in repair (≥5 net nuclear grains/nucleus) were also reported. Under the experimental conditions of the study, methylene bis(thiocyanate) did not exhibit any mutagenic potential in the UDS test. Methylene bis(thiocyanate) levels of 0.3-1.5 μg/mL induced neither any change in the number of net nuclear grains/nucleus, nor any increase in the number of cells in repair. Levels of 3-10 μg/mL induced a decrease in relative survival rate greater than 50%. In contrast, both doses of the reference chemical DMBA were devoid of cytotoxic action but significantly increased both the number of net nuclear grains/nucleus, and the number of cells in repair. A negative mutagenic response was obtained. (MRID 41003703)

g. Metabolism

Although there are two metabolism studies noted below, there is still a data gap for metabolism primarily due (but not limited) to inadequate metabolite identification. The first study is potentially upgradable. The additional metabolism data remains outstanding and should be submitted as confirmatory data.

The disposition and metabolism of [¹⁴C]methylene bis(thiocyanate) ([¹⁴C]methylene bis(thiocyanate)) was studied after oral (gavage) administration to Sprague-Dawley rats (1-9/sex/group). Male and female rats were dosed with [¹⁴C]methylene bis(thiocyanate) at single oral doses of 3 and 30 mg/kg and at repeated doses (14 daily doses) of 3 mg/kg. [¹⁴C]methylene bis(thiocyanate) was rapidly absorbed, extensively metabolized, and rapidly excreted. Over a 4-day period, most (94.87-99.95%) of the test compound administered was excreted from the animals. The radioactivity recovered in the urine, feces, and CO₂ in the exhaled air was 63-71, 14-19 and 11-14 percent of the administered dose, respectively.

Peak plasma concentrations of radioactivity occurred 1 to 2 hours after the administration of the test compound. A number of radioactive components (none of which co-chromatographed with [¹⁴C]methylene bis(thiocyanate)) were observed in the urine. Radiolabeled components found in fecal extracts from rats treated with a low dose did not co-chromatograph with [¹⁴C]methylene bis(thiocyanate), but one component found in fecal extracts from rats treated with a high dose did. However, the data provided on the identification of the metabolites of methylene bis(thiocyanate) in the urine, feces, expired air, and tissues is incomplete. The characterization of the unidentified radioactive components, the purity and composition of the unlabeled test material, and a statement of the adverse affect observed which validated the use of 30 mg/kg as the high dose in this study must be provided. (MRID 41088501)

A second metabolism study was conducted consisting of two experiments. In the first experiment, groups of three Fisher 344 rats were administered oral doses of 0.2, 1.0 or 10 mg/kg of [¹⁴C]methylene bis(thiocyanate)(99%). In a second experiment, methylene bis(thiocyanate) was administered orally to rats at a high dose of 10 mg/kg. In the first experiment, urine was the primary route of excretion (52-62%) followed by fecal elimination (14-28%) and expired CO₂ (9-11%). Total recovered radioactivity ranged from 92.29-98.96% at 48 hours. No radioactivity was found as volatile organics. Tissue levels ranged from 2.57-6.48% of the administered dose. Total radioactivity in the blood, blood cyanide and plasma thiocyanate exhibited biphasic elimination from the blood. The terminal elimination phase started 1 hour after dosing and had a half-life of 7 hours. When methylene bis(thiocyanate) was administered at 10 mg/kg, whole blood cyanide increased dramatically (64.9-198.2 mg/mL) over background levels at 0.5-1.0 hour post-dosing. Plasma thiocyanate was at a maximum concentration of 9.66 μg/mL at 2 hours post-dosing. These values decreased but did not reach background levels by 24 hours post-dosing. Two mechanisms may explain the reactions. One is the reaction of alkylmono thiocyanates with a soluble liver enzyme fraction containing glutathione S-transferase and glutathione (GSH). A second reaction involves P-450 isozymes. The additional thiocyanate group may make the methylene carbon suitable for oxygen insertion producing the corresponding aldehyde with the release of thiocyanate. Further oxidation of the aldehyde to the corresponding acid followed by decarboxylation would yield CO₂. The authors propose that the toxicity of methylene bis(thiocyanate) may be due to 1) cyanide release, 2) glutathione depletion, and 3) toxic metabolites other than cyanide and thiocarbamates.

The study is supplementary and cannot be upgraded. This study, while taking into account previously submitted studies, does not satisfy the

guideline 85-1 requirement for a metabolism study because 1) the single highest dose of 10 mg/kg (1/10 LD₅₀) did not produce a pharmacological or toxicological response, 2) too few animals had any data reported for them, and 3) metabolite analyses were incomplete and limited to CO₂, cyanide and thiocyanate measurements (no chromatography, etc. methods were employed). (MRID 41774501)

h. Dermal Absorption

In the absence of data on dermal absorption, a 5% absorption factor was calculated. The estimate of dermal absorption was made using the comparison between the rat developmental toxicity study (MRID 41171901) and the rat 21-day dermal toxicity study (MRID 4111901). In the developmental study the NOEL was 3 mg/kg/day with clinical signs occurring at 6 mg/kg/day. This NOEL is supported by results in the developmental range finding study where one death occurred at 10 mg/kg/day after 6 doses and two deaths occurred at 30 mg/kg/day after two doses. The 21-day dermal study had a NOEL of 60 mg/kg/day (high dose). Comparing the NOELs from the two studies indicates that dermal absorption is less than 5%.

i. Other Toxicological Information

Cyanide is a metabolite of methylene bis(thiocyanate). It appears that much of the toxicity of methylene bis(thiocyanate) is consistent with that of Cyanide. The August 1995 draft for public comment of the Toxicological Profile for Cyanide, U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (ATSDR) reported that cyanide is extremely toxic by all routes of exposure. Systems affected include, but are not limited to, the central nervous system (potentially resulting in death), the respiratory system, the cardiovascular system, and the gastrointestinal system. Cyanide is regulated by many Agencies. The oral minimal risk level (MRL) for exposure durations of 15-365 days was determined by the ATSDR to be 0.05 mg/kg/day. The MCL in water is 0.2 mg/L as free cyanide. In 1994, IRIS placed cyanide in the "D" carcinogenicity category, listed the RfD for HCN and free cyanide as 2×10^{-2} mg/kg/day and listed the RfC for HCN as 3×10^{-3} mg/m³. ATSDR also listed an RfD of 5×10^{-3} , but the source of this value is not given.

Qualitatively methylene bis(thiocyanate) and cyanide have similar toxicity. However, quantitatively their toxicity appears to be different.

2. Toxicological Endpoints for Risk Assessment

a. Reference Dose (RfD)

The Agency's OPP/RfD Peer Review Committee established the RfD for methylene bis(thiocyanate) at 0.005 mg/kg/day. An uncertainty factor (UF) of 100 was used. The NOEL from the chronic toxicity study in dogs is 0.5 mg/kg/day. The effects at the LOEL of 2 mg/kg/day are marginal changes in blood chemistry and pathology changes in the stomach and bone marrow. Although no dietary exposure is expected from the current non-food use pattern, the RfD is presented in the event that some future use results in the need to evaluate oral exposure.

b. Carcinogenic Classification

On February 2, 1996, the OPPRfD/Peer Review Committee determined that methylene bis(thiocyanate) should be classified as a "Group D", not classifiable as to human carcinogenicity. This is based on questionable increases in male rat adrenal pheochromocytomas and male mouse alveolar/bronchiolar tumors.

c. Other Toxicological Endpoints

The Agency's OPP Toxicology Endpoint Selection (TES) Committee considered the toxicity data available for this chemical at a meeting held on February 6, 1996. Based upon a review of the toxicology database for methylene bis(thiocyanate), toxicology endpoints and dose levels of concern have been identified for use in occupational and residential risk characterization; they are listed in Table 2.

TABLE 2. Summary of Toxicological Endpoints for methylene bis(thiocyanate).

EXPOSURE DURATION	EXPOSURE ROUTE	NOEL AND ENDPOINT
Short/Intermediate-Term (1 to 21 days) Occupational/Residential	DERMAL	60 mg/kg/day (systemic NOEL from the 21-day dermal rat study; HTD; no systemic effects at the highest tested dose) MRID 41111901
Chronic Exposure Occupational/Residential (greater than 21 days)	DERMAL	0.5 mg/kg/day (chronic oral NOEL from the one-year dog study for marginal changes in blood chemistry and pathology findings in the stomach and bone marrow seen at the LOEL of 2 mg/kg/day); assume 5% dermal absorption. MRID 41463201

3. Dietary Exposure and Risk Assessment/Characterization

There are currently no registered food-uses of methylene bis(thiocyanate); therefore, a dietary exposure and risk assessment/characterization is not required.

4. Toxicological Endpoints for Risk Assessment

a. Occupational and Residential Exposure

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

The first toxicological criteria which triggered the Agency's concern for occupational or residential inhalation exposure was the acute inhalation toxicity study (MRID 41201601) which identified high toxicity (mortality) of this chemical via the inhalation route of exposure. The only available information on inhalation toxicity is the acute inhalation study which is of poor quality and would usually be unacceptable. In addition, data are not readily available to further characterize the hazard due to inhalation exposure of methylene bis(thiocyanate).

A second toxicological criteria which triggered the Agency's concern for short- and intermediate-term occupational or residential exposure (1 to 7 days; 1 week to 21 days, respectively) was the dose related signs of dermal irritation. The dermal LOEL in the three-week subchronic dermal toxicity study is 10 mg/kg/day based on skin irritation. The dermal NOEL is less than 10 mg/kg/day. But the systemic NOEL of greater than or equal to 60 mg/kg/day will be used for risk assessment purposes. This value is supported by using the 3 mg/kg/day from the rat developmental study as a short-term NOEL with a dermal absorption of 5%. The 21-day endpoint is considered appropriate since there was no evidence of systemic toxicity at the highest dose. It cannot be determined whether the toxicity observed in longer oral studies would occur following dermal exposure of greater duration than 21 days. The toxicity has been observed to be cumulative with repeated oral exposure.

Lastly, the toxicological criteria which triggered the Agency's concern for chronic occupational or residential exposure (greater than 21 days) was the chronic one-year oral study in the dog (MRID 41463201) described in a previous section of this RED. The LOEL is 2.0 mg/kg/day based on the marginal changes in blood chemistry and pathology findings in the stomach and bone marrow. These effects observed at the LOEL are consistent with local gastric irritation and cyanide toxicity which include mild inflammation in the lamina propria of the stomach, increased hematopoiesis of the bone marrow, decreased albumin, total protein and

albumin/globulin ratio. The NOEL was 0.5 mg/kg/day. This endpoint is considered appropriate for exposures greater than 21 days.

In addition, the Agency has determined that there is a potential for exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with methylene bis(thiocyanate) and from use in commercial, industrial, and residential settings. The following levels of handler exposures have been identified:

Primary Occupational Handlers

- (1) mixing/loading the SC/L formulation using the open-pour technique;
- (2) mixing/loading the SC/L formulation using the pump-meter or automatic-dispensing technique;
- (3) applying the SC/L formulation using a dip-tank, including removing materials (such as leather) from treatment solutions;
- (4) applying the SC/L formulation as a spray;
- (5) applying the ready-to-use (RTU) liquid formulation as a spray;
- (6) applying the RTU liquid formulation with a brush;
- (7) applying the RTU liquid formulation with a roller; and
- (8) mixing/loading the SC/S formulation (crystalline/pellets) using the open-pour technique.

Secondary Occupational Handlers

- (1) exposures while handling methylene bis(thiocyanate)-containing paint;
- (2) exposures while handling methylene bis(thiocyanate)-containing adhesives;
- (3) exposures while handling methylene bis(thiocyanate)-containing water repellent for wood or forestry products; and
- (4) exposures while handling methylene bis(thiocyanate)-containing metalworking cutting fluids.

Homeowner Handlers

- (1) exposures while handling methylene bis(thiocyanate)-containing liquid RTU products for wood treatment;
- (2) exposures while handling methylene bis(thiocyanate)-containing paint; and
- (3) exposures while handling methylene bis(thiocyanate)-containing adhesives.

All handler use patterns were assessed for dermal exposure only. Although a potential inhalation hazard based on the high toxicity (mortality)

of this chemical by the inhalation route has been identified, no data are available to quantitatively assess inhalation toxicity or exposure. Therefore, the 90-day inhalation study is required and upon receipt, review and acceptance of that data, an inhalation risk assessment will be conducted.

The Agency has also determined two levels of potential exposure concerns relating to post-application exposure to methylene bis(thiocyanate) following applications in commercial, industrial, and residential settings (e.g., dermal from mist, steams and inhalation). They are:

Primary Occupational Post-Application Exposure

- (1) exposures following applications of methylene bis(thiocyanate) to open vats of liquids, such as paper-pulp, adhesives, coating, emulsions, and paints;
- (2) exposures during and immediately after indoor spray applications to seasoned and unseasoned wood; and
- (3) exposures to persons maintaining equipment, such as water systems and other industrial equipment, which contains product treated with methylene bis(thiocyanate).

Secondary Occupational Post-Application Exposure

- (1) exposures to persons occupying areas recently painted with methylene bis(thiocyanate)-containing paint and wood-treatment products;
- (2) exposures in areas where methylene bis(thiocyanate)-containing paper products are being manufactured;
- (3) exposures to methylene bis(thiocyanate)-treated wood products; and
- (4) exposures to methylene bis(thiocyanate)-treated leather.

Secondary Homeowner Post-Application Exposure

- (1) exposures while occupying areas recently painted with RTU methylene bis(thiocyanate) wood treatment products;
- (2) exposures while occupying areas recently painted with methylene bis(thiocyanate)-containing paint and wood treatment products;
- (3) exposures while occupying areas where methylene bis(thiocyanate)-containing adhesives have been used;
- (4) exposures to methylene bis(thiocyanate)-treated wood products (indoor furniture, and picnic tables/deck); and
- (5) exposures to methylene bis(thiocyanate)-treated leather products.

Table 3 below provides some examples of primary and secondary exposures in occupational and residential settings and Table 4 provides exposure estimates for use of methylene bis(thiocyanate) in various industrial/residential settings.

Therefore, because the toxicological criteria have been triggered and potential exposure to handlers during use or to persons entering treated sites after application exists, short-term, intermediate-term and chronic risk assessments are required.

Table 3. Examples of Primary and Secondary Exposures in Occupational and Residential Settings.

Type of Exposure		Occupational Settings Examples	Residential Settings Examples
Handler Exposure	Primary	Adding methylene bis(thiocyanate) to a vat of liquid (paint or water repellent for wood/forestry products)	Exposure to homeowner applying a methylene bis(thiocyanate)-containing RTU product to wood or wood structures (decking treatment)
	Secondary	Handling methylene bis(thiocyanate)-containing paint or wood treatment products	Exposure to homeowner using methylene bis(thiocyanate)-containing paint
Post-application Exposure	Primary	Standing near a vat where methylene bis(thiocyanate) was added or in an area where seasoned and unseasoned wood was treated	Exposure to homeowner applying a methylene bis(thiocyanate)-containing RTU product to wood or wood structures (decking treatment)
	Secondary	Being in a room recently painted with methylene bis(thiocyanate)-containing paint or with a wood treatment product	Being in a room recently painted with methylene bis(thiocyanate)-containing paint or with a wood treatment product

Table 4. Exposure Estimates/Assumptions of Methylene bis(thiocyanate) for Liquid Concentrates and Ready-To-Use Applications

Setting*	Pounds ai used
Oil well injection fluid*	Assumes 1000 barrels (42,000 gallons) treated per day and 75 pounds of product (BETZ ENCHEM 41-J2, EPA Reg. 48525-2, with 10% active ingredient) is used per 42,000 gallons of injection fluid. The total active ingredient handled per day is 7.5 pounds.
Cooling systems*	Assumes 20,000 gallons (4000 gallons for smaller systems) of water are treated per day and 14.8 fluid ounces of end-use product (M-202, EPA Reg. 1448-148 with 10% active ingredient — equal to 14.8 fl. oz/128 fl.oz per gal. x 9 pounds/gal. x 0.1 = 0.11 pounds of active ingredient) equaling 0.11 pounds of active ingredient is used per 1000 gallons of water. The total active ingredient handled per day is 2.2 pounds (0.44 pounds for smaller systems).
Paint manufacturing*	Assumes 300 gallons (2,700 pounds) of paint are treated per day and one pound of end-use product (Slime-trol RX-31, EPA Reg. 45017-28 with 5% active ingredient) equaling 0.5 pounds active ingredient is used per 1000 pounds of paint (1000 ppm). The total active ingredient handled per day is 0.14 pounds.
Metalworking cutting fluid*	Assumes 300 gallons of metalworking cutting fluid are treated per day and 0.4 gallons (0.4 gal. x 9.2 lbs/gal = 3.68 pounds) of end-use product (AMA-10W, EPA Reg. 9386-31 with 10% active ingredient) equaling 0.37 pounds active ingredient is used per 1000 gallons of metalworking cutting fluid. The total active ingredient handled per day is 0.11 pounds.
Pulp and paper mills*	Assumes 100 tons of pulp are treated per day and one pound of end-use product (Nalcon 7620-WB with 10% active ingredient) equaling 0.1 pounds active ingredient is added per ton of pulp. The total active ingredient handled per day is 10 pounds.
Oil drilling/mud fluids	Assumes 1,000 barrels of mud fluids are treated per day and 500 pounds of end-use product (Enchem 41-J5, EPA Reg. 48525-10 with 5% active ingredient) equaling 25 pounds of active ingredient is added per 1,000 barrel of mud fluids. The total active ingredient handled per day is 25 pounds.
Wood pressure treatment with dipping* and/or spray application method, and wood protection treatment to forest products.	the Agency has no data at this time.
Process preservative uses*	Assumes a total of 10,000 pounds of slurry are treated per day and 10 pounds of the end-use product (Betx Slime-trol RX-32P EPA Reg. 45017-19 with 7% active ingredient) equaling 0.7 pounds (1,000 ppm by weight) of active ingredient is added per 10,000 pounds of slurry. The total active ingredient handled per day is 0.7 pounds.
Uses in leather processing liquors, * leather processing, and leather products	The Agency has no data at this time.
Painting with a brush*	Assumes that an occupational painter uses five gallons of paint per day and a homeowner uses one gallon of paint per day, that each gallon contains 0.5 percent of active ingredient, and that one gallon of paint weighs 10 pounds. The total active ingredient handled per day is 0.25 pounds for occupational painters and 0.05 pounds for homeowner painters.
Painting with an airless sprayer (siphon* sprayer with 5 hp gasoline-powered engine; spray nozzle is attached to a hose)	Assumes that an occupational painter uses fifty gallons of paint per day and a homeowner users five gallons per day, that each gallon contains 0.5 percent active ingredient, and that one gallon of paint weighs approximately 10 pounds. The total active ingredient handled per day is 2.5 pounds for occupational painters and 0.25 pounds for homeowner painters.
Painting with a roller*	The Agency has no data at this time.

* The Agency assumes that the scenarios designated above represent exposures to mixers, loaders, and applicators handling methylene bis(thiocyanate) which are reasonably worst-case.

b. Occupational and Residential Risk Assessment and Characterization

Short-term, intermediate-term, and chronic risk assessments are required for exposure to methylene bis(thiocyanate). The Agency typically considers the exposure to primary occupational handlers in settings such as pulp and papermill, oil well injection fluid, metalworking cutting fluid, and water cooling systems to be short- to intermediate-term exposures. Commercial painters and general preservative uses (worst case, paint manufacturing) would typically be subject to chronic exposures. Homeowner handlers are assumed to be exposed less than 7 days per year.

In the case of methylene bis(thiocyanate), risk assessments for short/intermediate term exposure durations up to 21 days have been conducted for the homeowner handler using the NOEL of 60 mg/kg/day based on a 21-day dermal study. Methylene bis(thiocyanate) risk assessments for chronic exposure durations greater than 21 days have been conducted for the occupational handler in industrial settings using the NOEL of 0.5 mg/kg/day based on a one-year oral study. Exposure durations of 0-21 days and > 21 days have typically not been used by the Agency to define short/intermediate and chronic exposure scenarios. However, in the case of methylene bis(thiocyanate), toxicity data indicate that exposure to methylene bis(thiocyanate) for 21 days or longer may produce the same toxic effects seen in the chronic oral study. This partition of exposure durations most accurately reflects the toxic effects likely to be caused by use of this pesticide, therefore, the NOEL for the chronic study is used for exposures > 21 days. The actual daily exposure (ADE) for chronic exposures has been adjusted for 5% dermal absorption to account for route-to-route extrapolation. A MOE of 100 serves as a reference point for occupational/residential exposures.

(1) Risk from Dermal Exposures to methylene bis(thiocyanate)

Short/intermediate-term and chronic toxicity endpoints related to dermal exposures to methylene bis(thiocyanate) have been identified. An MOE of greater than 100 for methylene bis(thiocyanate) is considered to indicate no risk concern. The risk assessment for dermal exposures is calculated as follows:

$$\begin{aligned} & \text{Amount Daily Dermal Exposure (mg/day)} \\ & = \text{unit exposure (UE) (mg/lb ai) X daily use (lb ai/day)} \end{aligned}$$

$$\begin{aligned} & \text{Actual Daily Exposure (ADE) (mg/kg/day)} \\ & = \text{Amount Exposed (mg/day) } \div \text{ body weight (kg)} \end{aligned}$$

$$MOE = \frac{NOEL(mg/kg/day)}{ADEmg/kg/day}$$

Tables 5 and 6 contain the calculations of exposure and risk for both primary and secondary handler dermal exposures.

Table 5. Short/Intermediate (up to 21 days) Exposure and Risk Assessment for methylene bis(thiocyanate) Application Scenarios.

Handlers	Setting	UE* mg/lb ai	Lb ai / used**	Amount Exposed mg/day***	Actual**** Daily Exposure (mg/kg/day)	MOE (NOEL= 60 mg/kg/day)
Primary and Secondary Handlers	Brush Painting	182	(H) 0.05	(H) 9	(H) 0.13	(H) 464
	Spray Painting (Airless/ compressed-air sprayer)	39	(H) 0.25	(H) 9.75	(H) 0.14	(H) 429
	Roller Painting	No Data	No Data	No Data	No Data	No Data

*UE = Unit Exposure: For brush painting, UE dermal exposure (without gloves) derived from PHED (V1.1 Data Validation, March 28, 1996) and is based on 15 replicates, acceptable grades, medium confidence for using brush as wood painting application. For airless spray painting, UE dermal exposure (without gloves) derived from PHED (V1.1) based on 15 replicates, acceptable grades, high confidence.

**Lb ai/used was derived from the pesticide product labels.

***Amount Exposed (mg/day) = (UE x lb ai/used)

****ADE = Actual Daily Exposure (dermal) = Amount Exposed / BW (70 kg) = mg/kg/day

(H) = Homeowner calculations assume 1 gal used for brush painting and 5 gal for airless sprayer painting, 10 lbs/gal of RTU wood preservative and 5,000 ppm ai.

MOE = NOEL/ADE NOEL for exposures up to 21 days is 60 mg/kg/day from a rat 21-day dermal study.

NOTE: Primary handler exposures may result from applications with RTU formulations (wood protection treatments) and secondary handler exposures may result from applications of paints containing methylene bis(thiocyanate) as a preservative.

Table 6. Exposure (greater than 21 days) and Risk Assessment for methylene bis(thiocyanate) Application Scenarios.

Handlers	Operation	Setting	UE* mg/lb ai	Lb ai / used**	Amount Exposed mg/day***	Actual**** Daily Exposure, ADE (mg/kg/day)	Adjusted ADE (mg/kg/day)with 5% dermal absorption	MOE (NOEL = 0.5 mg/ kg/day)
Primary Handlers	Open-pour Liquid	Oil Well Injection Fluid	0.14	7.5	1.05	0.015	7.5 X 10 ⁻⁴	667
	Open-pour Liquid	Cooling System	10.23	2.2	22.51	0.32	0.016	31
	Pump Liquid	Cooling System	0.09	2.2	0.2	0.003	1.4 x 10 ⁻⁴	3524
	Open-pour Liquid	Cooling System (small)	10.23	0.44	4.5	0.064	0.0032	155
	Open-pour Liquid	Paint Manufacturing	0.14	0.14	0.0196	0.00028	1.4 X 10 ⁻⁵	35,714
	Open-pour Liquid	Metal Fluid	0.133	0.11	0.0146	0.00021	1.0 X 10 ⁻⁵	47,847
	Pump Liquid	Pulp and Paper mill	0.0039	10	0.039	0.00056	2.8 X 10 ⁻⁵	17,949
	Open-pour Solid	Pulp and Paper mill	0.479	10	4.79	0.068	3.4 X 10 ⁻³	146
	Open-pour Solid	Process Preservative	0.479	0.7	0.34	0.0048	2.4 x 10 ⁻⁴	2088
	Open-pour Liquid	Drilling Mud	0.14	25	3.5	0.05	2.5 x 10 ⁻³	200
	Wood Treatment	Spray	No data	No data	No data	No data	No data	No data
	Wood Treatment	Dipping	No data	No data	No data	No data	No data	No data
	Spray Application (other than wood treatment)	Spray	No data	No data	No data	No data	No data	No data
	Dip Application (leather processing)	No Data	No data	No data	No data	No data	No data	No data
Primary and Secondary Handlers	Painting	Brush Painting*	182* (21)	(O) 0.25	(O) 45 (5.25)	(O) 0.64 (0.075)	0.032 (0.00375)	(O) 16 (133)
	Painting	Spray* (Airless/ compressed-air sprayer)	39* (8.7)	(O) 2.5	(O) 97.5 (21.75)	(O) 1.4 (0.31)	0.07 (0.016)	(O) 7.1 (31)
	Painting	Roller Painting	No data	No data	No data	No data	No data	No data

* UE = Unit Exposure (dermal + inhalation) was derived from the CMA antimicrobial exposure data base (open-pour and pump liquid with gloves). Although the unit exposure values from the CMA data base represent combined dermal and inhalation exposure, the inhalation contribution is low (typically below the limit of detection) and will therefore not significantly affect the estimated exposure values used in this dermal exposure assessment. However, because of the high inhalation toxicity, inhalation exposure and toxicity data are required to allow accurate assessment of inhalation risk concerns.

* UE for brush painting was derived from PHED (V1.1 as amended Data Validation, March 28, 1996) dermal exposure only (without gloves), based on 15 replicates, acceptable grades, medium confidence for using brush as wood painting application. For airless spray painting, UE derived from PHED (V 1.1) dermal exposure only (without gloves) based on 15 replicates, acceptable grades, high confidence and is equipped with gasoline-powered siphon/nozzle sprayer. **(Values in parentheses reflect maximum PPE; i.e., coveralls over a single layer clothing and chemical-resistant gloves.)**

** Lb ai/used was derived from the pesticide product labels. The occupational painter calculation assumes 5 gal used for brush painting and 50 gal used for airless spray painting, 10 lbs/gal of RTU wood preservative and 5,000ppm ai.

*** Amount Exposed (mg/day) = (UE x Lb ai/used)

**** ADE = Actual Daily Exposure (dermal + inhalation for all operations except painting) = Amount Exposed / BW (70 kg) = mg/kg/day.

MOE = NOEL/ADE: NOEL for exposures greater than 21 days is 0.5 mg/kg/day (oral) from chronic dog toxicity study; ADE adjusted for 5% dermal absorption.

NOTE: For painting operations, primary handler exposures may result from applications with RTU formulations and secondary handler exposures may result from applications of paints containing methylene bis(thiocyanate) as a preservative.

As can be seen in Table 5, non-occupational uses, the primary and secondary application (dermal exposure) MOEs for exposure durations up to 21 days are greater than 100 for all scenarios. As seen in Table 6, the Agency does have concern for the occupational painter where the MOEs (without gloves) are 16 using a brush and 7.1 using an airless sprayer. Workers applying ready to use products or liquids with a brush, roller or sprayer would have the same risks. Additional use information for these scenarios is necessary before risk mitigation or a determination of eligibility can be made.

Risk assessments were not conducted for use of methylene bis(thiocyanate) in wood products manufacturing settings, leather processing settings, or for paint application using air sprayer or roller apparatus due to lack of dermal exposure data for primary and secondary handlers. Exposure data are being required for these scenarios and additional risk mitigation measures and an eligibility decision will be made upon receipt and evaluation of the data.

The Agency is concerned about risks to the primary handler open-pouring liquid formulations for large water cooling systems (> 4000 gallons per day) uses since the MOE is 31(wearing gloves) for this application method (See Table 6). However, in large cooling system settings if a pump-metering system was used, it would significantly reduce the exposure and risk associated with use of methylene bis(thiocyanate) (MOE of 3524). Therefore, the Agency is requiring the use of a pump-metering system for all water cooling systems of > 4000 gallons per day. For smaller cooling systems (< 4000 gallons per day), the MOE of 155 is above the Agency's level of concern for exposures due to open pouring situations and is, therefore, acceptable without further mitigation.

(2) Risk from Inhalation Exposures to Methylene bis(thiocyanate)

At the present time, there is no inhalation toxicity endpoint other than an LC₅₀ value for acute inhalation toxicity. A hazard was identified by the TES Committee based on the high toxicity (mortality) of this chemical by this route of exposure. However, the study would usually not be acceptable for regulatory purposes because (1) there were extreme differences in chamber concentration for measurements made at intervals for each and all exposures; (2) the mass median diameters of the particles were too large; (3) the relative humidity was too high suggesting that the airflow may have been inadequate; (4) the difference between the nominal and analytical values were 5000 fold; and (5) since this was whole body exposure, there could have been considerable oral exposure. An additional study was not required following review of this study (MRID 41201601)

because for labeling purposes, methylene bis(thiocyanate) was classified as Toxicity Category I (the highest toxicity category). This study is not useful in the characterization of short and intermediate term risk assessment. The Agency is requiring a 90-day study to characterize inhalation toxicity and to determine any potential inhalation risk from methylene bis(thiocyanate).

(3) Risk from Exposures to Methylene bis(thiocyanate) Degradates

The formation of additional degradates of methylene bis(thiocyanate), specifically formaldehyde and cyanide, is theoretically possible. Hydrolysis studies indicate that methylene bis(thiocyanate) degrades to thiocyanate ion, formic acid, and mercapto- (methylenethio cyanate) at various rates depending on the pH of the medium. The more alkaline the medium, the faster the degradation occurs. It is possible that the thiocyanate ion would degrade to cyanide, but degradation data are lacking that would indicate whether this occurs in the working environment and, if so, under what conditions. The Agency is concerned about the potential inhalation hazards from exposure to these degradates in occupational and residential settings. The Agency has no data upon which to conduct a risk assessment for primary and secondary handlers potentially exposed to methylene bis(thiocyanate) degradates. Additional exposure data are being required which may confirm the registrant's statements that there are no exposures to degradates of methylene bis(thiocyanate) as a result of the registered uses. In addition, if the required air monitoring data indicate the presence of cyanide and formaldehyde, inhalation toxicity data on cyanide and formaldehyde may be required as appropriate. If adequate data are available, this may be referenced. Otherwise, new study data are required.

Many of the occupational handler exposures of concern are in industrial or manufacturing settings, which are under the OSHA's purview. The Agency will inform OSHA about our concerns for occupational handler exposure and formaldehyde and cyanide formation in workplace settings where methylene bis(thiocyanate) is used. In addition, the Agency is requiring air monitoring studies for paint manufacturing uses and painter uses.

(4) Risk From Post-Application Exposures

The Agency is concerned about potential post-application exposures to methylene bis(thiocyanate) and its degradates in occupational and residential settings. The registrant indicates that the half-life of methylene bis(thiocyanate) is very short and should not be a post-application concern, since most use sites would by nature be alkaline and promote faster

degradation of the parent. However, the degradates are also a toxicity concern. The Agency is particularly concerned about potential primary and secondary post-application inhalation exposures to methylene bis(thiocyanate) degradates in indoor settings. There are no data upon which to conduct a risk assessment for post-application exposures to methylene bis(thiocyanate) or its degradates. Post-application dermal and inhalation exposure data are being required which may confirm the registrant's statements that there are no post-application exposures to methylene bis(thiocyanate) or its degradates.

Most of the occupational post-application exposures of concern are in industrial or manufacturing settings, which are under OSHA's purview. Following review of additional data/information the Agency will inform OSHA about any remaining concerns for potential occupational handler exposure and formaldehyde and/or cyanide formation in workplace settings where methylene bis(thiocyanate) is used. In addition, air monitoring studies for certain uses are being required (See Section V). If adequate data are available, this may be referenced. Otherwise, new study data are required.

(5) Incident Reports

Two incidents were reported to the Office of Pesticide Programs Incident Data System as of February 5, 1996. The first involved a man who was exposed to the chemical while dipping lumber. He developed swollen eyes, a rash on his cheeks and insomnia. An update to this case reported that the man was diagnosed with lupus erythematosus which the physician said had no probable relationship to the pesticide. In the second incident, a man was exposed to a multiple active ingredient formulation containing 10% ai methylene bis(thiocyanate) through a leaking line. He developed a rash on his arm, shortness of breath and a cough but recovered within 24 hours.

5. Other Considerations

The Food Quality Protection Act of 1996 amends both the FFDCA and FIFRA by setting a new safety standard for the establishment of tolerances. In determining whether or not a tolerance meets the new safety standard, FQPA directs EPA to consider information concerning the susceptibility of infants and children to pesticide residues in food; the potential for aggregate exposure from dietary as well as non-occupational sources, such as pesticide uses in and around the home; and the potential for cumulative effects from a pesticide and other substances that have a common mechanism of toxicity.

Because methylene bis(thiocyanate) has no food uses, and therefore no tolerances have been established, the specific considerations outlined in FQPA are not required for this chemical. Nevertheless, EPA believes that consideration of available data relating to the special sensitivity of infants and children, the potential for aggregate exposures and cumulative effects is prudent for methylene bis(thiocyanate).

Potential Risks to Infants and Children

In determining whether or not an additional uncertainty factor is appropriate for assessing risks to infants and children, EPA takes into account the completeness and reliability of the toxicity data base, the nature and severity of the effects observed in pre- and post-natal studies, and other information such as epidemiological data.

Based on current data requirements, only one developmental study is usually required for non-food use chemicals. However, for the purposes of assessing the pre-and post-natal toxicity of methylene bis(thiocyanate), two developmental and one reproduction study were available and have been evaluated by EPA. The effects observed in the methylene bis(thiocyanate) developmental and reproduction studies can be summarized as follows:

In a rat developmental toxicity study, pregnant CrI: CD BR rats were dosed with 0, 1, 3, or 6 mg/kg/day of methylene bis(thiocyanate) on days 6 through 15 of gestation. Methylene bis(thiocyanate) had no effect on any of the developmental toxicity parameters examined. No embryo toxicity, fetotoxicity, or indication of teratogenic effects were noted in the study. The developmental NOEL and LOEL were greater than 6 mg/kg/day, the highest dose tested. The maternal LOEL was 6 mg/kg/day based on a slight decrease in maternal body weight gain and a small increase in the incidence of resorptions. The maternal NOEL was 3 mg/kg/day.

In a rabbit developmental toxicity study, Hra:(NZW)SPF rabbits were dosed with 0, 1, 3, or 5(7) mg/kg/day by stomach tube. (The high dose was reduced from 7 to 5 mg/kg/day after day 5 due to excess mortality.) Methylene bis(thiocyanate) had no effect on any of the developmental toxicity parameters examined. No embryo toxicity, fetotoxicity, or indication of teratogenic effects were noted in the study. The developmental NOEL for methylene bis(thiocyanate) in rabbits was 5 mg/kg/day, and the developmental LOEL was greater than 5 mg/kg/day. The LOEL for maternal toxicity was 5 mg/kg/day based on mortality and decreased body weight gain. The NOEL was 3 mg/kg/day for maternal toxicity.

In a reproductive toxicity study in SD (CD) rats, the NOEL for parental systemic effects was 1.0 mg/kg/day and the LOEL was 2.5 mg/kg/day (mid - dose), based on one F₁ (female) mortality associated with necropsy findings of cecum distention with gas. Methylene bis(thiocyanate) at 1-4 mg/kg/day did not adversely affect body weight, body weight gain, feed consumption, or any reproductive parameter (precoital interval, oestrus state, male/female fertility indexes, duration of gestation, gestation index, number of implants/pregnancy, number of pups born dead or alive per dam) in either the F₀ or F₁ parental groups. Methylene bis(thiocyanate) at 1-4 mg/kg/day did not adversely affect any of the litter parameters (number of live pups/litter at lactation day 0, 4, 14, or 21, birth, live birth, viability, lactation, and overall survival indexes, male/female pup body weight, and litter weight during the entire lactation period) in either the F₁ or F₂ litter groups. The LOEL for reproductive effects was greater than 4 mg/kg/day; the NOEL was 4.0 mg/kg/day (high dose).

The developmental data for methylene bis(thiocyanate) indicate developmental effects did not occur at any dose in the above studies, including doses which resulted in maternal toxicity. The Agency would generally be concerned when developmental/reproductive effects are seen at doses lower than those which cause maternal effects. The developmental and reproductive toxicity data do not indicate any additional sensitivity of young organisms to methylene bis(thiocyanate). Therefore, the Agency concludes that an additional uncertainty factor is not warranted for methylene bis(thiocyanate) risk assessments at this time.

Aggregate Exposure

In examining aggregate exposure, EPA takes into account available information concerning exposures from the pesticide residue in food and other exposures for which there is reliable information. These other sources of exposure can include drinking water, and non-occupational exposures, e.g., to pesticides used in and around the home.

There are no food uses for methylene bis(thiocyanate), therefore, exposure to methylene bis(thiocyanate) in the diet is not expected. Laboratory data indicate that methylene bis(thiocyanate) degrades quickly and would not be persistent if it reached the environment. Methylene bis(thiocyanate) has a very low potential to leach into groundwater or to run off into surface water under typical use conditions.

Therefore, residential uses are the only sources of exposure which could be aggregated for methylene bis(thiocyanate). The Agency has identified several potential exposure scenarios for residential uses including mixing, handling and applying ready to use products for wood treatment and handling and applying paints: persons reentering areas recently treated

with products containing methylene bis(thiocyanate); and exposures to methylene bis(thiocyanate) treated wood. However, based on the high dermal exposure MOEs for homeowner applications (See Table 5), the Agency believes that the aggregate exposures to methylene bis(thiocyanate) for applicators in the home are not likely to be of concern.

However, the Agency does not have chemical specific post-application data to quantitatively determine the amount of pesticide to which a person re-entering a treated area would be exposed to nor chemical specific exposure data for persons applying methylene bis(thiocyanate) containing products, and has required data on these exposures.

Cumulative Effects

Consideration has been given to cumulative effects of methylene bis(thiocyanate) and other substances that have a common mode of toxicity. However, the Agency has not made a determination whether methylene bis(thiocyanate) and any other pesticide have a common mode of toxicity and require cumulative risk assessment. For the purposes of this Reregistration Eligibility Decision document, the Agency has considered only risks from methylene bis(thiocyanate). If required, cumulative risks will be assessed when methodologies for determining common mode of toxicity and for performing cumulative risk assessment are finalized.

C. Environmental Assessment

The Agency has adequate data to assess the environmental fate of methylene bis(thiocyanate) and the ecological hazard of methylene bis(thiocyanate) to nontarget terrestrial and aquatic organisms for the uses specified in the RED.

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

An oral (LD₅₀) study (preferably mallard or bobwhite quail) and two subacute dietary (LC₅₀) studies (one species of waterfowl, preferably the mallard duck and one species of upland game bird, preferably bobwhite quail) are required to establish the toxicity of a pesticide to birds. The results reported in Tables 7 and 8 indicate that methylene bis(thiocyanate) is moderately toxic to avian species on an acute oral basis and practically nontoxic to avian species on

a subacute dietary basis. The guideline requirements are fulfilled. (MRIDs 150231, 150232, and 150233)

Table 7: Avian Acute Oral Toxicity Findings.

Species	% A.I.	LD ₅₀ (ppm)	MRID	Toxicity Category
Northern Bobwhite Quail	99.0	50	150232	moderately toxic
Mallard Duck	99.4	45-68 (male-female, respectively)	150231	moderately toxic

Table 8: Avian Subacute Dietary Toxicity Findings.

Species	% A.I.	LC ₅₀ (ppm)	MRID	Toxicity Category
Northern Bobwhite Quail	99.4	> 5000	150233	practically nontoxic
Mallard Duck	99.4	> 5000	150232	practically nontoxic

(2) Mammals

Wild mammal testing is required on a case-by-case basis depending on the results of the lower tier studies, such as acute and subacute testing, intended use pattern and pertinent environmental fate characteristics. In most cases, a rat acute oral LD₅₀ obtained from the Agency's Health Effects Division (HED) Tox Oneliners is used as a surrogate for mammalian acute toxicity. This LD₅₀ reported in Table 9 below indicate that methylene bis(thiocyanate) is moderately toxic to small mammals on an acute oral basis.

Table 9: Mammalian Acute Oral Toxicity Findings.

Species	% A.I.	LD ₅₀ (mg/kg)	MRID.	Toxicity Category
Rat (small-mammal surrogate)	98	male 84.9 female 68.3	41592901	III

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

Two freshwater fish toxicity studies using the technical grade of the active ingredient are required to establish the toxicity of a pesticide to freshwater fish. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warm water species (preferably the bluegill sunfish). The results reported in Table 10 indicate that methylene bis(thiocyanate) is very highly toxic to rainbow trout and highly toxic to bluegill sunfish on an acute basis. The guideline requirement is fulfilled. (MRIDs 40518608 and 40518609)

Table 10: Freshwater Fish Acute Toxicity Findings.

Species	% A.I.	LC ₅₀ (ppm)	MRID	Toxicity Category
Rainbow trout	100.0	0.089	40518609	very highly toxic
Bluegill sunfish	100.0	0.25	40518608	highly toxic

(2) Freshwater Invertebrates

A freshwater aquatic invertebrate toxicity test using the technical grade of the active ingredient is required to assess the toxicity of a pesticide to freshwater invertebrates. The preferred test organism is *Daphnia magna*, but early instar amphipods, stoneflies, mayflies, or midges may also be used. The results reported in Table 11 indicate that methylene bis(thiocyanate) is very highly toxic to aquatic invertebrates on an acute basis. The guideline requirement is fulfilled. (MRID 40518601)

Table 11: Freshwater Invertebrate Toxicity Findings

Species	% A.I.	LC ₅₀ (ppm)	MRID No. Author/Year	Toxicity Category
Daphnid <i>Daphnia magna</i>	100.0	0.061 (0.036-0.10)	40518601	very highly toxic

(3) Freshwater Invertebrates, Chronic

Chronic freshwater invertebrate data are not required for methylene bis(thiocyanate). However, data were submitted, and the results are reported in Table 12. Results indicate a NOEC of 5.8 ppb. The LOEC is 16 ppb. The geometric mean (MATC) is 9.6 ppb which is the estimated low effect level. The effect observed was to the growth and reproductive processes of *Daphnia magna*. This study is acceptable for the guideline requirement. (MRID 42517001)

Table 12: Aquatic Invertebrate Life-Cycle Toxicity Findings

Species	% A.I.	NOEC (ppb)*	MATC (ppb)*	MRID	Endpoints Affected
Daphnid <i>Daphnia magna</i>	99.2	5.8/16.0	9.6 (mean)	42517001	reproductive and growth processes

* Measured in parts per billion.

(4) Estuarine and Marine Animals

Data from acute toxicity testing with estuarine and marine organisms (fish, shrimp and oyster embryo-larvae or shell deposition) using the technical grade of the active ingredient are

reported in Table 13. The results indicate that methylene bis(thiocyanate) is very highly toxic to eastern oyster and mysid shrimp, and highly toxic to sheepshead minnow on an acute basis. The guideline requirement is fulfilled. (MRIDs 42541601, 42513401, and 42513402)

Table 13: Estuarine/Marine Acute Toxicity Findings

Species	% A.I.	LC ₅₀ /EC ₅₀ (ppb)*	MRID	Toxicity Category
Eastern oyster (shell deposition or embryo-larvae)	99.2	EC ₅₀ = 3.0 (2.75-3.37)	42541601	very highly toxic
Mysid shrimp	99.2	LC ₅₀ = 36	42513401	very highly toxic
Sheepshead minnow	99.2	LC ₅₀ = 606 (529-719)	42513402	highly toxic

* Measured in parts per billion.

2. Environmental Fate

a. Environmental Fate Assessment

Data on hydrolysis and aqueous availability were submitted for methylene bis(thiocyanate). The registrant also submitted soil photolysis, aerobic soil metabolism, anaerobic aquatic metabolism, aerobic aquatic metabolism, however, these studies are not required for the current use patterns and did not meet acceptable guideline requirements, so they were not included in this document. No additional data are required at this time.

Methylene bis(thiocyanate) is susceptible to hydrolysis at higher pHs, but stable at lower pH's. The major hydrolysate observed is the thiocyanate ion (SCN⁻). Laboratory experiments conducted to assess the potential for leaching from wood show extensive leaching after a period of 30 days. Photolysis of methylene bis(thiocyanate) on wood surfaces is unlikely to occur.

At approximately 28 ppm, ¹⁴C-methylene bis(thiocyanate) (material radiolabeled in the methylene and thiocyanate carbons) hydrolyzed with registrant calculated half-lives of 6.18 days at pH 7 and 2.22 hours at pH 9. Methylene bis(thiocyanate) was stable at pH 5 after 30 days of incubation.

The major methylene bis(thiocyanate) hydrolysate observed was the thiocyanate ion (SCN⁻), which seems to be persistent once it is formed. Other hydrolysates observed are formic acid, CO₂, mostly present as the carbonate ion (CO₃²⁻), and mercaptomethylenethiocyanate (NC-SCH₂-SH). These hydrolysates were present at ≤26.1% of the Total Test Substance

(TTS). The percent TTS, is the observed degradate level (in percent initial radioactivity) following corrections and normalization for the presence of radioactive material labeled in the methylene and thiocyanate positions.

A significant amount of radioactivity leached from wood pieces treated with radiolabeled methylene bis(thiocyanate). The drying period appears to be the factor that most affects the potential for leaching. Generally, for the samples dried for 30 minutes, the majority ($\geq 70\%$) of the material leached within the first 3 days. For the samples dried for 21 days, the majority ($\geq 70\%$) of the material leached within the first 7 days. Bound residues (residues not readily extractable) were slightly greater for the wood samples dried for 21 days. Generally, leaching was slightly faster for samples leached in pH 7 and 9 buffered solutions and in synthetic seawater, compared to the samples leached in distilled water and pH 5 buffered solutions.

In the leaching studies, the degradates profile is similar to the one observed in the hydrolysis study. Methylene bis(thiocyanate) appeared to be stable in pH 5 buffer and distilled water. In the pH 7 and synthetic seawater, thiocyanate (SCN^-) and carbonate (CO_3^{2-}) were observed in small quantities. At pH 9, methylene bis(thiocyanate) was hydrolyzed to thiocyanate and carbonate.

[^{14}C]Methylene bis(thiocyanate) was relatively stable both on pine and oak wood surfaces irradiated with artificial light (xenon arc lamp). In the pine and oak woods, the photo degradation half-lives were in excess of 48 days.

For the outdoor wood preservative use of methylene bis(thiocyanate), the potential of environmental exposure of the chemical under actual use conditions is small. The chemical hydrolyses quickly at neutral and alkaline pHs. Also, the Agency believes that the extensive leaching observed in the laboratory study is probably not characteristic of the end-use (formulated) products of methylene bis(thiocyanate). The end-use products are applied with a sealant/water repellent. This probably inhibits the leaching process. Additionally, most of the applications are residential, which involves little environmental exposure.

Therefore, methylene bis(thiocyanate) degrades quickly and would not be persistent if it reached the environment. Methylene bis(thiocyanate) has a very low potential to leach into groundwater or to run off into surface water under typical use conditions.

b. Environmental Fate, Chemistry and Transport

(1) Hydrolysis

[¹⁴C]methylene bis(thiocyanate) material radiolabeled in the methylene and the thiocyanate positions, at approximately 28 ppm, hydrolyzed with registrant calculated half-lives of 6.18 days at pH 7 and 2.22 hours at pH 9. Methylene bis(thiocyanate) was stable at pH 5 after 30 days of incubation.

The major methylene bis(thiocyanate) hydrolysate observed was the thiocyanate ion (SCN⁻), which was a maximum of 52.4% TTS after 30 days in the pH 7 solution, and reached 50.1% TTS after 24 hours in the pH 9 solution, with little change thereafter.

The hydrolysate formic acid steadily increases at pH 7 to a maximum of 16.4% TTS at 30 days. In the pH 9 solution, it reaches a maximum of 26.1% TTS after 720 hours (last test interval).

CO₂ was observed mostly as the carbonate ion in solution (CO₃²⁻) and as volatiles (about 80% of the amount trapped in the NaOH traps). The carbonate ion was a maximum of 5.9% TTS at 14 days at pH 7, and 15.1% TTS at 24 hours at pH 9.

Unknown No. 1, whose proposed structure based on spectral data is mercaptomethylenethiocyanate (NC-SCH₂-SH), was a maximum of 20.1% TTS at 30 days in the pH 7 solution and 12.7% TTS at 24 hours in the pH 9 solution. This study is acceptable and satisfies the hydrolysis data requirement. No additional data are required. (MRID 43092101)

(2) Aqueous Availability Degradation

Leaching from Wood. Methylene bis(thiocyanate) was applied to dried wood pieces of constant weight (within ±1.0 g) by submersion with periodic agitation for 30 minutes into an aqueous solution of active ingredient at 1000 and 2000 ppm. The wood samples were then dried for 30 minutes at room temperature or 21 days at 25±1.0°C and 50% relative humidity (RH). The wood samples were leached in distilled water, pH 5, 7, and 9 buffered aqueous solutions, and synthetic seawater for up to 30 days at 25±1.0°C in sealed containers.

A significant amount of radioactivity leached from the wood pieces. Radiolabelled [^{14}C] material found in the leachates 30 days after treatment averaged 91.1% for the samples that were dried for 30 minutes, and 85.6% for the samples that were dried for 21 days. For the samples dried for 30 minutes, the majority ($\geq 70\%$) of the material leached within the first 3 days. For the samples dried for 21 days, the majority ($\geq 70\%$) of the material leached within the first 7 days. More than 50% of the initial radioactivity was leached within one day from all the samples dried for 30 minutes. For the samples dried for 21 days, 50% of the initial radioactivity leached within the first 3 days of incubation. Bound residues were slightly greater for the wood samples dried for 21 days.

Methylene bis(thiocyanate) appeared to be stable in pH 5 buffer and distilled water. In the pH 7 and synthetic seawater, thiocyanate (SCN^-) and carbonate (CO_3^{2-}) were observed in small quantities. At pH 9, the methylene bis(thiocyanate) was degraded to thiocyanate and carbonate, and there was an unknown (7.2-9.9%) that was speculated to be $\text{NCS-CH}_2\text{-SH}$, based on the results of the hydrolysis study. This study satisfies the leaching from wood data guideline. No additional data are required. (MRID# 43545601)

Photolysis on Wood. [^{14}C]Methylene bis(thiocyanate) was relatively stable on wood surfaces irradiated with artificial light (xenon arc lamp) for 360 hours (12 hours of exposure per day). In the pine wood, the normalized concentration of methylene bis(thiocyanate) decreased with an estimated half-life of 734 hours (61 days). In contrast, the half life was of 2805 hours (234 days) in the control samples. In the oak wood, the normalized concentration of methylene bis(thiocyanate) decreased with a half-life of 578 hours (48 days) and 799 hours (65 days) in the dark control. The only degradate identified was the thiocyanate ion, which was $\leq 2.948\%$ of time zero [^{14}C] recovery at all test intervals in the pine samples, $\leq 6.20\%$ in the irradiated oak samples, and up to 18.81 in the non-irradiated sample. This study satisfies the photolysis on wood data guideline. No additional data are required. (MRID 43511101)

3. Exposure and Risk Characterization

The Agency requires only a limited set of ecotoxicology and environmental fate studies for microbiocides. Methylene bis(thiocyanate) is moderately toxic to practically nontoxic to avian species on an acute basis, very highly toxic to highly toxic to freshwater fish on an acute basis, and very highly toxic to aquatic

invertebrates on an acute basis. Chronic effects were observed in freshwater fish and aquatic invertebrates.

While the hazard to aquatic organisms from methylene bis(thiocyanate) 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. Labels for all methylene bis(thiocyanate) products must require that discharges to aquatic environments comply with an NPDES permit.

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 exposed to methylene bis(thiocyanate) from its wood preservative uses, therefore, there is little likelihood of adverse effects occurring to wildlife.

The Agency does not anticipate any exposure of concern to fish, wildlife, and/or endangered species providing that all methylene bis(thiocyanate) products are handled and applied as specified in the product labeling and that discharges to the environment comply with all Federal disposal laws and NPDES.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

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

The Agency is concerned about possible effects from inhalation exposure to methylene bis(thiocyanate) based on the only methylene bis(thiocyanate) inhalation data available, an acute study, which showed very high toxicity. Cyanide is a metabolite of methylene bis(thiocyanate) and both cyanide and formaldehyde are potential degradates

of methylene bis(thiocyanate). It is possible that the thiocyanate ion would degrade to cyanide, but degradation data are lacking that would indicate whether this occurs in the working environment and, if so, under what conditions. However, notwithstanding these concerns, the Agency believes many uses of methylene bis(thiocyanate) are eligible for reregistration. The existing acute inhalation study is of very poor quality and can only be used for establishing a labeling toxicity category and not for risk assessment. Surrogate data for industrial biocide uses show that dermal exposure is 2 or 3 orders of magnitude greater than inhalation exposure and that inhalation exposure for some use scenarios is below the limit of detection. In addition, the Agency is requiring the use of a respirator for all methylene bis(thiocyanate) product labels in Toxicity Category I or II because of acute inhalation toxicity. The Agency is also requiring a subchronic inhalation study and air monitoring data that will quantitate amounts of cyanide and formaldehyde that might be present during application and post-application.

Generally, methylene bis(thiocyanate) uses that showed acceptable Margins of Exposure (MOE) from dermal exposure have been determined to be eligible for reregistration. The Agency could not make a decision for those uses for which there was no dermal exposure data and no way to determine if these uses posed no worse exposure than uses where data were available. The Agency also determined that it could not make a decision on the use of paints and ready-to-use products that are applied with a paint brush, roller or compressed sprayer even though MOE's are very low for occupational handlers. Before a decision can be made information on what types of paints contain methylene bis(thiocyanate) and what levels of post-application exposure (dermal and inhalation) result from painting and applications of ready-to-use products are necessary. The eligibility of specific uses is detailed in Section IV.B.1. below.

To confirm the Agency's assessment and quantify any potential inhalation risk to methylene bis(thiocyanate) and its degradates, the Agency is requiring the registrants to conduct a subacute inhalation study which is the appropriate Tier I study to quantify inhalation toxicity. Additionally, upgraded information to the supplementary metabolism studies is required. This information, as well as the exposure and post-application data being required can be used to determine risk and eligibility for those uses for which a decision cannot be made. The Agency will also notify OSHA if there is a concern for workers from inhalation exposures to methylene bis(thiocyanate) and its degradates following review of the subchronic inhalation study and the required exposure data.

The Agency, therefore, finds that only the specific products containing methylene bis(thiocyanate) as the active ingredient bearing uses as specified in Section IV.B.1. below are eligible for reregistration.

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 the uses of methylene bis(thiocyanate)

can not all be assessed for reregistration at this time, 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 methylene bis(thiocyanate), 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

1. Uses Eligible at This Time

Based on the reviews of the generic data for the active ingredient methylene bis(thiocyanate), the Agency has sufficient information on the health effects of methylene bis(thiocyanate) and on its potential for causing adverse effects in fish and wildlife and the environment when used for the following uses:

- Industrial preservatives with oil recovery drilling muds/packer fluids (both off-shore and/or terrestrial sites);
Air washer water systems;
Commercial/industrial water cooling systems;
Evaporative condenser water systems;
Heat exchanger water systems;
Industrial auxiliary water systems;
Industrial scrubbing systems;
Industrial waste disposal systems;
Pulp/paper mill water systems;
Adhesives, industrial;
Coatings, industrial;
Emulsions, resin/latex/polymer
Secondary oil recovery injection water;
Sewage systems;
Pasteurized/warmer/cannery cooling water systems;
Reverse osmosis water systems;
Fuel/oil storage tank bottom water additive;
Metal working cutting fluid;
Paper/paper products;
Speciality industrial products; and
Wet-end additives/industrial processing chemicals.

The Agency has determined that these methylene bis(thiocyanate) products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that these products containing methylene bis(thiocyanate) are eligible for reregistration.

2. Uses for Which a Reregistration Decision Cannot be Made

The Agency has determined that a decision cannot be made at this time for the following products containing methylene bis(thiocyanate) as an active ingredient until the data required in Section V of this document are provided:

- Wood or wood structure protection treatments to both seasoned and unseasoned forest products;
Wood or wood structure protection treatments;
Wood protection treatment to buildings/products;
Leather processing liquids;
Leather/leather products; and
Paints (in-can).

C. Regulatory Position

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

1. Occupational and Residential Labeling Rationale/Risk Mitigation Measures

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.

The Agency is developing standardized requirements for occupational handlers of industrial biocides, based on the acute toxicity characteristics of each end-use product. Comments on these requirements should be addressed during the public comment period for methylene bis(thiocyanate).

The Agency has determined that handlers (mixers, loaders, applicators, etc.) of all industrial biocides must wear long-sleeve shirts, long pants, shoes, and socks as minimum work attire. For industrial biocide end-use products that are classified as toxicity category I or II for acute dermal or skin irritation potential, handlers are required to wear chemical-resistant gloves and a chemical-resistant apron in addition to the minimum work attire. For industrial biocide end-use products classified as toxicity category I or II for eye irritation potential, handlers are required to wear protective eyewear. For industrial biocide end-use products

classified as toxicity category I or II for acute inhalation toxicity, handlers are required to wear a respirator. The type of respirator must be established based on the acute toxicity category and the vapor pressure and must be specified on the end-use product labeling. The Agency will assist registrants in determining the appropriate type of respirator during the end-use product stage of reregistration.

Table 14: Personal Protective Equipment Standard Requirements

Route of Concern	Toxicity Category I	Toxicity Category II	Toxicity Category III	Toxicity Category IV
Acute Dermal Toxicity or Skin Irritation Potential	Long sleeve shirt, long pants, shoes, socks, & chemical- resistant gloves & apron	Long sleeve shirt, long pants, shoes, socks, & chemical- resistant gloves, & apron	Long sleeve shirt, long pants, shoes, & socks	Long sleeve shirt, long pants, shoes, & socks
Eye Irritant	Protective Eyewear	Protective Eyewear	No minimum	No minimum
Acute Inhalation Toxicity	Respirator	Respirator	No minimum	No minimum

a. Personal Protective Equipment Requirements for Occupational Handlers

The Agency has determined that active-ingredient based handler safety requirements must be established due to the acute and other adverse effects of methylene bis(thiocyanate) as follows:

- **Dip Application (e.g., leather or wood processing)** The Agency is requiring the handlers participating in hand-dip applications to wear chemical-resistant full-front aprons with attached full-sleeve gloves due to concerns about potentially high dermal exposures during introduction and removal of materials, such as leather or wood products, by hand from dip vats.
- **Spray Applications** The Agency is requiring that persons not directly participating in spray applications in enclosed or indoor areas must be excluded from the treated area and from an area extending at least 25 feet from the perimeter of the treatment site until application is complete and sprays have settled out of the air due to inhalation concerns.

The Agency has determined that for all other handler tasks, handler safety requirements for products containing methylene bis(thiocyanate) must be determined based on the acute toxicity characteristics of the end-use products. However, the Agency is concerned about the dermal and

inhalation exposures to occupational handlers in many exposure scenarios and is requiring data for those scenarios. (See Section V for details).

b. Engineering Control Requirements for Occupational Handlers

The Agency has determined that engineering control requirements must be established based on unacceptable margins of exposure for the following use pattern:

- **Cooling Water Systems - Open Pouring** The Agency is concerned about risks to the primary handler open-pouring liquid formulations for large water cooling systems (> 4000 gallons per day) uses since the MOE is 31 (wearing gloves) for this application method. However, in large cooling system settings if a pump-metering system was used, it would significantly reduce the exposure and risk associated with use of methylene bis(thiocyanate) (MOE of 3524). Therefore, the Agency is requiring the use of a pump-metering system for all water cooling systems of > 4000 gallons per day. For smaller cooling systems (< 4000 gallons per day), the MOE is 155 for exposures due to open pouring situations which is below the Agency's level of concern. Therefore, no additional mitigation is required for smaller cooling systems (< 4000 gallons per day).

c. Post-Application Safety Requirements

The Agency is establishing safety requirements for post-application exposure to methylene bis(thiocyanate) following applications in commercial, industrial and residential settings (e.g., dermal (mist, steams) and inhalation) as follows:

- **Spray Applications** The Agency is establishing a requirement that all persons, other than handlers involved in the spray application, remain at least 25 feet outside the treatment site during application and until sprays have settled out of the air, due to inhalation concerns when methylene bis(thiocyanate) is applied as a spray in indoor or enclosed areas.
- **Spray and Dip Applications - Handlers** The Agency is requiring that all persons handling treated materials, such as leather or wood products, still wet with the application wear a chemical-resistant apron and chemical resistant gloves due to skin irritation concerns.

The Agency is requiring exposure data and air-monitoring data for post-application exposures from commercial wood treatment process and post-application inhalation exposures in occupational and residential settings from methylene bis(thiocyanate) and its potential degradates. See Section V for details for all requirements.

d. Other Mitigation Measures

The Agency is also concerned about dermal and inhalation exposures to occupational handlers in many exposure scenarios and possible inhalation hazards to homeowner handlers and is requiring air-monitoring data for all applicable scenarios.

Under section 5 of the Occupational Safety and Health Act, 29 U.S.C. 651 *et seq*, every employer has a general duty to furnish a place of employment which is free from recognized hazards that are causing, or are likely to cause, serious physical harm. Every employer is also required to comply with occupational safety and health standards promulgated by OSHA. Operations such as blending and formulating using methylene bis(thiocyanate) in general industry (i.e., Standard Industrial Codes 20 - 39) may be subject to other Occupational Safety and Health Administration (OSHA) requirements. There is no OSHA Permissible Exposure Limit (PEL) for methylene bis(thiocyanate), but particulate exposures to methylene bis(thiocyanate) in general industry are subject to the OSHA PEL for Particulates Not Otherwise Regulated, of 15 mg/m³ as an 8-hour Time-Weighted Average (TWA). In addition, OSHA has established requirements for hazard communication and use of personal protective equipment for protection of workers potentially exposed to chemical or other types of hazards in the workplace.

OSHA's hazard communication standard (29 CFR 1910.1200) establishes requirements for labeling, preparation and dissemination of Material Safety Data Sheets (MSDSs), training, etc., for workers potentially exposed to hazardous chemicals. OSHA requirements for the selection and use of personal protective equipment (29 CFR 1910, Subpart I) include an assessment of the workplace to determine if hazards potentially requiring the use of head, eye, face or foot protection are present or are likely to be present. If hazards are identified, employers must select and have employees use appropriate personal protective equipment (PPE) which has been properly fitted and selected based on the potential hazard present. Employers are required to provide training on the proper use of personal protective equipment, when it is required, what PPE is needed, how to properly don, doff, adjust and wear the PPE, the

limitations of the equipment, and the proper care and maintenance, useful life, and disposal of the PPE.

For methylene bis(thiocyanate) end-use products, the MSDS recommends specific personal protective equipment including rubber gloves, safety glasses or chemical splash goggles, body protective clothing such as long sleeve shirts and long trousers and protective shoes. Provided this equipment is appropriately selected, maintained, and used, worker exposures during operations where methylene bis(thiocyanate) is used in preservatives, metal working cutting fluids, oil recovery and drilling mud/packer fluid, and in paper coating are expected to be reduced. For methylene bis(thiocyanate) the MSDS provides information on the reactivity of methylene bis(thiocyanate) with strong acids, strong alkali and strong oxidizers and warns of its possible decomposition products to such chemicals as cyanide. It should be noted that OSHA generally does not inspect workplaces with fewer than 10 employees.

f. Other Labeling Requirements

The Agency is requiring additional use and safety information to be placed on the labeling of all end-use products containing methylene bis(thiocyanate) to afford supplemental protection to handlers. For specific labeling statements addressing application restrictions, user safety requirements and recommendations, and a skin sensitization statement, 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. Manufacturing-Use Products

1. Additional Generic Data Requirements

a. Toxicology Studies

The toxicological database for methylene bis(thiocyanate) is not complete. Data are not available to characterize the risk due to inhalation exposure of methylene bis(thiocyanate). The Agency has required in a Data Call-In issued in March 1997, a 90-day inhalation study (GDLN 82-2) to quantify the level of hazard posed by exposure via the inhalation route. If the required air monitoring data indicate the presence of cyanide and formaldehyde, inhalation toxicity data on cyanide and formaldehyde

may be required as appropriate.

Although there are two supplementary metabolism studies, there is still a data gap for metabolism primarily due (but not limited) to inadequate metabolite identification. One study is potentially upgradable. The additional metabolism data remains outstanding and the registrant has been required to submit information to upgrade this data. In addition to the data discussed above the Agency will be asking for additional use information on what types of paints contain methylene bis(thiocyanate) in order to make an eligibility decision on occupational uses of paint and ready-to-use products.

b. Handler Studies

EPA is requiring the following data for handler exposures:

- For uses as a wood pressure treatment to forest products;
- For uses in leather processing liquors, leather processing, and leather products;
- For application as a dip for leather products and for wood preservation, including removal of products from the dip.
- For painting with a roller;
- Spray treatments for wood and other industrial/manufacturing treatments.

For each of these exposure scenarios, studies should be conducted using guideline numbers: 231, 232, 233 and 234. The air monitoring studies must include monitoring for potential degradates (formaldehyde and cyanide) as well as monitoring for methylene bis(thiocyanate) itself. For the wood pressure treatments, data required must include uses by occupational handlers who (1) operate the solution supply system, (2) use dip tanks, and (3) drive forklifts or carrier trucks to dip lumber.

c. Post-Application Studies

EPA is requiring data for post-application exposures: (1) in painted areas where paint is applied by brush, roller, and sprayer; and (2) associated with wood-product treatments. For these exposure scenarios, studies should be conducted using guideline numbers: 133-3 and 133-4. The air monitoring studies for paint uses must include monitoring for potential degradates (formaldehyde and cyanide) as well as monitoring for methylene bis(thiocyanate) itself. Data required for use scenarios associated with wood-product treatments must include exposures to (1) workers (graders, lumber pullers, etc.) who handle wood wet from the

treatment, (2) workers who handle dry treated wood, and (3) workers who perform maintenance on any part of the treatment system or machinery.

The above mentioned generic data on occupational and post-application exposures will be required as part of a subsequent Data Call-In Notice. However, because much of the exposure data needed for methylene bis(thiocyanate) is generic in nature and will also be required for other antimicrobial chemicals with similar characteristics and the same uses, EPA is developing a generic exposure DCI. Methylene bis(thiocyanate) registrants will receive the generic exposure DCI at the same time as registrants of other chemicals with similar uses.

2. Labeling Requirements for Manufacturing-Use Products

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

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

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

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

Effluent Discharge Labeling Statements

"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."

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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

2. Labeling Requirements for End-Use Products

a. PPE/Engineering Control Requirements for Occupational Users

For sole-active-ingredient end-use products that contain methylene bis(thiocyanate), the product labeling must be revised to adopt the handler personal protective equipment/engineering control 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 methylene bis(thiocyanate), the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

(1) Minimum (Baseline) PPE/Engineering Control Requirements

EPA is requiring the following PPE based on the acute toxicity of the methylene bis(thiocyanate) end-use products.

"Mixers, loaders, applicators and other handlers must wear:

- Long-sleeve shirt and long pants,
- Shoes plus socks."

If the end-use product is classified as toxicity category I or II for eye irritation potential, add to the above list of PPE:

-- "Protective eyewear."

If the end-use product is classified as toxicity category I or II for acute dermal toxicity or skin irritation potential, add to the above list of PPE:

-- "Chemical-resistant apron, and chemical-resistant gloves*."

If the end-use product is classified as toxicity category I or II for acute inhalation toxicity, a respirator requirement must be added. 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.

* For the glove statement, use the statement established for methylene bis(thiocyanate) through the instructions in Supplement Three of PR Notice 93-7. In addition, for concentrated methylene bis(thiocyanate) products, the corrosiveness and penetration of methylene bis(thiocyanate) must be considered. Appropriate chemical-resistant materials must be listed on the product labeling.

(2) Other PPE/Engineering Control Requirements

In addition to the PPE specified above, the following specific PPE requirements must be added to labels containing the following uses.

When labeling permits application as a dip, add the following:

"Handlers participating in hand-dip applications, including introduction of materials to and removal from the dip and handling materials still wet from the dip, must wear chemical-resistant full-front aprons with attached full-sleeve gloves."

For liquid product formulations applied to cooling water systems of > 4000 gallons the following engineering control restriction is required on product labels.

"Do not apply by open pouring of liquid to cooling water systems; a metering pump delivery system is required for this use and application method."

(3) Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the format and language specified above and

must be placed in the "Hazards to Humans" section of the pesticide labeling.

b. Other Application Restrictions

Other application restrictions for methylene bis(thiocyanate) product labels are:

1. For all end-use products: "Do not apply this product in a way that will contact workers or other persons."

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

2. When the labeling permits application as a spray, add the following:

"All persons not directly participating in such spray applications in enclosed or indoor areas must be excluded from the treatment site and from an area extending at least 25 feet from the perimeter of the treatment site until application is complete and sprays have settled out of the air."

3. For liquid end-use products only: "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

c. User Safety Recommendations

Add the following user safety recommendations to labels of all methylene bis(thiocyanate) end-use products:

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

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

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

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

For Homeowner use products, add:

“Do not apply this product in a way that will contact any person or pet.

d. Effluent Discharge and Disposal Labeling Statements

See statement under Manufacturing Use Products, Section V.A.2.

e. Directions for Use

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

C. Existing Stocks

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

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

VI. APPENDICES

APPENDIX A REPORT

Case 2415[Methylene bis(thiocyanate)] Chemical 068102[Methylenebis(thiocyanate)]

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

NON-FOOD/NON-FEED (con't)

)))))))))) COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS (con't) Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)

Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. /crop /year	# Apps @ Max. Rate	Max. Dose (AI unless noted otherwise) /crop /year	Min. Interv (days)	Restr. Entry	Geographic Allowed	Disallowed	Limitations	Use Limitations Codes
SC/L	W .48	W 3	*	NS	NS	NS	NS	NS	NS		A08, C18, C24, CAD
SC/L	W .49	W 3	*	NS	NS	NS	NS	NS	NS		A08, C18, C22, C24
SC/L	W .66	W 4.1	*	NS	NS	NS	NS	NS	NS		A08, C18, C24, C92
SC/L	W .93	W 5.7	*	NS	NS	NS	NS	NS	NS		A08, C24, CAD
SC/L	W 2	W 12	*	NS	NS	NS	NS	NS	NS		A08, C18, C22, C24
SC/L	W 4.4	W 5.4	*	NS	NS	NS	NS	NS	NS		A08, C22, C24
SC/L	W 4.4	W 5.5	*	NS	NS	NS	NS	NS	NS		A08, C22, CAH
SC/L	W 4.8	W 9.7	*	NS	NS	NS	NS	NS	NS		C18, C24
SC/L	W 4.9	W 9.7	*	NS	NS	NS	NS	NS	NS		A08, A11(4), C18, C24
Water treatment (recirculating system), Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	SC/L	V .47	V 2.9	*	NS	NS	NS	NS	NS		A08, C12, C18
SC/L	W .45	W 2.8	*	NS	NS	NS	NS	NS	NS		A08
SC/L	W .49	W 3	*	NS	NS	NS	NS	NS	NS		A08, C12, C18
SC/L	W .51	W 3.1	*	NS	NS	NS	NS	NS	NS		A08
SC/L	W .59	W 8.8	*	NS	NS	NS	NS	NS	NS		A08, C12, C18
SC/L	W .6	W 3	*	NS	NS	NS	NS	NS	NS		A08, C12, C18
SC/L	W 1.2	W 6	*	NS	NS	NS	NS	NS	NS		A08, C12, C18
SC/L	W 1.2	W 6	*	NS	NS	NS	NS	NS	NS		A08, C18, C24

APPENDIX A REPORT

Case 2415[Methylene bis(thiocyanate)] Chemical 068102[Methylenebis(thiocyanate)]

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

NON-FOOD/NON-FEED (con't)

COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS (con't)

Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)

Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Rate @ Max. /crop /year	# Apps	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Restr. Entry	Geographic Allowed	Disallowed	Limitations	Use Codes
SC/L	W 1.3	W 6.4	* NS	NS	NS	NS	NS	NS	NS		A08, C18, C24
SC/L	W 1.8	W 6	* NS	NS	NS	NS	NS	NS	NS		A08, C12, C18
SC/L	W 2.4	W 4.8	* NS	NS	NS	NS	NS	NS	NS		A08, C12
SC/L	V .16	V .94	* NS	NS	NS	NS	NS	NS	NS		A08, C12, C18
SC/L	V 2.3	V 4.7	* NS	NS	NS	NS	NS	NS	NS		A08, C18, C24
SC/L	W .15	W .9	* NS	NS	NS	NS	NS	NS	NS		A08
SC/L	W .16	W .98	* NS	NS	NS	NS	NS	NS	NS		A08, C12, C18
SC/L	W .17	W 1	* NS	NS	NS	NS	NS	NS	NS		A08
SC/L	W .59	W 5.9	* NS	NS	NS	NS	NS	NS	NS		A08, C12, C18
SC/L	W .6	W 4.5	* NS	NS	NS	NS	NS	NS	NS		A08, C12, C18
SC/L	W .6	W 4.5	* NS	NS	NS	NS	NS	NS	NS		A08, C18, C24
SC/L	W .89	W 1.8	* NS	NS	NS	NS	NS	NS	NS		A08, C12
SC/L	W .9	W 3	* NS	NS	NS	NS	NS	NS	NS		A08, C12, C18
SC/L	W 4.7	W 10	* NS	NS	NS	NS	NS	NS	NS		A08, C18, C24
SC/L	NA	UC	* NS	NS	NS	NS	NS	120	NS		
SC/L	NA	UC	* NS	NS	NS	NS	NS	120	NS		C12, C18
SC/L	NA	UC	* NS	NS	NS	NS	NS	120	NS		C18, C22, C24

APPENDIX A REPORT

Case 2415[Methylene bis(thiocyanate)] Chemical 068102[Methylenebis(thiocyanate)]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI un- less noted otherwise)	Max. Appl. Rate (AI Tex. unless noted otherwise)	Soil Max. # @ Max. Rate Dose cycle	Max. # Apps unless noted /crop /year /year cycle	Max. Dose [(AI Min. Restr. Interv Entry (days) Interv [day(s)]	Geographic Limitations Disallowed Limitations	Use Codes
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USES ELIGIBLE FOR REREGISTRATION								
NON-FOOD/NON-FEED (con't)								
))))))))))								

COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS (con't)

Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)

	SC/L	NA		UC	* NS NS	NS NS 120	NS		C18, C24,CAD
	SC/L	NA		UC	* NS NS	NS NS 120	NS		C24, CAD
Water treatment (recirculating system), Shock/slug, Not on label, Not Applicable, Not applicable for this use	SC/L	V 4.7	V 9.4	* NS NS	NS NS NS	NS	NS		A08, C18, C24
Water treatment (recirculating system), Subsequent/maintenance, Not on label, Not Applicable, Not applicable for this use	SC/L	V 2.3	V 4.7	* NS NS	NS NS NS	NS	NS		C18, C24
	SC/L	W .15	W .93	* NS NS	NS NS NS	NS	NS		A08, C18, C24, C92
	SC/L	W .15	W .9	* NS NS	NS NS NS	NS	NS		C18, C24,CAD
	SC/L	W .15	W .93	* NS NS	NS NS NS	NS	NS		C24, CAD
	SC/L	W .16	W .98	* NS NS	NS NS NS	NS	NS		A08, C18, C22, C24
	SC/L	W .16	W .97	* NS NS	NS NS NS	NS	NS		A08, C18, C24, CAD
	SC/L	W .16	W .98	* NS NS	NS NS NS	NS	NS		C18, C22,C24
	SC/L	W .25	W 1.3	* NS NS	NS NS NS	NS	NS		C18, C24,C92
	SC/L	W .31	W 1.9	* NS NS	NS NS NS	NS	NS		C24, CAD
	SC/L	W .56	W 2.7	* NS NS	NS NS NS	NS	NS		A08, C22,C24
	SC/L	W .56	W 2.7	* NS NS	NS NS NS	NS	NS		A08, C22,CAH
	SC/L	W .66	W 3.9	* NS NS	NS NS NS	NS	NS		C18, C22,C24
	SC/L	W 2.4	W 4.9	* NS NS	NS NS NS	NS	NS		A08, A11(4), C18, C24

APPENDIX A REPORT

Case 2415[Methylene bis(thiocyanate)] Chemical 068102[Methylenebis(thiocyanate)]

SITE Application Type, Application	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. /crop /year	# Apps @ Max. Rate unless noted otherwise)	Max. Dose [(AI otherwise)/A]	Min. Restr. Interv (days)	Geographic Limitations Allowed	Disallowed Limitations	Use Codes
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

EMULSIONS, RESIN/LATEX/POLYMER (con't)

Use Group: INDOOR NON-FOOD (con't)

Additive treatment, Not on label, Not on label, Not applicable, Not applicable for this use	SC/L	U 5	U 40	* NS NS	NS	NS	NS	NS		
Industrial preservative treatment, During manufacture, Not on label, Not applicable, Not applicable for this use	SC/L	W 7.5	W 20	* NS NS	NS	NS	NS	NS		A38, C18, C24
	SC/L	W 7.5	W 75	* NS NS	NS	NS	NS	NS		C18, C24
	SC/L	W 7.5	W 75	* NS NS	NS	NS	NS	NS		CAH
	SC/L	W 10	W 50	* NS NS	NS	NS	NS	NS		C12, C18
	SC/S	W 9.8	W 49	* NS NS	NS	NS	NS	NS		C12, C18
	SC/S	W 14	W 70	* NS NS	NS	NS	NS	NS		C12, C18
SC/S	W 14	W 70	* NS NS	NS	NS	NS	NS		C18, C24	

EVAPORATIVE CONDENSER WATER SYSTEMS

Use Group: AQUATIC NON-FOOD INDUSTRIAL

Water treatment (recirculating system), Continuous feed (initial), Not on label, Not applicable, Not applicable for this use	SC/L	W .59	W 8.8	* NS NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W .6	W 3	* NS NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 1.2	W 6	* NS NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 1.2	W 6	* NS NS	NS	NS	NS	NS		A08, C18, C24
	SC/L	W 1.3	W 6.4	* NS NS	NS	NS	NS	NS		A08, C18, C24
	SC/L	W 1.8	W 6	* NS NS	NS	NS	NS	NS		A08, C12, C18

APPENDIX A REPORT

Case 2415[Methylene bis(thiocyanate)] Chemical 068102[Methylenebis(thiocyanate)]

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

))))))))))

USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

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FUELS/OIL STORAGE TANK BOTTOM WATER ADDITIVE Use Group: INDOOR NON-FOOD

Form(s)	Min. Appl.	Max. Appl.	Soil Max. # Apps	Max. Dose [(AI Min. Restr. Geographic Limitations Use	Use Codes
SC/L	V .47	V 4.7	* NS NS	NS NS NS NS	
SC/L	V .47	V 4.7	* NS NS	NS NS NS NS	C12, C18
SC/L	V .47	V 5.2	* NS NS	NS NS NS NS	C22, C24
SC/L	V .47	V 5.2	* NS NS	NS NS NS NS	C22, CAH
SC/L	V .47	V 4.7	* NS NS	NS NS NS NS	C18, C22, C24
SC/L	V .47	V 4.7	* NS NS	NS NS NS NS	C18, C24, C92
SC/L	V .47	V 4.7	* NS NS	NS NS NS NS	C18, C24, CAD
SC/L	V .47	V 5.2	* NS NS	NS NS NS NS	C22, C24
SC/L	V .47	V 4.7	* NS NS	NS NS NS NS	C24, CAD
SC/L	V .62	V 6.2	* NS NS	NS NS NS NS	C18, C24, C92
SC/L	V .94	V 9.4	* NS NS	NS NS NS NS	C24, CAD
SC/L	V 1.9	V 19	* NS NS	NS NS NS NS	C18, C22, C24
SC/L	W 1	W 10	* NS NS	NS NS NS NS	C18, C24
SC/L	V .47	V 5.2	* NS NS	NS NS NS NS	C22, CAH
SC/L	V 5	V 10	* NS NS	NS NS NS NS	C18, C24

APPENDIX A REPORT

Case 2415[Methylene bis(thiocyanate)] Chemical 068102[Methylenebis(thiocyanate)]

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

NON-FOOD/NON-FEED (con't)

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LEATHER/LEATHER PRODUCTS (con't)

Use Group: INDOOR NON-FOOD (con't)

	SC/L	W 30		W 200	* NS NS	NS NS	NS NS	NS NS	
	SC/L	W 30		W 199	* NS NS	NS NS	NS NS	NS NS	C18, C24, C92
	SC/L	W 30		W 198	* NS NS	NS NS	NS NS	NS NS	C18, C24, CAD
	SC/L	W 50		W 299	* NS NS	NS NS	NS NS	NS NS	C22, CAH
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	W 25		W 200	* NS NS	NS NS	NS NS	NS NS	C18, C24
	SC/L	W 40		W 269	* NS NS	NS NS	NS NS	NS NS	C18, C24, C92
	SC/L	W 50		W 249	* NS NS	NS NS	NS NS	NS NS	
	SC/L	W 50		W 248	* NS NS	NS NS	NS NS	NS NS	C18, C24, CAD

METALWORKING CUTTING FLUIDS

Use Group: INDOOR NON-FOOD

Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 15		V 15	* NS NS	NS NS	NS NS	NS NS	C18, C24
	SC/L	W 10		W 1000	* NS NS	NS NS	NS NS	NS NS	C12, C18
Preservative treatment, Shock/slug, Not on label, Not Applicable, Not applicable for this use	SC/L	V 10		V 40	* NS NS	NS NS	NS NS	NS NS	C18, C24
Water treatment, Not on label, Metering pump, Not Applicable, Not applicable for this use	SC/L	W 46		W 459	* NS NS	NS NS	NS NS	NS NS	CAH
Water treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	W 46		W 459	* NS NS	NS NS	NS NS	NS NS	CAH

APPENDIX A REPORT

Case 2415[Methylene bis(thiocyanate)] Chemical 068102[Methylenebis(thiocyanate)]

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

USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

METALWORKING CUTTING FLUIDS (con't)

Use Group: INDOOR NON-FOOD (con't)

Water treatment, Shock/slug, Not on label, Not Applicable, Not applicable for this use SC/L V 10 V 40 * NS NS NS NS NS NS NS C18, C24

SC/L W 10 W 41 * NS NS NS NS NS NS NS C22, CAH

OIL RECOVERY DRILLING MUDS/PACKER FLUIDS

Use Group: AQUATIC NON-FOOD INDUSTRIAL

Additive treatment, Not on label, Not on label, Not Applicable, Not applicable for this use SC/L W 50 W 250 * NS NS NS NS NS NS NS C12, C18

SC/L W 50 W 250 * NS NS NS NS NS NS NS C12, C18

Make-up fluids treatment, Initial, Not on label, Not Applicable, Not applicable for this use SC/L V 477 V 477 * NS NS NS NS NS NS NS C18, C24

Make-up fluids treatment, Not on label, Not on label, Not Applicable, Not applicable for this use SC/L V 456 V 456 * NS NS NS NS NS NS NS C18, C22, C24

Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use SC/L V 6.5 V 65 * NS NS NS NS NS NS NS C12, C18, C24

SC/L V 6.7 V 67 * NS NS NS NS NS NS NS C12, C18, C24

SC/L V 7.3 V 72 * NS NS NS NS NS NS NS C18, C22, C24

SC/L W 10 W 1000 * NS NS NS NS NS NS NS C12, C18

SC/L W 50 W 250 * NS NS NS NS NS NS NS

SC/L W 50 W 250 * NS NS NS NS NS NS NS C18, C22, C24

SC/L W 50 W 250 * NS NS NS NS NS NS NS C18, C24, C92

APPENDIX A REPORT

Case 2415[Methylene bis(thiocyanate)] Chemical 068102[Methylenebis(thiocyanate)]

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SITE Application Type, Application Timing, Application Equipment)	Form(s)	Min. Appl. Rate (AI un-less noted otherwise)	Max. Appl. Rate (AI Tex. @ Max. Rate unless noted otherwise) Dose cycle	Soil Max. # Apps	Max. Dose [(AI Min. Restr. Interv Entry Allowed Disallowed Limitations	Use Codes
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))))))
 USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

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OIL RECOVERY DRILLING MUDS/PACKER FLUIDS (con't)

Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)

SC/L	W 50	W 250	* NS NS NS NS NS NS NS	C18, C24, CAD
SC/L	W 50	W 280	* NS NS NS NS NS NS NS	C22, C24
SC/L	W 50	W 280	* NS NS NS NS NS NS NS	C22, CAH
SC/L	W 50	W 250	* NS NS NS NS NS NS NS	C24, CAD
SC/L	W 70	W 330	* NS NS NS NS NS NS NS	C18, C24, C92
SC/L	W 100	W 500	* NS NS NS NS NS NS NS	C24, CAD
SC/L	W 200	W 1000	* NS NS NS NS NS NS NS	C18, C22, C24

Use Group: TERRESTRIAL NON-FOOD CROP

Additive treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	W 50	W 250	* NS NS NS NS NS NS NS	C12, C18
Make-up fluids treatment, Initial, Not on label, Not Applicable, Not applicable for this use	SC/L	V 477	V 477	* NS NS NS NS NS NS NS	C18, C24
Make-up fluids treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 456	V 456	* NS NS NS NS NS NS NS	C18, C22, C24
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 6.5	V 65	* NS NS NS NS NS NS NS	C12, C18, C24
	SC/L	V 6.7	V 67	* NS NS NS NS NS NS NS	C12, C18, C24
	SC/L	V 7.3	V 72	* NS NS NS NS NS NS NS	C18, C22, C24

APPENDIX A REPORT

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

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 USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

)))))))))

PAPER/PAPER PRODUCTS (con't)

Use Group: INDOOR NON-FOOD (con't)

	SC/S	W 14		W 70	* NS NS	NS NS	NS NS			C18, C24
Preservative treatment, Not on label, Applicator rolls, Not Applicable, Not applicable for this use	SC/L	W 25		W 200	* NS NS	NS NS	NS NS			
Preservative treatment, Not on label, Not on label	SC/L	NA		UC	* NS NS	NS NS	NS NS			
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	W 25		W 75	* NS NS	NS NS	NS NS			
Preservative treatment, Not on label, Sprayer, Not Applicable, Not applicable for this use	SC/L	W 25		W 200	* NS NS	NS NS	NS NS			
Wood chip treatment, Not on label, Sprayer, Not Applicable, Not applicable for this use	SC/L	W 25		W 100	* NS NS	NS NS	NS NS			

PASTEURIZER/WARMER/CANNERY COOLING WATER SYSTEMS

Use Group: INDOOR NON-FOOD

Water treatment (recirculating system), Continuous feed (initial), Not on label, Not Applicable, Not applicable for this use	SC/L	W .59		W 8.8	* NS NS	NS NS	NS NS			A08, C12, C18
	SC/L	W .6		W 3	* NS NS	NS NS	NS NS			A08, C12, C18
	SC/L	W 1.2		W 6	* NS NS	NS NS	NS NS			A08, C12, C18
	SC/L	W 1.2		W 6	* NS NS	NS NS	NS NS			C18, C24
	SC/L	W 1.8		W 6	* NS NS	NS NS	NS NS			A08, C12, C18

APPENDIX A REPORT

Case 2415[Methylene bis(thiocyanate)] Chemical 068102[Methylenebis(thiocyanate)]

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

NON-FOOD/NON-FEED (con't)

PASTEURIZER/WARMER/CANNERY COOLING WATER SYSTEMS (con't)

Use Group: INDOOR NON-FOOD (con't)

Water treatment, Continuous feed (initial), Not on label, Not Applicable, Not applicable for this use	SC/L	W 2.1	W 4.2	* NS	NS	NS	NS	NS	NS		A08, C18, C24
	SC/L	W 3	W 4.5	* NS	NS	NS	NS	NS	NS		C18, C24
	SC/L	W 3.2	W 6.4	* NS	NS	NS	NS	NS	NS		A08, C22, C24
	SC/L	W 3.2	W 6.5	* NS	NS	NS	NS	NS	NS		A08, C22, CAH
	SC/L	W 3.2	W 4.8	* NS	NS	NS	NS	NS	NS		C18, C24
Water treatment, Continuous feed (subsequent), Not on label, Not Applicable, Not applicable for this use	SC/L	W 1	W 3.1	* NS	NS	NS	NS	NS	NS		A08, C18, C24
	SC/L	W 1.5	W 1.5	* NS	NS	NS	NS	NS	NS		C18, C24
	SC/L	W 1.6	W 3.2	* NS	NS	NS	NS	NS	NS		A08, C22, C24
	SC/L	W 1.6	W 3.2	* NS	NS	NS	NS	NS	NS		A08, C22, CAH
	SC/L	W 1.6	W 1.6	* NS	NS	NS	NS	NS	NS		C18, C24
Water treatment, Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	SC/L	W 2.1	W 4.2	* NS	NS	NS	NS	NS	NS		A08, C18, C24
	SC/L	W 3	W 4.5	* NS	NS	NS	NS	NS	NS		C18, C24
	SC/L	W 3.2	W 6.4	* NS	NS	NS	NS	NS	NS		A08, C22, C24
	SC/L	W 3.2	W 6.5	* NS	NS	NS	NS	NS	NS		A08, C22, CAH
	SC/L	W 3.2	W 4.8	* NS	NS	NS	NS	NS	NS		C18, C24

APPENDIX A REPORT

Case 2415[Methylene bis(thiocyanate)] Chemical 068102[Methylenebis(thiocyanate)]
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| SITE Application Type, Application Timing, Application Equipment )<br>Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only) | Form(s) | Min. Appl. Rate (AI unless noted otherwise) | Max. Appl. Rate (AI unless noted otherwise) | Soil Max. @ Max. /crop /year | # Apps unless noted | Max. Dose [(AI otherwise)/A] | Min. Restr. Interv (days) | Geographic Limitations Allowed | Geographic Limitations Disallowed | Use Limitations Codes |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---------------------------------------------|---------------------------------------------|------------------------------|---------------------|------------------------------|---------------------------|--------------------------------|-----------------------------------|-----------------------|
|------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---------------------------------------------|---------------------------------------------|------------------------------|---------------------|------------------------------|---------------------------|--------------------------------|-----------------------------------|-----------------------|

USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

SECONDARY OIL RECOVERY INJECTION WATER (con't) Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)

|                                                                                                              |      |       |  |       |      |    |    |    |    |                                          |
|--------------------------------------------------------------------------------------------------------------|------|-------|--|-------|------|----|----|----|----|------------------------------------------|
|                                                                                                              | SC/L | W 3.1 |  | W 10  | * NS | NS | NS | NS | NS | A27(4),A28(8),<br>C18, C24, CAD          |
|                                                                                                              | SC/L | W 3.2 |  | W 11  | * NS | NS | NS | NS | NS | A27(4),A28(8),<br>C18, C22, C24          |
|                                                                                                              | SC/L | W 3.2 |  | W 11  | * NS | NS | NS | NS | NS | C12, C18                                 |
|                                                                                                              | SC/L | W 3.3 |  | W 11  | * NS | NS | NS | NS | NS |                                          |
|                                                                                                              | SC/L | W 6   |  | W 20  | * NS | NS | NS | NS | NS | A27(4),A28(8),<br>C24, CAD               |
|                                                                                                              | SC/L | W 13  |  | W 43  | * NS | NS | NS | NS | NS | A27(4),A28(8),<br>C18, C22, C24          |
| Water treatment, Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use     | SC/L | W .43 |  | W 14  | * NS | NS | NS | NS | NS | A08, A27(4),<br>A28(8), C12,<br>C18, C24 |
|                                                                                                              | SC/L | W 1.4 |  | W 11  | * NS | NS | NS | NS | NS | A08, A27(4),<br>A28(8), C12,<br>C18, C24 |
|                                                                                                              | SC/L | W 1.4 |  | W 7.1 | * NS | NS | NS | NS | NS | A08, A27(4),<br>A28(8), C18,<br>C22, C24 |
| Water treatment, Intermittent (slug)(subsequent), Metering pump, Not Applicable, Not applicable for this use | SC/L | V .47 |  | V 3.1 | * NS | NS | NS | NS | NS | A27(4),A28(8),<br>C18, C24               |
|                                                                                                              | SC/L | V .94 |  | V 3.1 | * NS | NS | NS | NS | NS | C12, C18                                 |
|                                                                                                              | SC/L | W .48 |  | W 3.2 | * NS | NS | NS | NS | NS | A27(4),A28(8),<br>C22, C24               |
|                                                                                                              | SC/L | W .48 |  | W 3.2 | * NS | NS | NS | NS | NS | A27(4),A28(8),<br>C22, CAH               |



















APPENDIX A REPORT

Case 2415[Methylene bis(thiocyanate)] Chemical 068102[Methylenebis(thiocyanate)]

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USE LIMITATIONS CODES

A :

A08 : Preclean claim.

A11 : \_\_ hour(s) contact time.

A27 : \_\_ hour(s) contact time (minimum).

A28 : \_\_ hour(s) contact time (maximum).

A38 : This product is not cleared for use in defoamers and/or coatings that may come in contact with food.

C12 : Do not apply in marine and/or estuarine, oil fields, or discharge effluent into lakes, streams, ponds or public water. (NPDES license restriction)

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

C22 : Do not apply in marine and/or estuarine oil fields.

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

C65 : Do not use on wood intended for food, feed or potable water contact surfaces.

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

C93 : Do not apply directly to water.

CAD : Do not apply directly to water or wetlands.

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

CAL : Do not contaminate water, food or feed.

CSK : Do not use on wood which will come in contact with food.

CSL : Do not use on interior wood.

\* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

## GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case methylene bis(thiocyanate) covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to methylene bis(thiocyanate) 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 Methylene bis(thiocyanate)

| REQUIREMENT              | USE PATTERN                            | CITATION(S)                                                     |
|--------------------------|----------------------------------------|-----------------------------------------------------------------|
| <b>PRODUCT CHEMISTRY</b> |                                        |                                                                 |
| <b>61-1</b>              | <b>Chemical Identity</b>               | ALL<br>MRID 41648001, 41607701, 41611902,<br>41611901, 40518601 |
| <b>61-2A</b>             | <b>Start. Mat. &amp; Mnfg. Process</b> | ALL<br>MRID 41607701, 42739201, 41648001,<br>41611901, 40518601 |
| <b>61-2B</b>             | <b>Formation of Impurities</b>         | ALL<br>MRID 41607701, 42739202, 41648001,<br>41611901, 40518601 |
| <b>62-1</b>              | <b>Preliminary Analysis</b>            | ALL<br>MRID 41607702, 41648001, 41648002,<br>41611902, 40518602 |
| <b>62-2</b>              | <b>Certification of limits</b>         | ALL<br>MRID 41607702, 41648001, 41648002,<br>41611902, 40518602 |
| <b>62-3</b>              | <b>Analytical Method</b>               | ALL<br>MRID 41607702 41648001, 41648002,<br>41611902, 40518602  |
| <b>63-2</b>              | <b>Color</b>                           | ALL<br>MRID 41648003                                            |
| <b>63-3</b>              | <b>Physical State</b>                  | ALL<br>MRID 41648003                                            |
| <b>63-4</b>              | <b>Odor</b>                            | ALL<br>43328601                                                 |
| <b>63-5</b>              | <b>Melting Point</b>                   | ALL<br>MRID 41648003                                            |
| <b>63-7</b>              | <b>Density</b>                         | ALL<br>MRID 41648003                                            |
| <b>63-8</b>              | <b>Solubility</b>                      | ALL<br>43328601, 41648003                                       |
| <b>63-9</b>              | <b>Vapor Pressure</b>                  | ALL<br>MRID 41648003                                            |
| <b>63-10</b>             | <b>Dissociation Constant</b>           | ALL<br>MRID 41648003                                            |
| <b>63-11</b>             | <b>Octanol/Water Partition</b>         | ALL<br>MRID 41648003                                            |

## **Data Supporting Guideline Requirements for the Reregistration of Methylene bis(thiocyanate)**

| <b>REQUIREMENT</b>                                      | <b>USE PATTERN</b> | <b>CITATION(S)</b>   |
|---------------------------------------------------------|--------------------|----------------------|
| <b>63-12</b> <b>pH</b>                                  | ALL                | MRID 41648003        |
| <b>63-13</b> <b>Stability</b>                           | ALL                | 43328601, 41648003   |
| <b><u>ECOLOGICAL EFFECTS</u></b>                        |                    |                      |
| <b>71-1A</b> <b>Acute Avian Oral - Quail/Duck</b>       | FM                 | MRIDs 150232, 150231 |
| <b>71-2A</b> <b>Avian Dietary - Quail</b>               | FM                 | MRID 150233          |
| <b>71-2B</b> <b>Avian Dietary - Duck</b>                | FM                 | MRID 150232          |
| <b>71-3</b> <b>Wild Mammal Toxicity</b>                 | FM                 | MRID 41592901        |
| <b>72-1A</b> <b>Fish Toxicity Bluegill</b>              | FM                 | MRID 40518608        |
| <b>72-1C</b> <b>Fish Toxicity Rainbow Trout</b>         | FM                 | MRID 40518609        |
| <b>72-2A</b> <b>Invertebrate Toxicity</b>               | FM                 | MRID 40518601        |
| <b>72-3A</b> <b>Estuarine/Marine Toxicity - Fish</b>    | FM                 | MRID 42513402        |
| <b>72-3B</b> <b>Estuarine/Marine Toxicity - Mollusk</b> | FM                 | MRID 42441601        |
| <b>72-3C</b> <b>Estuarine/Marine Toxicity - Shrimp</b>  | FM                 | MRID 42513401        |
| <b>72-4B</b> <b>Life Cycle Invertebrate</b>             | FM                 | MRID 42517001        |
| <b><u>TOXICOLOGY</u></b>                                |                    |                      |
| <b>81-1</b> <b>Acute Oral Toxicity - Rat</b>            | FM                 | MRID 41592901        |
| <b>81-2</b> <b>Acute Dermal Toxicity - Rabbit/Rat</b>   | FM                 | MRID 42873101        |
| <b>81-3</b> <b>Acute Inhalation Toxicity - Rat</b>      | FM                 | MRID 41201601        |
| <b>81-4</b> <b>Primary Eye Irritation - Rabbit</b>      | FM                 | WAIVED               |
| <b>81-5</b> <b>Primary Dermal Irritation - Rabbit</b>   | FM                 | MRID 43699601        |
| <b>81-6</b> <b>Dermal Sensitization - Guinea Pig</b>    | FM                 | MRID 159567          |

## **Data Supporting Guideline Requirements for the Reregistration of Methylene bis(thiocyanate)**

| <b>REQUIREMENT</b>                              | <b>USE PATTERN</b>                               | <b>CITATION(S)</b>                     |
|-------------------------------------------------|--------------------------------------------------|----------------------------------------|
| <b>82-1A</b>                                    | <b>90-Day Feeding - Rodent</b>                   | FM<br>MRID 43420001                    |
| <b>82-2</b>                                     | <b>21-Day Dermal - Rat</b>                       | FM<br>MRID 41111901                    |
| <b>82-4</b>                                     | <b>90-Day Inhalation - Rat</b>                   | FM<br>REQUIRED                         |
| <b>83-1A</b>                                    | <b>Chronic Feeding Toxicity - Rodent</b>         | FM<br>MRID 42777601                    |
| <b>83-1B</b>                                    | <b>Chronic Feeding Toxicity -<br/>Non-Rodent</b> | FM<br>MRID 41463201                    |
| <b>83-2A</b>                                    | <b>Oncogenicity - Rat</b>                        | FM<br>MRID 42777601                    |
| <b>83-2B</b>                                    | <b>Oncogenicity - Mouse</b>                      | FM<br>MRID 42777301                    |
| <b>83-3A</b>                                    | <b>Developmental Toxicity - Rat</b>              | FM<br>MRID 41171901                    |
| <b>83-3B</b>                                    | <b>Developmental Toxicity - Rabbit</b>           | FM<br>MRID 41171902                    |
| <b>83-4</b>                                     | <b>2-Generation Reproduction - Rat</b>           | FM<br>MRID 42028601                    |
| <b>84-2A</b>                                    | <b>Gene Mutation (Ames Test)</b>                 | FM<br>MRID 41003701                    |
| <b>84-2B</b>                                    | <b>Structural Chromosomal Aberration</b>         | FM<br>MRID 41503801                    |
| <b>84-4</b>                                     | <b>Other Genotoxic Effects</b>                   | FM<br>MRIDs 41503802, 151926, 41003703 |
| <b>85-1</b>                                     | <b>General Metabolism</b>                        | FM<br>MRID 41088501, 41774501          |
| <b><u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u></b> |                                                  |                                        |
| <b>133-3</b>                                    | <b>Dermal Passive Dosimetry Exposure</b>         | FM<br>REQUIRED                         |
| <b>133-4</b>                                    | <b>Inhalation Passive Dosimetry<br/>Exposure</b> | FM<br>REQUIRED                         |
| <b>231</b>                                      | <b>Dermal Exposure at Outdoor Sites</b>          | FM<br>REQUIRED                         |
| <b>232</b>                                      | <b>Respiratory Exposure at Outdoor<br/>Sites</b> | FM<br>REQUIRED                         |

## **Data Supporting Guideline Requirements for the Reregistration of Methylene bis(thiocyanate**

| <b>REQUIREMENT</b>        | <b>USE PATTERN</b>                          | <b>CITATION(S)</b> |                      |
|---------------------------|---------------------------------------------|--------------------|----------------------|
| <b>233</b>                | <b>Dermal Exposure at Indoor Sites</b>      | <b>FM</b>          | <b>REQUIRED</b>      |
| <b>234</b>                | <b>Respiratory Exposure at Indoor Sites</b> | <b>FM</b>          | <b>REQUIRED</b>      |
| <b>ENVIRONMENTAL FATE</b> |                                             |                    |                      |
| <b>161-1</b>              | <b>Hydrolysis</b>                           | <b>FM</b>          | <b>MRID 43092101</b> |
| <b>168-1-ss</b>           | <b>Aqueous Availability</b>                 | <b>FM</b>          | <b>MRID 43545601</b> |
| <b>168-2-ss</b>           | <b>Photodegradation - On Wood</b>           | <b>FM</b>          | <b>MRID 43511101</b> |





## 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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**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 © 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 upgradable (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 upgradable, 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 upgradable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

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

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

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

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



the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

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

### III-D REQUESTS FOR DATA WAIVERS

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

## IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

### IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

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

#### IV-C EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

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

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

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

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

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

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

**SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE**

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

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form 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

## METHYLENE BIS(THIOCYANATE) DATA CALL-IN CHEMICAL STATUS SHEET

### INTRODUCTION

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

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

### DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for methylene bis(thiocyanate) are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on methylene bis(thiocyanate) 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 methylene bis(thiocyanate) 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 Karen Jones at (703) 308-8047.

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

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

**RE: methylene bis(thiocyanate)**

## 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 METHYLENE BIS(THIOCYANATE); 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 MBTC 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 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.

Sixty two active products were found which contain MBTC as an active ingredient. One product, 10445-92, will not be batched because of insufficient CSF. The remaining products have been placed into 3 Tables in accordance with the active and inert ingredients, type of formulation and current labeling.

**TABLE I**

Batch 1 Active Ingredients of Methylene bis(thiocyanate)

**TABLE II**

Batch 1 Methylene bis(thiocyanate) and Bis (trichloromethyl) Sulfone  
 Batch 2 Methylene bis(thiocyanate) and beta-Bromo-beta-Nitrostyrene  
 Batch 3 Methylene bis(thiocyanate) and dodecyl guanidine HCl  
 Batch 4 Methylene bis(thiocyanate) and 2-(Thiocyanomethylthio) benzothiazole  
 Batch 5 Methylene bis(thiocyanate) and chlorothalonil

**TABLE III**

Batch 1 Methylene bis(thiocyanate) at low concentrations of Methylene bis(thiocyanate) and solvents, and surfactants.

**TABLE I**

Batch 1 consists of Active Ingredients (AIs) or concentrations of Methylene bis(thiocyanate). Data are available to identify the toxicity of these products. Products containing data reviews are identified with an asterisk (\*). They are summarized below:

| <u>Data Required</u> | <u>Toxicity Category</u> | <u>Classification</u> |
|----------------------|--------------------------|-----------------------|
| Acute Oral (§81-1)   | II                       | A                     |
| Acute Dermal (81-2)  | III                      | A                     |
| Eye Irr. (§81-4)     | I                        | A                     |
| Dermal Irr. (§81-5)  | I                        | A                     |
| Dermal Sens. (§81-6) | Sens.                    | A                     |

| EPA Reg# | %AI   | Formulation Type |
|----------|-------|------------------|
| 1448-80* | 99.0  | G                |
| 8622-42* | 98.5  | G                |
| 9386-12  | 100.0 | G                |
| 33766-1* | 99.0  | G                |
| 64715-1* | 99.0  | G                |
| 67869-17 | 100.0 | G                |

**Table II**

Batch 1 consists of products containing bistrichloromethyl sulfone (BisTCMS). No data are available for these products.

**Batch 1**

| EPA Reg.# | %MBTS/%AI | Formulation Type |
|-----------|-----------|------------------|
| 45017-27  | 5.0/ 49.6 | EC               |
| 68329-11  | 5.0/17.4  | EC               |
| 68329-15  | 5.0/20.4  | EC               |

Batch 2 consists of products containing 2-(thiocyano-methylthio) benzothiazole (TCMBT).

Data are available to identify the toxicity of these products. Products containing data reviews are identified with an asterisk (\*). They are summarized below:

| <u>Data Required</u> | <u>Toxicity Category</u> | <u>Classification</u> |
|----------------------|--------------------------|-----------------------|
| Acute Oral (§81-1)   | II                       | A                     |
| Acute Dermal (81-2)  | II                       | A                     |
| Eye Irr. (§81-4)     | I                        | A                     |
| Dermal Irr. (§81-5)  | I                        | A                     |
| Dermal Sens. (§81-6) | Sens.                    | A                     |

**Batch 2**

| EPA Reg. % | %MBTS/%AI   | Formulation Type |
|------------|-------------|------------------|
| 458-31     | 10%/10%     | EC               |
| 577-548    | 0.5%/0.5%   | WdPr             |
| 1448-81*   | 10%/10%     | EC               |
| 1448-101   | 5%/5%       | EC               |
| 1448-102*  | 2.5%/2.5%   | EC               |
| 1448-179   | 5%/5%       | EC               |
| 1448-344   | 10%/5%      | EC               |
| 7053-30    | 10%/5%      | EC               |
| 10445-92   | 10.4%/12.8% | EC               |
| 56156-1    | 0.5%/0.5%   | WdPr             |

Batch 3 consists of products containing *beta*-bromo-*beta* nitrostyrene (BNS).

Data are available to identify the toxicity of these products. Products containing data reviews are identified with an asterisk (\*). They are summarized below:

|                  |                 |                       |
|------------------|-----------------|-----------------------|
| <u>Data</u>      | <u>Toxicity</u> | <u>Classification</u> |
| <u>Required</u>  | <u>Category</u> |                       |
| Eye Irr. (S81-4) | I               | A                     |

**Batch 3**

| EPA Reg. # | %MBTS/%AI | Formulation Type |
|------------|-----------|------------------|
| 3876-90    | 5%/17.4%  | EC               |
| 3876-127*  | 5%/36.8%  | EC               |
| 45017-25   | 5%/36.8%  | EC               |
| 68329-13   | 5%/36.8%  | EC               |

Batch 4 consists of products containing dodecyl guanidine HCl (DGH).

Data are available to identify the toxicity of these products. Products containing data reviews are identified with an asterisk (\*). They are summarized below:

| <u>Data Required</u> | <u>Toxicity Category</u> | <u>Classification</u> |
|----------------------|--------------------------|-----------------------|
| Acute Oral (§81-1)   | II                       | A                     |
| Acute Dermal (81-2)  | III                      | A                     |
| Acute Inhal. (81-3)  | II                       | A                     |
| Eye Irr. (§81-4)     | I                        | A                     |
| Dermal Irr. (§81-5)  | III                      | A                     |
| Dermal Sens. (§81-6) | Sens.                    | V                     |

**Batch 4**

| EPA Reg.# | %MBTS/%AI | Formulation Type |
|-----------|-----------|------------------|
| 3876-121* | 5%/10%    | EC               |
| 34571-13  | 5%/10%    | EC               |
| 45017-28  | 5%/10%    | EC               |
| 68329-10  | 5%/10%    | EC               |

Batch 5 consists of products containing chlorothalonil (CTN).

Data are available to identify the toxicity of these products. Products containing data reviews are identified with an asterisk (\*). They are summarized below:

| <u>Data Required</u> | <u>Toxicity Category</u> | <u>Classification</u> |
|----------------------|--------------------------|-----------------------|
| Acute Oral (§81-1)   | III                      | A                     |
| Acute Dermal (81-2)  | III                      | A                     |
| Acute Inhal. (81-3)  | II                       | A                     |
| Eye Irr. (§81-4)     | I                        | A                     |
| Dermal Irr. (§81-5)  | II                       | A                     |
| Dermal Sens. (§81-6) | Sens                     | A                     |

**Batch 5**

| EPA Reg.#  | %MBTS/%AI   | Formulation Type |
|------------|-------------|------------------|
| 50534-208* | 14.7%/14.5% | EC               |

**Table III**

Batch 1 consists of products containing low levels of Methylene bis(thiocyanate) (10% or less). Data are available to identify the toxicity of these products. Products containing data reviews are identified with an asterisk (\*). They are summarized below:

| <u>Data Required</u> | <u>Toxicity Category</u> | <u>Classification</u> |
|----------------------|--------------------------|-----------------------|
| Acute Oral (§81-1)   | III                      | A                     |
| Acute Dermal (81-2)  | III                      | A                     |
| Acute Inhal. (81-3)  | II                       | A                     |
| Eye Irr. (§81-4)     | I                        | A                     |
| Dermal Irr. (§81-5)  | I                        | A                     |
| Dermal Sens. (§81-6) | Sens.                    | A                     |

**Batch1**

| EPA Reg. # | %AI  | Formulation Type |
|------------|------|------------------|
| 1409-58    | 0.2  | WdPr             |
| 1448-34    | 10.0 | EC               |
| 1448-94*   | 5.0  | EC               |
| 1448-147*  | 10.0 | EC               |
| 1448-171   | 2.5  | EC               |
| 1448-172*  | 2.5  | EC               |
| 1448-178*  | 5.0  | EC               |
| 1448-249   | 2.5  | EC               |
| 1448-357   | 10.0 | EC               |
| 1448-358   | 10.0 | EC               |
| 1448-359   | 10.0 | EC               |
| 1448-360   | 10.0 | EC               |
| 1706-112   | 10.0 | EC               |
| 1757-42    | 10.0 | EC               |
| 3876-61    | 5.0  | EC               |
| 4654-14    | 10.0 | EC               |
| 4654-16    | 9.5  | EC               |
| 6832-139   | 5.90 | EC               |
| 7053-31    | 2.5  | EC               |
| 9386-4*    | 10.0 | EC               |
| 9386-26    | 10.0 | EC               |
| 9386-31    | 10.0 | EC               |
| 10445-61   | 10.0 | EC               |
| 10445-60   | 10.2 | EC               |
| 33677-4*   | 10.0 | EC               |
| 38635-5    | 10.0 | EC               |

|          |      |    |
|----------|------|----|
| 44392-11 | 2.5  | EC |
| 45017-13 | 7.1  | EC |
| 45017-19 | 7.0  | EC |
| 45017-28 | 5.0  | EC |
| 47091-12 | 12.0 | EC |
| 56473-2  | 1.0  | EC |
| 55710-2  | 2.5  | EC |
| 68329-10 | 5.0  | EC |

The remaining product is unbatched due to insufficient CSF:

| EPA Reg. # | %A.I. | Type of Formulation |
|------------|-------|---------------------|
| 10445-92   | 7.1   | GR                  |

**Abbreviations:**

A = Acceptable

EC = Emulsifiable Concentrate

GR = Granular

WdPr = Wood Preservative

**Attachment 5. List of Registrants Sent This Data Call-In Notice**



## **Instructions for Completing the Confidential Statement of Formula**

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

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









United States Environmental Protection Agency  
 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 |
| Product Name | EPA Reg. No.   |

**I Certify that:**

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

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

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

**Certification:**

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

|                                                  |      |
|--------------------------------------------------|------|
| Signature of Company's Authorized Representative | Date |
|--------------------------------------------------|------|

Name and Title (Please Type or Print)



**CERTIFICATION WITH RESPECT TO  
DATA COMPENSATION REQUIREMENTS**

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

**Please fill in blanks below.**

Company Name

Company Number

Product Name

EPA Reg. No.

**I Certify that:**

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.
2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)  
  
 The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"
3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature

Date

Name and Title (Please Type or Print)

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

Signature

Date

Name and Title (Please Type or Print)

The following is a list of available documents for methylene bis(thiocyanate) 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 by using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV.

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 methylene bis(thiocyanate).

The following documents are part of the Administrative Record for methylene bis(thiocyanate) 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

