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R.E.D. FACTS

Bromohydroxy-acetophenone (BHAP)

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 announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 3032, bromohydroxyacetophenone or BHAP.

Use Profile

Bromohydroxyacetophenone, also known as BHAP, is a microbicide or microbistat used to inhibit the growth of bacteria and fungi that cause the microbiological degradation of papermaking chemicals. Two of the three registered pesticide products containing this active ingredient are also used to inhibit the growth of bacteria that cause loss of viscosity in emulsions, paints, adhesives, waxes and polishes. BHAP products, which are marketed under the trade name Busan, are formulated as a soluble concentrate/liquid. Treatments are made using a variety of types of equipment including drip-feed devices, measuring containers and metering pumps.

Use practice limitations include an equipment precleaning requirement; a warning not to expose the product to extreme temperatures; and a prohibition against discharging effluent into sewage systems without notifying the sewage treatment plant authority, or into public waters except under an NPDES permit.

Regulatory History

BHAP was first registered as a pesticide in the U.S. in 1964 for use as a microbicide/microbiostat. Currently, three Busan products are registered for various industrial water treatment uses.

Human Health Assessment

Toxicity

BHAP generally is of moderate acute toxicity but is corrosive to the eyes and has been placed in Toxicity Category I (the highest of four levels) indicating the greatest degree of primary eye irritation effects. BHAP is moderately toxic by the oral and inhalation routes (Toxicity Category II). It is slightly toxic by the dermal route and is a mild irritant to the skin (Toxicity Category III). BHAP also is a skin sensitizer.

A subacute dermal toxicity study using rabbits resulted in no systemic toxicity, but BHAP induced dermal irritation at all dose levels. Since use of BHAP will not result in human exposure over a significant portion of a human life span, chronic toxicity, carcinogenicity and reproduction studies were not required. BHAP does not cause developmental toxicity or mutagenic effects.

Dietary Exposure

A food additive tolerance, or maximum residue limit, has been established for BHAP residues remaining in food contact paper and paperboard. However, this tolerance is under FDA's regulatory purview.

Occupational and Residential Exposure

Based on current use patterns, workers may be exposed to BHAP during and immediately after water treatment in pulp and paper manufacturing, paint manufacturing and industrial solution preparation. However, the toxicological endpoints of concern for workers (eye irritation and inhalation toxicity) can be mitigated through use of personal protective equipment (PPE). The PPE recommended for handlers using BHAP in industrial/manufacturing settings is: goggles or faceshield to prevent eye contact, chemical resistant gloves, and a NIOSH/MSHA approved organic vapor removing cartridge respirator with prefilter (TC-23). Since BHAP has low vapor pressure, inhalation by workers immediately after BHAP use is likely to be negligible.

People also could be exposed to BHAP when using substances that contain BHAP residues such as paints, waxes, polishes and adhesives. However, the amount of BHAP in these substances is minimal, so both exposure and risk are expected to be negligible.

Human Risk Assessment

BHAP is corrosive to the eyes (Toxicity Category I for primary eye irritation effects) and is moderately toxic by the oral and inhalation routes (Toxicity Category II). It has no significant food uses; a single food additive tolerance for residues in food contact paper and paperboard is regulated by FDA. Although workers may be exposed to BHAP during and

immediately after water treatment, risks of severe eye irritation and inhalation exposure can be mitigated through use of the recommended PPE. Exposure and risk to the public from using paints, waxes, polishes and adhesives containing BHAP residues are believed to be negligible.

Environmental Assessment

EPA has sufficient data at this time to conduct only a qualitative environmental fate assessment of BHAP. Additional data requirements for the pulp and papermill use still must be satisfied.

Environmental Fate

BHAP appears to be nonpersistent, and photolysis plays a major role in its degradation pathway. BHAP photodegrades in water with a half-life of less than two days. It appears to be immobile to moderately mobile in clay and loam soils, but very mobile in sandy soils.

BHAP's indoor, nonfood use pattern involves no direct exposure to the environment. However, its industrial uses result in indirect environmental exposures from discharges to water. These discharges are regulated by EPA's Office of Water and the states through the National Pollutant Discharge Elimination System (NPDES) permit program.

Ecological Effects

BHAP is moderately toxic to birds on an acute oral basis, but is no more than slightly toxic to birds on a subacute dietary basis. BHAP is moderately to highly toxic to freshwater fish, and is moderately toxic to freshwater invertebrates.

Ecological Effects Risk Assessment

BHAP's acute ecological risk is based on the residue levels in natural water receiving effluent from facilities using the pesticide. If residues should exceed one-half of the established EC_{50} levels for aquatic invertebrates or freshwater fish, these organisms would be acutely at risk.

By their nature, industrial biocides are often toxic to aquatic organisms. While the use of BHAP as a pesticide is regulated by EPA's Office of Pesticide Programs (OPP) under the federal pesticide law, FIFRA, the discharge of effluent containing DCDIC to surface waters is regulated under the NPDES permit program administered by EPA's Office of Water (OW) with the states. The NPDES process takes local conditions into account in issuing permits for the discharge of pollutants to bodies of water. EPA's OPP and OW will share information and cooperate in overseeing the use of biocides such as BHAP.

Additional Data Required

EPA is requiring several additional generic environmental fate studies for BHAP to confirm its regulatory assessments and conclusions. The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs) and revised labeling for reregistration.

Product Labeling Changes Required

All BHAP end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Labeling Requirements - For end-use products intended primarily for occupational use:

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."

Sensitization Statement: Required in the "Hazards to Humans (and Domestic Animals)" section of Precautionary Statements on the labeling of all end-use products, because BHAP is a skin sensitizer:

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

Effluent Discharge Labeling Statements - All BHAP products that may be contained in an effluent discharged to the waters of the U.S. or municipal sewer systems must bear the following statement:

"This pesticide is toxic to fish. Do not use in facilities discharging directly or indirectly to the estuarine or marine environment. Do not discharge effluent containing this product into freshwater lakes, streams and ponds unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. Secondary biological treatment of BHAP effluent discharging to freshwater environments is required for all uses except for use in secondary oil recovery systems discharging to freshwater environments. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

Regulatory Conclusion

The use of currently registered products containing BHAP 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.

Discharge of effluent containing BHAP from industrial facilities using this pesticide generally will not cause unreasonable adverse effects on the environment. EPA's OPP and OW will share information to improve the regulation of BHAP's use at specific sites across the country.

Products containing BHAP will be reregistered once the required 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 (RED) document for BHAP 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 BHAP 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 BHAP RED, or reregistration of individual products containing BHAP, 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.