



# R.E.D. FACTS

## Alkyl Imidazoline

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### 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 before November 1, 1984, 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 develops any mitigation measures or regulatory controls needed to effectively reduce 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 3010, Alkyl Imidazoline.

### Use Profile

Alkyl imidazoline (1-(2-Hydroxyethyl)-2-alkyl\*-2-imidazoline) is a microbiocide/microbiostat used in fuel and oil storage tank bottom water. It prevents the growth of slime-forming bacteria and fungi which might interfere with the use and quality of oils and fuels in storage tanks. Formulations include two soluble concentrate liquid products, one with 1.19% and the other with 25.0% active ingredient. Products are loaded and applied through a closed delivery system that has a proportioning pump or siphon-type feeder to meter the pesticide product directly from its container into the fuel oil as it is pumped into storage tanks. Products are not intended for homeowner use or for use in or around residences.

### Regulatory History

Products containing alkyl imidazoline were registered in the United States in 1970. Currently, 2 products are registered for use as a microbiocide in fuel oil.

### Human Health Assessment

#### Toxicity

In studies using laboratory animals, alkyl imidazoline generally has been shown to be of mild acute toxicity via oral and dermal routes. It has

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been placed in Toxicity Category III (indicating the next to lowest degree of acute toxicity) for these effects. However, alkyl imidazoline is highly corrosive and a severe eye and skin irritant. It is placed in Toxicity Category I (indicating the highest degree of acute toxicity) for these effects.

The appropriate toxicological endpoint for assessing short-term or intermediate-term occupational risk for alkyl imidazoline is maternal toxicity. Developmental toxicity studies using rats showed decreased body weight gain, decreased food consumption, and decreased food efficiency.

### **Dietary Exposure**

Alkyl imidazoline has no registered food uses. Application is via a closed delivery system in industrial sites only. No dietary exposure is expected.

### **Occupational and Residential Exposure**

Minimal occupational and no residential exposure are expected from the current uses of alkyl imidazoline. These products are loaded and applied through a *closed delivery system* that has a proportioning pump or siphon-type feeder to meter the pesticide product directly from the product container into the fuel oil as it is pumped into storage tanks. Products are used in industrial sites and are not intended for homeowner use or for use in or around residences.

### **Human Risk Assessment**

No significant human health risk is expected from the use of alkyl imidazoline. Based on the exposure assessment and the toxicological endpoint of concern (developmental toxicity), the calculated risks to handlers are well within the boundaries that the Agency considers reasonable. Furthermore, post-application exposure to workers should be minimal because of the dilution of the product in fuel oil bottom water and precautions that are used to minimize exposure to fuel oil.

## **Environmental Assessment**

### **Environmental Fate**

EPA has not required environmental fate testing to support the reregistration eligibility decision for alkyl imidazoline. Because of the pesticides limited use pattern, only in fuel storage tanks, high dilution rate, and use only in closed systems, alkyl imidazoline is expected to result in minimal exposure to the environment when used according to directions on the label. Also, alkyl imidazoline has chemical properties that suggest it will remain in the organic phase (fuel/oil) of any mixture with water.

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## **Ecological Effects**

Due to its indoor non-food use pattern, use only in closed systems, high dilution rates, and the high probability that it will remain in the fuel portion of any mixture with water, EPA expects minimal environmental exposure and has not required extensive studies on the ecotoxicology of these alkyl imidazoline products. However, the Agency is requiring acute toxicity studies on birds, fish, and aquatic invertebrates. The Agency will use these data to characterize alkyl imidazoline's acute toxicity to these non-target species in case of accidents and to determine appropriate environmental labeling for products.

## **Ecological Effects Risk Assessment**

EPA has not conducted an ecological risk assessment for alkyl imidazoline because it is only used inside fuel storage tanks. Exposure to the environment is expected to be negligible. If contaminated water is pumped from tanks holding fuel treated with alkyl imidazoline, the pesticide concentration in the water should be very low due to its high dilution rate and its affinity to the organic (fuel) phase of the mixture. Treated fuel must be disposed of in accordance with U.S. EPA's Resource Conservation and Recovery Act (RCRA).

## **Risk Mitigation**

To lessen the human health risks posed by alkyl imidazoline, EPA is requiring the following risk mitigation measures.

- Use of PPE, personal protective equipment; and
- Continued use of closed delivery systems (historically used).

No environmental risk mitigation measures are being imposed for alkyl imidazoline because exposure to the environment is expected to be negligible.

## **Additional Data Required**

The generic data base supporting the reregistration of alkyl imidazoline has been reviewed and determined to be substantially complete. The registrant must submit three acute ecotoxicity studies to characterize alkyl imidazoline's toxicity to fish, birds, and aquatic invertebrates. This information is required for labeling in case of an accident or misuse of the pesticide product or technical material.

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 alkyl imidazoline end-use products must comply with EPA's current pesticide product labeling requirements and with the following. For

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a comprehensive list of labeling requirements, please see the Alkyl Imidazoline RED document.

## **Labeling Requirements for Manufacturing-Use Products**

### Effluent Discharge Labeling Statements

All manufacturing-use or end-use products that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems must bear the effluent discharge labeling statements as described in PR Notice 93-10.

## **Labeling Requirements for End-Use Products**

### Handler (Mixer, Loader, Applicator) PPE

The Agency is imposing minimum personal protective equipment (PPE), long-sleeve shirt, long pants, chemical-resistant gloves, shoes, and socks for the application of the currently registered alkyl imidazoline products and is not imposing post-application entry restrictions. If the *end-use* product is classified as toxicity category I or II for eye irritation potential, protective eyewear is also required. The requirements are based on the absence of significant toxicological concerns for alkyl imidazoline. However, the Agency may find that imposing the use of more protective PPE and/or other restrictions could be necessary upon the review of toxicity data for the end-use products during product reregistration.

### Labeling Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing alkyl imidazoline that are intended primarily for industrial or occupational use.

"Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application."

### Engineering Controls:

"Since handlers must use closed metering systems, the handler requirements are reduced to long-sleeve shirt, long pants, chemical-resistant gloves, shoes, and socks."

### User Safety Requirements:

"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."

### User Safety Recommendations:

"Users should remove clothing immediately if pesticide gets inside. Users should wash thoroughly and put on clean clothing."

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"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."

Application Method Timing and Equipment:

"The registrant must state when the preservative is added. For example: 'Alkyl imidazoline products are loaded and applied through a closed delivery system that has a proportioning pump or siphon-type feeder to meter the pesticide product directly from the container into the fuel oil as it is pumped into storage tanks'."

Effluent Discharge Labeling Statements:

Refer to Labeling Requirements for Manufacturing-Use Products above for labeling requirements for effluent discharge.

## **Regulatory Conclusion**

The use of currently registered products containing alkyl imidazoline 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.

Alkyl imidazoline products 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 alkyl imidazoline 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 Alkyl Imidazoline RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

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For more information about EPA's pesticide reregistration program, the Alkyl Imidazoline RED, or reregistration of individual products containing alkyl imidazoline, 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 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.