



R.E.D. FACTS

Methylene bis(thiocyanate)

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA, and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 2415, methylene bis(thiocyanate).

Use Profile

Methylene bis(thiocyanate) is used as a microbiocide/microbiostat, fungicide/fungistat, algicide, and disinfectant. End-use products are formulated as a soluble concentrate/liquid, a ready-to-use liquid, and a soluble concentrate/solid. Methylene bis(thiocyanate) is employed in water cooling systems, paint manufacturing, metalworking cutting fluids, pulp and paper mills, oil drilling/mud packing fluids, leather processing, wood pressure treatments (forest products), wood protection treatments to buildings/products, and latex paints (in-can). The chemical is applied by applicator rolls; brush; chemical pump; dip tank; drip-feed device; metering pump; paintbrush; roller; sprayer; sprinkler can; or from a tank.

Regulatory History

Methylene bis(thiocyanate) was first registered as a pesticide active ingredient in the United States in 1949. An Antimicrobial Data Call-In was issued in March 1987 for methylene bis(thiocyanate). 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 April, 1997 for inhalation toxicity data. Currently, 59 methylene bis(thiocyanate) products are registered.

Human Health Assessment

Toxicity

In a study using laboratory animals, methylene bis(thiocyanate) has been shown to be of high acute toxicity by the inhalation route, is a severe eye irritant, and is a moderate to severe dermal irritant. The chemical has, therefore, been placed in Toxicity Category I (the highest of four categories) for these effects. Methylene bis(thiocyanate) also is a skin sensitizer. Additional data on metabolism are needed to confirm the identity of its metabolites. Methylene bis(thiocyanate) is a Group D carcinogen, not classifiable as to human carcinogenicity.

Cyanide is a metabolite of methylene bis(thiocyanate), and both cyanide and formaldehyde are potential degradates. The thiocyanate ion may degrade to cyanide, but degradation data are lacking that would indicate whether this occurs in the working environment and, if so, under what conditions. Cyanide is extremely toxic by all routes of exposure.

Dietary Exposure

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

Occupational and Residential Exposure

There is potential for exposure to mixers, loaders, applicators, and others, during and after usual uses of methylene bis(thiocyanate) in commercial, industrial, and residential settings. EPA assessed the primary and secondary dermal exposure and risk to homeowners and occupational users, during and post-application.

EPA is concerned about risks to occupational painters, for whom Margins of Exposure (MOE's) without gloves are 16 using a brush and 7.1 using an airless sprayer (MOE's of 100 or greater would be considered acceptable). Additional use information is necessary before risk mitigation or a determination of eligibility can be made for those uses. The Agency also is concerned about risks to primary handlers open-pouring liquid formulations for large water cooling systems since their MOE is 31 (wearing gloves). EPA is requiring the use of a pump-metering system for these situations, which will increase the MOE to an acceptable 3,524.

Human Risk Assessment

Since methylene bis(thiocyanate) has no food or feed uses, dietary risk is not expected.

EPA is concerned about possible effects from inhalation exposure to methylene bis(thiocyanate), based on a study which shows very high acute toxicity. The inhalation toxicity study is of poor quality, however, and cannot be used for risk assessment purposes. Surrogate data for industrial biocide uses show that inhalation exposure for some use scenarios is below the limit of detection. The Agency is requiring a sub-acute, 90-day inhalation study to quantify the level of hazard posed by exposure via the inhalation route. Once those data are received, reviewed, and accepted, EPA will conduct an inhalation risk assessment for methylene bis(thiocyanate).

Although methylene bis(thiocyanate) may release formaldehyde or cyanide, OSHA has a standard to monitor workers' exposure to these chemicals during industrial uses of methylene bis(thiocyanate) in occupational settings. No additional human health risk of concern, therefore, is expected. In addition, EPA is requiring, through labeling, the use of a respirator for all methylene bis(thiocyanate) end-use products in Toxicity Categories I and II, because of acute inhalation toxicity concerns. The Agency has required a subacute inhalation study. Additional studies measuring handler exposure including air monitoring studies will be addressed in a future Generic Data Call-In affecting all industrial biocide chemicals.

Of greatest concern is the risk posed to methylene bis(thiocyanate) handlers, particularly occupational applicators who come into contact with methylene bis(thiocyanate) during treatment of wood and paint products, along with post-application exposures to methylene bis(thiocyanate) and its degradates. Exposure and risk to workers will be mitigated by the use of Personal Protective Equipment (PPE) and engineering controls, as required by the RED.

FQPA Considerations

In developmental toxicity studies for methylene bis(thiocyanate), developmental effects did not occur at any dose level, including doses which resulted in maternal toxicity. EPA generally would 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, 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 cumulative risks will be assessed when methodologies for determining common mode of toxicity and performing cumulative risk assessment are finalized.

Environmental Assessment**Environmental Fate**

The Agency does not anticipate ground water contamination from the pesticidal uses of methylene bis(thiocyanate). The chemical 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. However, in actual outdoor wood treatment situations, methylene bis(thiocyanate) products are applied with a sealant/water repellent which inhibits the leaching process. Most applications are residential, and involve little environmental exposure.

Ecological Effects

Methylene bis(thiocyanate) is practically nontoxic to moderately toxic to birds on an acute basis; highly toxic to very 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.

Environmental Fate and Ecological Effects Risk Assessment

The Agency requires only a limited set of ecotoxicology and environmental fate studies for microbiocides. While the hazard to aquatic organisms from methylene bis(thiocyanate) has been characterized, a 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. Product labels must require that discharges to aquatic environments comply with an NPDES permit.

Methylene bis(thiocyanate) has a very low potential to leach into groundwater or to run off into surface water under typical use conditions.

Wildlife are not expected to be exposed to methylene bis(thiocyanate) from its outdoor wood preservative uses. There is little likelihood, therefore, of adverse effects occurring to wildlife.

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. Further, methylene bis(thiocyanate) degrades quickly and would not be persistent if it reached the environment.

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 requirements.

Risk Mitigation

To lessen the risk of occupational/residential inhalation or dermal exposure posed by methylene bis(thiocyanate), EPA is requiring the following risk mitigation measures.

PPE for Occupational Handlers

- Leather or Wood Processing Dip Applications - Handlers must wear chemical-resistant full-front aprons with attached full-sleeve gloves due to concerns about potentially high dermal exposures during introduction and removal of leather or wood products, by hand, into and from dip vats.
- Spray Applications - 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.

Engineering Controls for Occupational Uses

- Cooling Water Systems - Instead of open-pouring, use of a pump-metering system is required for all cooling water systems with a capacity of > 4000 gallons using methylene bis(thiocyanate), to reduce dermal exposure and risk to handlers.

Post-Application Safety Requirements

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

- Spray Applications in Indoor or Enclosed Areas - All persons, other than handlers involved in the spray application, must remain at least 25 feet outside the treatment site during application and until sprays have settled out of the air, due to inhalation concerns.
- Spray and Dip Applications - All persons handling treated materials, such as leather or wood products, still wet with the application must wear a chemical-resistant apron and chemical resistant gloves due to skin irritation concerns.

Additional Data Required

EPA will require the following additional generic studies for methylene bis(thiocyanate) to confirm its regulatory assessments and conclusions:

- A 90-day inhalation study (GDLN 84-2), required as part of a Generic Data Call-In issued in August 1997, to quantify the level of hazard posed by exposure via the inhalation route.
- Additional metabolism data, to adequately identify metabolites.
- Additional use information on what types of paints contain methylene bis(thiocyanate), to make an eligibility decision on occupational uses of paint and ready-to-use products.
- Additional data on occupational and post application exposures. Much of the exposure data needed for methylene bis(thiocyanate) is generic in nature and also will be required for other antimicrobial chemicals with similar

characteristics and the same uses. EPA is therefore developing a generic exposure DCI. Methylene bis(thiocyanate) registrants will receive this generic exposure DCI at the same time as registrants of other chemicals with similar uses. Data will be required:

- 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; and
- For painting with a sprayer.

Through this DCI, EPA also will require 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.

EPA also requires product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All methylene bis(thiocyanate) end-use products must comply with EPA's current pesticide product labeling requirements and with the following. For a comprehensive list of labeling requirements, please see the methylene bis(thiocyanate) RED document.

Personal Protective Equipment (PPE) Requirements

EPA is requiring the following minimum, baseline PPE, based on the acute toxicity of methylene bis(thiocyanate). Handlers must wear:

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

If the end-use product is classified as Toxicity Category I or II for eye irritation potential, add to the above 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:

- Chemical-resistant apron, and
- Chemical-resistant gloves.

If the end-use product is classified as Toxicity Category I or II for acute inhalation toxicity, add:

- Respirator (the type must be specified; EPA will assist registrants in determining appropriate respirators during product reregistration).

When labeling permits application as a dip, add this statement:

“Handlers participating in hand-dip applications, including introduction of material 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.”

Engineering Control Restriction

Liquid product formulations applied to cooling water systems of > 4000 gallons per day must include this label statement:

“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.”

Application Restrictions

All end-use product labels must bear the following restrictions:

"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.”

When labeling permits application as a spray, include:

“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.”

For liquid end-use products:

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

User Safety Recommendations

All end-use product labels must contain the following statements:

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

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

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

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).

Effluent Discharge Labeling Statement

All end use products must include this statement:

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.”

Regulatory Conclusion

EPA has determined that products containing methylene bis(thiocyanate) are eligible for reregistration **except** products labeled for paint uses and ready-to-use products that are applied with a paint brush, roller or compressed air sprayer. Before a decision can be made on those uses, 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 is needed.

Generally, methylene bis(thiocyanate) uses that showed acceptable Margins of Exposure (MOE's) from dermal exposure are eligible for reregistration. The Agency could not make a decision on uses for which there is no dermal exposure data, and where there is no way to determine if exposure is more or less than for uses with data available.

The Agency, therefore, finds that products containing methylene bis(thiocyanate) as the active ingredient bearing the following uses only are eligible for reregistration:

- 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 use of eligible methylene bis(thiocyanate) products in accordance with labeling specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required confirmatory generic data, product specific data, CSFs, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to methylene bis(thiocyanate) will be reregistered when all of their other active ingredients also are eligible for reregistration.

EPA does not have enough information at this time to make an eligibility decision for methylene bis(thiocyanate) products labeled for the following uses:

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).

The Agency is requiring additional data in order to develop a more complete data base regarding these uses of methylene bis(thiocyanate).

Additional Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for methylene bis(thiocyanate) during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the methylene bis(thiocyanate) RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the methylene bis(thiocyanate) RED, or reregistration of individual products containing methylene bis(thiocyanate), please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.