

R.E.D. FACTS

Potassium Bromide

Pesticide Reregistration

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 from pesticide producers and reviews a complete set of studies showing 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 Document, or RED. This fact sheet summarizes the information in the RED for potassium bromide.

Potassium Bromide

In addition to having many other non-pesticidal uses, potassium bromide is an active ingredient in two registered pesticide products. The first product, registered since 1960, is a liquid antimicrobial sanitizer used on food contact surfaces, food handling equipment, and utensils in food processing and eating establishments. The second product, registered in 1987, is an algaecide tablet used to control bacteria and algae in indoor spa water. Both of these pesticide products are eligible for reregistration.

Regulatory History

Potassium bromide is a well known inorganic chemical whose chemical and toxicological properties are extensively documented in the public literature. The non-pesticidal uses of this chemical outweigh the pesticidal uses, both in number and in economic importance. No manufacturing use potassium bromide product is registered. Instead, the technical grade chemical is available as an unregistered material from chemical supply houses at about 99% purity.

Potassium bromide was initially registered for use as a pesticide (antimicrobial sanitizer) in August 1960. EPA issued a Registration Standard for potassium bromide in September 1984, and required certain additional data. In May 1987, the algaecide product was registered.

Health Effects

All of EPA's generic toxicology data requirements for potassium bromide have been satisfied.

The human health effects of potassium bromide are well understood, and are minimal. Potassium bromide dissolves in water and breaks down into potassium and bromide ions. The potassium ion is present in relatively large amounts in all living organisms and is essential for life. The bromide ion is present in small amounts in man and all other organisms, and has no discernable effect at such low levels. The use of bromide salts as tranquilizers for many years has demonstrated the low and reversible toxicity of the bromine ion.

Acute Effects

Potassium bromide is not acutely toxic and it poses a low toxicity hazard. Its oral toxicity is well known and is very low. A high dose will cause only nausea and vomiting. Similarly, its dermal toxicity is low, and it is not a skin irritant.

Chronic Effects

EPA has reviewed information in the public literature on potassium bromide, and finds that it raises no concerns regarding the chronic or long term toxicology of the approved pesticidal uses.

Routes Of Exposure

Through the Diet

The use of potassium bromide as a sanitizing solution on food-contact surfaces is considered to be an indirect food additive use. This use is regulated and has been approved by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act. (Please see section 178.1010(b)(1) of 21 CFR.)

Residues of potassium bromide otherwise are not expected to occur in food or feed commodities. Therefore, no tolerances (legal residue limits) or exemptions from the requirement of a tolerance have been established by EPA, and none are needed.

During Application

Due to the low toxicity and registered use patterns of potassium bromide, no occupational or residential exposure data have been required or are needed.

Environmental Hazards

All environmental fate and ecological effects data for potassium bromide have been reviewed. EPA has sufficient information to conclude that indoor use of potassium bromide will not result in unreasonable adverse effects to humans or the environment.

Environmental Fate

Because of its use pattern, potassium bromide is not expected to produce any adverse effects in the environment. Therefore, environmental fate data are not required to support reregistration of this pesticide.

Ecological Effects

The 1984 Registration Standard required the submission of certain ecological effects studies to allow EPA to characterize the toxicity of potassium bromide to birds and fish.

Based on the studies submitted, potassium bromide was found to be practically non-toxic to bobwhite quail. However, it is highly toxic to rainbow trout and <u>Daphnia magna</u>. No additional label precautions or use restrictions are being imposed in spite of this finding, however, since the indoor use of potassium bromide is not expected to result in significant exposure to aquatic organisms.

Additional Data Required

The generic data base for potassium bromide has been reviewed and found to be complete. No further generic data are required to support reregistration.

Product Labeling Changes Required

The labels of end-use products containing potassium bromide must comply with EPA's current regulations and requirements. However, no particular labeling changes are required by the RED.

Regulatory Conclusion

- * The two registered pesticide products containing potassium bromide can be used without causing unreasonable adverse effects in people or the environment. Therefore, they are eligible for reregistration.
- * Since both of these products contain other active ingredients in addition to potassium bromide, they will be fully eligible for reregistration

only when the other active ingredients also are determined to be eligible.

* EPA will reregister the individual products containing potassium bromide once product specific data are submitted to and accepted by the Agency, and when similar information is submitted and accepted in response to the REDs issued for the other active ingredients in these products.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document for potassium bromide 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 Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, U.S. EPA, Washington, D.C. 20460, telephone 703-557-4436, or Fax #703-557-1884. Please note that after the comment period closes, the RED will be available from NTIS, at the address and telephone number below.

To obtain a copy of the September 1984 Registration Standard for potassium bromide, please contact the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA. 22161, telephone 703-487-4650. Request document #PB89-187256.

For more information about potassium bromide, or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (7508W), Office of Pesticide Programs, U.S. EPA, Washington, D.C. 20460, telephone 703-808-8000, or Fax #703-308-8005.

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, 24 hours a day, seven days a week, or Fax your inquiry to 806-743-3094.