United States Environmental Protection Agency | Office of Prevention, Pesticides And Toxic Substances (7508W) | December 1993 | EPA-738-F-93-023

R.E.D. FACTS

Bromine

Pesticide Reregstration

All pesticides sold or used 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 undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision Document, or RED. This fact sheet summarizes the information in the RED for bromine.

Use Profile

Bromine is registered for use in water filters to purify drinking water aboard U.S. Naval ships and offshore oil well platforms. It also is used as a general disinfectant and sanitizer in indoor, non-food contact areas such as commercial establishments, hospitals and households, to control bacteria and fungi. Bromine pesticide products may be formulated as a solid soluble concentrate or ready-to-use liquid. They are applied using a water filter unit, drip dispenser, automated metering system, fogger, or hand held or power sprayer.

Regulatory History

Bromine was first registered in May of 1976 for use in treating potable water through a polybrominated ion exchange resin aboard Naval surface ships. A food additive tolerance for 1.0 ppm residual bromine in potable water aboard Naval surface ships was established in April 1976 by the Environmental Protection Agency. Bromide ion levels in potable water were exempted from the requirement of a tolerance. (40 CFR § 185.425).

Toxicity

Human Health Assessment

In water and living organisms, bromine reacts with other compounds to form bromides. A great deal of information is available in the literature on bromides, which have long been used as human drugs (primarily as oral sedatives, diuretics and anti-epileptic treatments). Their human health effects are well known. Bromides depress the central nervous system when taken daily at a level of 1 to 2 grams per day. The effect is slowly reversed when dosing is stopped. Bromide has a half-life of about 12 days in the human body.

The levels of bromides consumed as drugs are far greater than the amounts that are ingested from the registered water purification uses. A moderate dose to treat epilepsy would be 50 milligrams per kilogram (mg/kg) per day. By comparison, ingestion of water treated with the bromine water filter unit results in consumption of no more than approximately 0.03 mg/kg/day from water containing up to 1 ppm available bromine for a 70 kg adult.

The lowest level of oral exposure known to result in bromide intoxication was 100 mg/dl (milligrams per deciliter), but signs of such effects may not occur even when blood levels are over 200 mg/dl. Most people develop signs of bromide intoxication at blood levels between 200 and 300 mg/dl.

Doses of 1.9 to 2.9 grams per day given to patients over a four month period did not induce signs of bromide intoxication. However, tremendous variation in responses among patients was noted. Acute overdoses in humans have produced vomiting or stupor, while chronic use has caused depression, loss of muscle coordination and psychoses. Two cases of human reproductive effects have been reported.

Based on acute toxicity studies using laboratory animals, sodium bromide has been placed in Toxicity Category III for acute oral and acute dermal effects, and in Toxicity Category IV (indicating the lowest level of acute toxicity) for eye and skin irritation. Sodium bromide is nonsensitizing to skin.

In subchronic feeding studies, at the highest dose level, effects on rats included lack of grooming, motor incoordination, growth retardation and thyroid inaction. In a chronic toxicity study using dogs, at the highest dose level, signs of bromide intoxication were seen. Pregnant rats fed bromide produced offspring with reduced learning ability.

In addition to bromide, bromate may form as a by-product under some conditions. The Agency believes there is sufficient and clear evidence that chronic oral exposure to bromate causes increased renal tumors in rats.

Based on information from several studies and the incidence of renal tumors in male rats, the Agency has assigned the bromate ion a Group B2 (probable human carcinogen) classification. A low dose linearized extrapolation model was used to quantitatively characterize risk for humans. A Q_1^* of 4.9×10^{-1} $(mg/kg/day)^{-1}$ for the potassium bromate was derived

from the combined renal adenoma and adenocarcinoma data (Kurokowa et al., 1986a). It is expected that other soluble salts of bromate are equally carcinogenic. Adjusting for the molecular weight, the unit risk for the bromate ion is calculated to be 6.5×10^{-1} $(mg/kg/day)^{-1}$.

Dietary Exposure

People may consume small amounts of bromine residues in treated drinking water aboard Navy ships or on oil well drilling platforms. However, adequate controls are in effect to ensure that residues will not exceed 1.0 ppm, the food additive tolerance level established for bromine in potable water (please see 40 CFR 185.425). EPA has reassessed this tolerance and found that it is set at an appropriate level and provides an adequate margin of safety to protect the public health.

However, there are no data on the amount of bromate, a species of potential concern. In the absence of actual data on the magnitude of bromate ion in potable water generated via bromination, the Agency attempted to determine the likelihood of the presence of bromate ion based on theoretical considerations. Information obtained from registrants, a bromine producer, other EPA offices, the bromine test kit manufacturer, a halogen chemist, and both medical and engineering specialists within the Navy Dept. indicate that when at port, virtually all potable water is obtained from an approved water source, and bromination is not necessary as such water has already been chlorinated. Virtually all (99%) brominated potable water used on board naval vessels has been derived via desalination using distillation. The pH of distilled water is known generally to be close to 6. Also, the "total available bromine" (TAB) concentrations in the potable water are initially ≤ 2 ppm (usually much less) but that the typical (and required) concentration is about 0.2 ppm in water after exposure to bromine for 30 min. The concentration of bromate ion in water cannot be calculated because the kinetics of bromine disproportionation have not been elucidated as they have for chlorine and iodine. However, the Agency expects that bromate ion would be nondetectable (< 0.5 ppb) in water of pH 5-6.

The available information does not allow the Agency to calculate the bromate ion concentration in potable water. A concentration of approximately 0.7 ppb bromate ion in water would correspond to a risk of 1×10^{-6} assuming 1.2 liters of water consumed per day and that ship personnel would be exposed for 6 months a year for 7 years, a typical exposure based on information provided by the Navy. If bromate ion were present at 0.7 ppb in water, this would represent 0.035% of the total bromine if the water had been treated with bromine at 2 ppm. (For comparison, a risk of 1×10^{-6} would correspond to a daily exposure of 0.054 ppb bromate ion in drinking water, over a 70-year lifetime.)

Because there is not enough information to permit the Agency to estimate the dietary exposure to bromate ion via potable water aboard Navy

vessels, the Agency has required representative monitoring data for the pH and bromate ion concentration of brominated, desalinated water.

Occupational and Residential Exposure

EPA is not concerned with potential human exposure from the surface sanitizer uses of bromine. The active ingredient in sanitizer products is present as bromide, and exposure to only very small amounts, below the level of toxicological concern, is expected. For large volume applications such as fogging, product labels instruct users to wear protective clothing, gloves and a respirator, to adequately ventilate spaces treated, and to avoid reentry of treated spaces for at least one hour after treatment.

Human Risk Assessment

Human health risks from exposure to bromine residues in potable drinking water are expected to be minimal because water must be tested to ensure that residues are at a sufficiently low level prior to consumption, and since the principal residue in water purification systems is bromide rather than bromine.

The two surface sanitizer products have a very low bromide content (0.04%). The potential for human exposure to bromide in these products is low and will not pose an unacceptable risk to humans, provided that current end-use product labeling which requires Personal Protective Equipment (gloves, protective clothing and respirator for large volume applications) and reentry restrictions is maintained.

Environmental Assessment

Environmental Fate

Bromine is a naturally occurring element that normally is found as bromide in living organisms and the environment. It is a common component in seawater and volcanic rocks.

The current use patterns of pesticide products containing bromine do not result in environmental exposure. Therefore, the RED includes no discussion of bromine's environmental fate.

Ecological Effects and Risk Assessment

Since bromine is only used indoors, EPA did not prepare an ecological effects risk assessment. Only two studies were required (a fish acute and an aquatic invertebrate acute study). These studies were used to determine the environmental hazard statement for labeling. These data show that bromine is highly toxic to freshwater fish and aquatic invertebrates.

Additional Data Required

The generic data base for bromine is substantially complete. The Agency is requiring product-specific data, including product chemistry, acute toxicity and efficacy studies, as well as revised Confidential Statements of Formula and revised labeling, for reregistration of pesticide products containing bromine.

Product Labeling Changes Required

The labels of all registered pesticide products containing bromine must comply with EPA's current pesticide labeling requirements.

All end-use bromine products must comply with EPA's current pesticide product labeling requirements. In addition, since bromine is highly toxic to aquatic organisms, end-use labels must contain the following statement:

"This pesticide is toxic to fish and aquatic invertebrates."

Regulatory Conclusion

The use of currently registered pesticide products containing bromine as labeled and specified in the RED document will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

These bromine products may be reregistered, if all active ingredients in the product are eligible, once the product-specific 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 Document (RED) for bromine 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.

Following the comment period, the bromine RED 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 bromine or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000. For information about reregistration of individual products containing bromine, please contact Frank Rubis, Product Reregistration Branch (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8184.