



R.E.D. FACTS

Bis(trichloromethyl) sulfone

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. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that 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 2055, bis(trichloromethyl) sulfone.

Use Profile

Bis(trichloromethyl) sulfone is used to control microbes, algae, and fungi in cooling water systems, waste disposal systems, pulp and paper mill water systems, oil extraction systems, and other industrial settings (adhesives, industrial coatings, industrial emulsions, etc.). Formulations include soluble concentrated liquids, ready-to-use liquids, and soluble concentrated solids. These products are added to systems and industrial products using pouring and pumping methods. Product labeling includes National Pollutant Discharge Elimination System (NPDES) license requirements.

Regulatory History

Bis(trichloro)methyl sulfone was first registered in the U.S. in 1967 as a fungicide. In 1968, another registration was issued for a bis(trichloromethyl) sulfone product with additional biocide uses. Currently there are five companies with fourteen products. One of these products is registered as a technical with an active ingredient declaration of 98%. The

others are end-use products containing from 2.5% to 49% bis(trichloromethyl) sulfone.

In 1987 the Agency issued the Antimicrobial Data Call-In Notice to obtain additional chronic and subchronic toxicity data for this and other antimicrobial chemicals.

Human Health Assessment

Toxicity

Bis(trichloromethyl) sulfone is slightly toxic to non-toxic in acute oral and dermal toxicity tests. However, it is highly toxic in eye irritation, dermal irritation, and inhalation acute toxicity studies.

In an acute neurotoxicity study with rats, decreased food consumption, body weights, core body temperatures, and motor activity were observed in the low dose animals. In a subchronic dermal rabbit toxicity study changes in the blood and clinical chemistry values occurred. In developmental studies in the rat and rabbit, signs of maternal toxicity included decreased body weight gains and reduced food consumption. Incidences of clinical toxicity were observed in maternal rabbits at the mid-dose. Although no developmental treatment-related effects were noted in rabbits, decreased fetal body, skeletal, and external abnormalities were identified in the mid-dose animals. Evidence of mutagenicity was observed in several studies. Because the findings were equivocal in the gene mutation study, an assay that involves animal germ cells is required.

Dietary Exposure

Tolerances or residue limits are established for bis(trichloromethyl) sulfone in adhesives, paper and paper products which may contact food. These uses of bis(trichloromethyl) sulfone in the manufacture of paper, paperboard (21 CFR §176.300) and adhesives (21 CFR §175.105) which may contact food are regulated by the U.S. Food and Drug Administration (FDA). There are no other registered food uses of bis(trichloromethyl) sulfone.

Occupational and Residential Exposure

Based on the current use patterns, handlers (mixers, loaders, and applicators) may be exposed to bis(trichloromethyl) sulfone during and after normal use of the liquid and solid soluble concentrates and the ready-to-use liquid formulations. An exposure assessment is appropriate based on the toxicological endpoints from the subchronic dermal and developmental toxicity studies in the rat.

Several exposure scenarios were considered in the Agency's exposure assessment, including both open and closed application systems. Data suggest that for the estimation of dermal exposures were appropriate. As expected, exposures to handlers were greatest from open systems, particularly in cooling water and oil drilling muds/packer fluid applications. For these scenarios, margins of exposure (MOEs) were less than 100 for

both the short-term and intermediate term exposures. An MOE of less than 100 is of concern to the Agency.

To mitigate these risks to handlers, EPA is requiring use of a closed system for loading and application in water cooling systems and oil drilling muds/packer fluid scenarios. For all other uses of bis(trichloromethyl) sulfone, baseline personal protective equipment (PPE) equivalent to those worn in the exposure study are required.

Although exposures to workers in areas where bis(trichloromethyl) sulfone has recently been applied are expected, EPA believes that these exposures would be significantly less than those for handlers applying the pesticide.

There are no bis(trichloromethyl) sulfone products labeled for homeowner use. Exposures to homeowners may occur from products, such as adhesives or paper products, treated with bis(trichloromethyl) sulfone. Again, the Agency believes that these exposures would be minimal.

Human Risk Assessment

Bis(trichloromethyl) sulfone was determined to be highly toxic in eye irritation, dermal irritation and inhalation acute toxicity studies, but was slightly toxic to non-toxic in other acute toxicity tests.

The use of bis(trichloromethyl) sulfone in the manufacture of paper, paperboard, and adhesives which may contact food are regulated by FDA. There are no other registered food uses.

The Agency is concerned for exposures to bis(trichloromethyl) sulfone in the workplace, especially for handlers open-pouring the pesticide in cooling water and oil drilling mud/packer fluid applications. To protect these workers, the Agency is requiring closed system loading and application methods. Baseline PPE is required for other uses of bis(trichloromethyl) sulfone.

Environmental Assessment

Environmental Fate

Marginal data are available to estimate the environmental fate of bis(trichloromethyl) sulfone. These data suggest that the primary route of dissipation is through microbial action, with a half-life of less than 0.5 days.

Ecological Effects

Bis(trichloromethyl) sulfone is practically non-toxic to birds, and highly to very highly toxic to freshwater and estuarine/marine organisms.

Ecological Effects Risk Assessment

While the hazard to aquatic organisms from bis(trichloromethyl) sulfone has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments from this use are regulated under the NPDES permitting program of EPA's Office of Water. The Agency currently requires that labels for all bis(trichloromethyl) sulfone

products require that discharges to aquatic environments comply with an NPDES permit.

Risk Mitigation

To lessen the risks posed by bis(trichloromethyl) sulfone, EPA is requiring the following risk mitigation measures.

- EPA is requiring meter-pump loading and application of bis(trichloromethyl) sulfone for the following uses: pasteurizer/warmer/cannery cooling water systems, commercial/industrial water cooling systems, evaporative-condenser water systems, heat-exchanger water systems, and oil recovery drilling muds/packer fluids.
- The Agency is establishing active ingredient based minimum PPE requirements for primary occupational handlers. Since all the MOEs generated are based on units of exposure from the Chemical Manufacturers Association exposure study in which handlers wore chemical resistant gloves, such chemical-resistant gloves are required for occupational handlers of bis(trichloromethyl) sulfone.

Additional Data Required

EPA is requiring additional generic information for bis(trichloromethyl) sulfone to confirm its regulatory assessments and conclusions, including an acute neurotoxicity study in rats, gene mutation study, and a sister chromatid exchange study.

Data generated by the Antimicrobial Task Force of the Chemical Manufacturers Association have been used to address these exposures in the bis(trichloromethyl) sulfone RED document; however, the Agency requires offers of compensation be made for the use of these data or new, adequate data be submitted. A Data Call-In has been issued to the registrants of bis(trichloromethyl) sulfone requiring these actions.

Product Labeling Changes Required

All bis(trichloromethyl) sulfone end-use products must comply with EPA's current pesticide product labeling requirements and with the following.

- PPE/Engineering Control Requirements for Pesticide Handlers
For sole-active-ingredient end-use products that contain bis(trichloromethyl) sulfone, the product labeling must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth below. Any conflicting PPE/engineering control requirements on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain bis(trichloromethyl) sulfone, the PPE/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) Engineering Control Requirements

Products with bis(trichloromethyl) sulfone must be labeled to require pump engineering controls during loading and application for the following uses: oil recovery drilling muds/packer fluids, pasteurizer/warmer/cannery cooling water systems, commercial/industrial water cooling systems, evaporative-condenser water systems, and heat exchanger water systems.

In the "Directions For Use" portion of the label referring to these uses, registrants must insert the following language:

"This product must be loaded and applied only using a meter-pump system or a closed loading/application system for the following uses: {list uses}. Open pouring is prohibited."

(2) Minimum (Baseline) Personal Protective Equipment Requirements

EPA is establishing active-ingredient-based minimum (baseline) PPE for bis(trichloromethyl) sulfone end-use products that are intended for occupational use. Product labels must be amended to include the following statement:

"Applicators and other handlers must wear: chemical resistant gloves, long pants, a long sleeved shirt, shoes and socks."

Placement in labeling: The PPE must be placed on the end-use product labeling in the location specified in PR Notice 93-7 and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Determining PPE Requirements for End-Use Product Labels:

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) PPE specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, its placement, format, and wording refer to PR Notice 93-7. NOTE: If the end-use product is classified as toxicity category I or II for eye irritation potential, protective eyewear is also required.

- The Agency is requiring the following labeling statements to be located on all end-use products containing bis(trichloromethyl) sulfone that are intended primarily for occupational use.

Application Restrictions

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

User Safety Requirements

--Registrants: add the following statements if coveralls are required for pesticide handlers on the end-use product label:

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

--Registrants: add the following statements always:

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

User Safety Recommendations

- "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."
- To clarify the intent of the oil recovery drilling muds/packer fluids use (as an indoor or outdoor use pattern) the following statement must be added to the labels for terrestrial non-food oil/gas drilling muds and packer fluids:
- "For use on terrestrial oil wells only."
- And the following statement must be added to the precautionary labeling:
- "Do not apply in marine and/or estuarine oil fields."
- The following statement must be added to the labels for aquatic non-food industrial drilling muds and packer fluids:
- "For use on offshore oil wells only."
- For use in both terrestrial and offshore oil drilling muds and packer fluids, the following statement must be added:
- "This product may be used for terrestrial and offshore oil drilling muds and packer fluids."
- 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).

- To clarify that water cooling uses do not include once-through systems, the following statement must be added:

"This product may not be used in once-through cooling systems."

For a comprehensive list of labeling requirements, please see the Bis(trichloromethyl) sulfone RED document.

Regulatory Conclusion

The use of currently registered products containing bis(trichloromethyl) sulfone in accordance with approved labeling and as described in the Reregistration Eligibility Document will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Bis(trichloromethyl) sulfone products will be reregistered once the required product-specific data, confirmatory generic data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for bis(trichloromethyl) sulfone 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 on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV.

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 [name] 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 bis(trichloromethyl) sulfone RED, or reregistration of individual products containing bis(trichloromethyl) sulfone, 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.