United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-029 October 1995

R.E.D. FACTS

Bronopol

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 years ago 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 imposes any regulatory controls that are needed to effectively manage 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 2770, bronopol.

Use Profile

Bronopol is used as a microbiocide/microbiostat in oil field systems, air washer systems, air conditioning/humidifying systems, cooling water systems, papermills, absorbent clays, metal working fluids, printing inks, paints, adhesives and consumer/institutional products. A formulating technical material is also registered.

Regulatory History

A pesticide product containing bronopol as an active ingredient was first registered in the United States in 1984 for use in industrial bactericides, slimicides and preservatives.

In 1987, EPA issued the Antimicrobial Data Call-In Notice to obtain chronic and subchronic toxicity data for bronopol and other antimicrobials. A Data Call-In was issued for this chemical as part of the reregistration program in June 1991, and a second Data Call-In, for confirmatory exposure data, was issued in September 1995.

Human Health Assessment

Toxicity

In laboratory animal studies measuring acute toxicity, technical grade bronopol has been shown to cause severe effects by the dermal route, placing it in Toxicity Category I (the highest of four categories) for dermal toxicity. It has been shown to produce irritation in eye and dermal irritation studies, placing it in Toxicity Category I for eye irritation and Toxicity Category II for skin irritation. It is moderately toxic in oral toxicity studies, placing it in Toxicity Category II for oral toxicity. In an acute inhalation study, bronopol was found to be slightly toxic, placing it in Toxicity Category IV. This chemical is not a skin sensitizer based on a study using guinea pigs.

A 90-day oral toxicity study using rats indicated that bronopol is a severe gastrointestinal irritant. A similar study in beagle dogs indicated only treatment related effects of increased liver and spleen weights in the high dose group.

In a 90-day dermal toxicity study in rabbits, the NOEL for systemic toxicity was 2 mg/kg/day.

A chronic feeding/carcinogenicity study with rats resulted in high mortality, stomach lesions, and severe reduction in body weight gain. From a chronic dermal/carcinogenicity study, mice exhibited, moderate reduction in body weight gain. The Office of Pesticide Programs Reference Dose (RfD)/Peer Review Committee evaluated the carcinogenic potential of bronopol on April 18, 1995. The Committee classified bronopol as a Group E chemical (one for which there is evidence of noncarcinogenicity for humans), based on a lack of evidence of cancer effects in acceptable studies with two animal species, the rat and mouse.

Developmental toxicity studies were conducted using rats and rabbits. The results showed marginal to no effects in the rat study and effects only at the high dose level in the rabbit study.

A reproductive toxicity study using rats resulted in effects at the mid to high dose levels. The results included increases in kidney, thyroid and adrenal weights, decreases in liver weights, and decreased body weights. Bronopol was not mutagenic in four mutagenicity studies. Metabolism studies indicate that bronopol is primarily excreted in the urine.

Dietary Exposure

No dietary exposure is expected from the pesticide uses of bronopol since no food or feed uses are registered. However, an RfD was established recently at 0.1 mg/kg/day because the data base is available and because of possible long-term exposure to bronopol-containing products.

Occupational and Residential Exposure

Based on current use patterns, the potential exists for exposure and risks to handlers using open pour application methods for liquid formulations in water cooling systems. The margin of exposure (MOE) for the above liquid formulation application method is 14 which is unacceptable to the Agency. However, the MOE for the same liquid formulation application method using a metered systems is acceptable at 1,596. The Agency also believes formaldehyde may be released when bronopol decomposes in aqueous solutions.

Human Risk Assessment

Since bronopol has no food or feed uses, dietary risk is not expected. Bronopol is severely acutely toxic by the dermal route and is a corrosive eye irritant (Toxicity Category I). Based on unacceptable MOE for handlers using open pour application methods of liquid formulations to water cooling systems, the Agency is requiring metered pump systems for all water cooling system uses.

EPA is requiring that labels contain a statement advising workers to wear personal protective equipment(PPE), consisting of a long sleeved shirt and long pants, socks plus shoes, and chemical resistant gloves. Chemical resistant gloves are required for application of the end-use product to protect applicators' skin.

Although bronopol may release formaldehyde in aqueous solutions, minimal risk is expected due to the chemical's slow decomposition, and because OSHA has a standard to monitor workers' exposure to formaldehyde during industrial uses of bronopol in occupational settings. No additional human health risk of concern is expected.

Environmental Assessment

Environmental Fate

The Agency does not anticipate ground water contamination from the uses of bronopol. Although bronopol has high water solubility, high solubility in polar solvents, low solubility in nonpolar solvents, and favorable partitioning into water, the Agency feels that bronopol's short-lived environmental persistence reduces the potential for groundwater contamination.

Bronopol is stable to hydrolysis under normal conditions. However, at warmer temperatures and/or higher pH's, rapid hydrolysis may occur. Under these conditions, hydrolysis products include formaldehyde and lesser amounts of other degradates. Judging from its low octanol/water ratio and high solubility in water, bronopol is not expected to bioaccumulate. In tested mammalian species metabolism is reported to be rapid and complete, and accumulation does not occur.

Ecological Effects

Bronopol is practically nontoxic to slightly toxic to birds; slightly to moderately toxic to freshwater fish and terrestrial invertebrates; moderately

to highly toxic to estuarine/marine invertebrates; and slightly toxic to estuarine/marine fish.

Ecological Effects Risk Assessment

Risk to nontarget aquatic organisms can be expected through point source discharge of industrial microbiocides. In the case of bronopol, there are several use sites and environmental conditions where exposure to aquatic organisms is a possibility. However, industrial effluent discharges are governed by NPDES permits granted by state regulatory agencies and EPA.

Additional Data Required

EPA is requiring product-specific data, including product chemistry and efficacy data, revised Confidential Statements of Formula (CSFs), and revised product labeling for reregistration of products containing bronopol.

Product Labeling Changes Required

The labels of all registered pesticide products containing bronopol must comply with EPA's current pesticide labeling requirements. In addition:

Requirements:

All end-use (and manufacturing-use) products that may be contained in an effluent discharged to the waters of the U.S. or municipal sewer systems must be used in accordance with the requirements of the National Pollutant Discharge Elimination System (NPDES) permitting program.

Application Restrictions -The labels of all end-use products containing bronopol must bear the following restrictions:

"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."

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 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 drilling muds and packer fluids:

"For use in off-shore wells only."

For use in both terrestrial and offshore drilling muds and packer fluids:

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

Handler PPE for Occupational-Use Products - The personal protective equipment (PPE) for handlers engaged in occupational uses is long sleeve shirt and long pants, socks plus shoes, as well as chemical-resistant gloves.

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

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

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

Recommendations:

The labels of all bronopol end-use products 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."

Regulatory Conclusion

The uses of currently registered bronopol products with the above limitations, will not pose unreasonable risks to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

These bronopol products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and r

evised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for bronopol 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 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 bronopol 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 bronopol RED, or reregistration of individual products containing bronopol, 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 8:00 am and 6:00 pm Central Time, Monday through Friday.