



R.E.D. FACTS

Alkyl Amine Hydrochloride

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 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 Document, or RED. This fact sheet summarizes the information in the RED for alkyl amine hydrochloride.

Use Profile

Alkyl amine hydrochloride is an antimicrobial pesticide registered for use as a self-sanitizer for floors and equipment and as a preservative in paints and coatings. As a constituent of liquid floor wax, it inhibits the further growth of bacteria when used in hospitals, laboratories, nursing homes, commercial buildings and households. As an industrial preservative, it prevents the growth of bacteria in paints, adhesives and coatings. The pesticide products containing this active ingredient are used only indoors.

Regulatory History

Pesticide products containing alkyl amine hydrochloride were first registered in September 1971. At present, three such products are registered: one liquid floor wax containing only 0.063 percent of the active ingredient, and two industrial preservatives used in paints and coatings containing 21.2 and 25 percent of the active ingredient, respectively. Two of these products contain alkyl amine hydrochloride as their only active

ingredient; the third (an industrial preservative product) also contains another active ingredient.

Human Health Assessment

EPA has determined that only a minimal set of studies are needed to assess the potential risks of alkyl amine hydrochloride because of its very limited use as a pesticide, and since none of the uses result in residues in the food supply.

Toxicity

Alkyl amine hydrochloride, per se, is corrosive to the eyes, skin and lungs. It has been placed in Toxicity Category I (indicating the highest degree of toxicity) for these effects.

In a subchronic dermal toxicity study in rats, inflammation of the skin and increased adrenal weights were observed, but only at the highest dose level. In a developmental toxicity study also in rats, no developmental malformations or variations were observed. Some early fetal loss and decreased fetal body weights were observed, however EPA does not consider these effects to be of significant toxicological concern because the Agency believes they were caused by toxicity to the mother.

Occupational Exposure

Workers may be exposed to alkyl amine hydrochloride when applying the liquid floor wax product. However, since this product contains only 0.063 percent of the antimicrobial and is applied using a hand mop, only low exposure is expected from this use. The current product labeling bears the signal word "CAUTION," and notes that the product is harmful if swallowed and may cause skin irritation. It does not recommend any measures to reduce applicator exposure.

Workers may be exposed to greater amounts of alkyl amine hydrochloride when handling or applying either of the two industrial preservative products. These products contain relatively high concentrations of alkyl amine hydrochloride (21.2 and 25 percent, respectively), and are added during the formulation of paints and coatings. Product labeling currently bears the signal word "DANGER," and the precautions:

"Concentrated solutions are corrosive and cause severe eye and skin damage. Do not get in eyes, on skin or clothing. MAY BE FATAL OR HARMFUL IF SWALLOWED. Precautions should include the use of eye shields, long rubber gloves and a vapor respirator. Do not breathe spray mist. Use with adequate ventilation. Wash thoroughly after handling."

EPA believes that these label precautions are necessary to protect mixers, loaders and applicators in the coatings industry, and is continuing and strengthening them.

The concentration of alkyl amine hydrochloride in finished, formulated paints and coatings is only about 0.038 to 0.16 percent. Thus,

people applying these finished paints and coatings are exposed to only low levels of the active ingredient.

Human Risk Assessment

EPA has reviewed data adequate to assess the potential human health risks from the pesticide uses of alkyl amine hydrochloride. The Agency believes that these uses should not result in any unreasonable risks to workers, provided that the directions and precautions on product labels are followed.

Environmental Assessment

Environmental Risk Assessment

EPA did not perform an environmental risk assessment for alkyl amine hydrochloride, since pesticide products containing this active ingredient are used only indoors. Virtually no exposure to nontarget organisms or the environment is expected to result from use of the registered alkyl amine hydrochloride products. EPA is not requiring any environmental fate studies or any additional ecological effects studies at this time.

Additional Data Required

No additional generic data are required to support the reregistration of alkyl amine hydrochloride. However, product-specific acute toxicity and product chemistry studies are required.

Product Labeling Changes Required

The labels of the alkyl amine hydrochloride products must comply with EPA's current pesticide labeling requirements. In addition, the Precautionary Statements on all labels must include the warning, "Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."

Floor Wax Product

Directions for Use must include the statement, "Avoid contamination of foods."

Industrial Preservative Products

Labels must carry the skull and crossbones along with the signal word, "POISON."

Labels must continue to warn that, "Concentrated solutions are corrosive and cause severe eye and skin damage," and must require the use of eye shields, rubber gloves, a pesticide respirator and protective clothing.

In the Directions for Use, products labeled "For manufacturing use only as a preservative" must delete the word "manufacturing."

Labels must include the following Environmental Hazards warning: "This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds,

estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of U.S. EPA."

Regulatory Conclusion

- The registered floor wax and industrial coatings uses of alkyl amine hydrochloride are not likely to cause unreasonable adverse effects in people or the environment, and are eligible for reregistration.
- The two registered products containing alkyl amine hydrochloride as the sole active ingredient will be reregistered once product-specific data and amended labeling are received and accepted by EPA.
- The third registered alkyl amine hydrochloride product will be reregistered when such data and labeling are received and accepted by EPA, and when its other active ingredient also is eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for alkyl amine hydrochloride 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 (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

In the future, the alkyl amine hydrochloride 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 alkyl amine hydrochloride 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 alkyl amine hydrochloride products, please contact the Registration Division (7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-5447.

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.