United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-96-011 June 1996

R.E.D. FACTS

DIBROMODICYANO-BUTANE

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 2780, dibromodicyanobutane.

Use Profile

Dibromodicyanobutane (1, 2-dibromo-2, 4-dicyanobutane) is a microbiocide/microbiostat used to control slime-forming bacteria and fungi in commercial/industrial water cooling systems (recirculating), oil recovery

drilling muds/packer fluids, pulp/paper mill water systems, secondary oil recovery rejection water, industrial adhesives and coatings, resin/latex/polymer emulsions, metalworking cutting fluids, paints, specialty industrial products (including fiber processing fluids, waxes, polishes and inks), and wet-end additives/industrial processing chemicals. Formulations include soluble concentrates both liquid and solid, pellets and tablets. Dibromodicyanobutane is applied by metering pump and chemical pump. The use practice limitations include NPDES permit restriction. There are no residential products registered.

Regulatory History

Dibromodicyanobutane was first registered as a pesticide in the U.S. in 1980. Data Call-Ins were issued by the Agency in March, 1987 (Antimicrobial Data Call-In) and during the Phase IV Reregistration process in June of 1991. Currently eight products formulated with dibromodicyanobutane are registered by the Agency. Indirect food additive tolerances have been established for dibromodicyanobutane as a preservative in food grade adhesives (see 21 CFR § 175.105) and as a slimicide in the manufacture in food grade paper and paperboard at a maximum level of 0.005% of dry weight fiber (see 21 CFR § 176.300). These tolerances are under the jurisdiction of the U.S. Food and Drug Administration and are not directly regulated by EPA.

Human Health Assessment

Toxicity

In studies using laboratory animals, dibromodicyanobutane generally has been shown to be slightly to practically non-toxic for acute toxicity and has been placed in Toxicity Category III. However, it is a severe eye irritant and a human skin sensitizer. In subchronic studies using dibromodicyanobutane conducted in several mammalian species, no unusual compound related effects were observed except for thyroid follicular cell hyperplasia observed in the high dose group in dogs. This finding was further studied in a special study conducted at the lowest dose tested in the dog study (4.8 mg/kg/day). While the thyroid effect was considered significant by the oral route, dietary exposure to dibromodicyanobutane is expected to be negligible. Several developmental toxicity studies showed no compound-related external, visceral or skeletal abnormalities. Dibromodicyanobutane was positive in one mutagenicity assay, however, this positive finding was not confirmed in multiple other mutagenicity studies.

Dietary Exposure

The use of dibromodicyanobutane as an indirect food additive to adhesives or food grade paper and paperboard is expected to be negligible. There are no registered uses of dibromodicyanobutane directly on food, therefore, a dietary exposure and risk assessment are not applicable.

Occupational and Residential Exposure

No toxicological endpoints of concern were determined for short-term and intermediate term occupational/residential risk, except skin sensitization and eye irritation. A subchronic dermal toxicity study indicated that dibromodicyanobutane is not absorbed via the dermal route because no systemic toxicity was observed following repeated dermal application.

Human Risk Assessment

No subchronic endpoints of concern were triggered for dibromodicyanobutane. Its use pattern would not typically result in chronic exposure, and there are no registered direct food uses, therefore, a dietary exposure and risk assessment are not applicable.

No toxicological endpoints of concern, except for skin sensitization and eye irritation from acute exposures, were identified for occupational exposures. Therefore, an applicator exposure analysis and quantitative risk assessment are not warranted. To protect occupational handlers (mixers/loaders/applicators) from potential exposure, appropriate personal protective equipment (PPE) will be required based on the acute toxicity category of the end-use product.

Additionally, secondary occupational and residential handler exposure from treated paint, ink and wax products Are not expected to pose a significant risk because of the low concentration/dilution factor associated with these products.

Environmental Assessment

Environmental Fate

Dibromodicyanobutane is expected to be very mobile and non-persistent in aquatic and soil environments. Dissipation is expected to be controlled by rapid alkaline-catalyzed hydrolysis and microbially-mediated degradation. However, there is little information on the identity and environmental behavior of degradates.

Ecological Effects

Dibromodicyanobutane is slightly toxic to avian species on an acute oral and subacute dietary basis. It is also moderately toxic to fish and aquatic invertebrates on an acute basis. Because the fish studies conducted in 1975 provided only supplemental information and were not upgradeable to the current standards, a new freshwater acute toxicity fish study in bluegill sunfish has been required.

Ecological Effects Risk Assessment

Only a limited set of ecotoxicology and environmental fate studies for microbiocides such as dibromodicyanobutane are required. The information available on ecological effects of dibromodicyanobutane indicates slight toxicity to birds on an acute oral and subacute dietary basis and moderate toxicity to aquatic invertebrates and estuarine/marine animals. The chemical is expected to degrade rapidly in aquatic environments. While the hazard to aquatic organisms has been characterized to a limited extent, a quantitative risk assessment has not been conducted. The Agency currently requires that labels for dibromodicyanobutane products specify that discharges to aquatic environments must comply with NPDES permitting requirements.

Additional Data Required

The generic data base supporting the reregistration of dibromodicyanobutane for the above eligible uses has been reviewed and determined to be substantially complete. No new additional studies on dibromodicyanobutane are being required at this time. However, additional information about the identity of the hydrolysis degradates has been required because hydrolysis appears to be the major route of degradation.

The Agency is also requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula, and revised labeling for reregistration for product reregistration.

Product Labeling Changes Required

All dibromodicyanobutane end-use products must comply with EPA's current pesticide product labeling requirements. The Agency believes it is prudent to require additional use precautions to afford product users increased protection from unnecessary exposure to dibromodicyanobutane. For similar reasons the Agency is retaining current worker and environmental restrictions and precautions for risk reduction as specified below and in Section V of the dibromodicyanobutane RED.

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

"Only for formulation into a microbiocide/microbiostat/ bacteriostat for use as an additive for industrial adhesives, emulsions, resin/latex and polymer systems, metalworking cutting fluids, secondary oil recovery injection water, drilling muds, wet-end additives/industrial processing chemicals, specialty industrial products (includes fiber processing fluids, waxes, polishes, and inks), and latex and oil paints (varnish applied film).

A MP registrant may, at his/her discretion, add one of the following statements to a 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 use in facilities discharging directly or indirectly to the estuarine or marine environment."

To reduce environmental risk from dibromodicyanobutane discharge and disposal, product labels must include the statements pertaining to effluent discharge under the NPDES permitting system (refer to PR Notice 93-10) and disposal under any applicable federal laws after the above statement.

Personal Protective Equipment for Occupational Uses

The minimum handler labeling requirements for occupational uses of dibromodicyanobutane end-use products is:

"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:

-- "Protective eyewear."

If the end-use product is classified as toxicity category I or II for 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, 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.

*For the glove statement, use the statement established for dibromodicyanobutane through the instructions in Supplement Three of PR Notice 93-7. However, the corrosiveness and penetration of dibromodicyanobutane must be considered and appropriate chemical-resistant materials must be listed.

Placement in Labeling

The personal protective equipment requirements 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.

The agency is requiring the following labeling statements to be located on all end-use products containing dibromodicyanobutane that are intended primarily for occupational use.

Application Restrictions

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

User Safety Requirements

Registrant: add the following statements only if gloves or protective eyewear are required PPE on the end-use product:

"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."

Registrant: add the following statements only if gloves are required PPE on the end-use product:

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

Skin Sensitizer Statement

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

Clarification of Oil Drilling Mud Use

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

"For use in terrestrial wells only"

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

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

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

"For use in offshore wells only."

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

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

Additional 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)."

Regulatory Conclusion

The use of currently registered products containing dibromodicyanobutane in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Dibromodicyanobutane products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for dibromodicyanobutane 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 dibromodicyanobutane 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 dibromodicyanobutane RED, or reregistration of individual products

containing dibromodicyanobutane, 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.