

US EPA ARCHIVE DOCUMENT



R.E.D. FACTS

2-[(Hydroxymethyl)-amino]ethanol

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 Decision (RED) document. This fact sheet summarizes the information in the RED document for 2-[(hydroxymethyl)amino]ethanol.

Use Profile

2-[(hydroxymethyl)amino]ethanol is a bacteriostat and fungicide used as an industrial preservative to prevent bacterial and fungal deterioration of water-based products including latex paints and adhesives, metalworking cutting oil fluids, resin emulsions, specialty industrial products and ready-mixed joint cements. 2-[(hydroxymethyl) amino]ethanol products are formulated as soluble and emulsifiable concentrates and liquids. They are added to industrial products during the manufacturing process using pouring and pumping methods.

Regulatory History

2-[(hydroxymethyl)amino]ethanol was first registered in the United States in 1970 for use as an industrial preservative, and currently is used in the manufacture of many water-based industrial products. Three pesticide products are registered which contain this active ingredient.

**Human Health
Assessment****Human Toxicity**

2-[hydroxymethyl]amino]ethanol generally is of moderate to low acute toxicity but is a severe eye irritant. It has been placed in Toxicity Category I, indicating the greatest degree of acute toxicity, for eye effects. It has been placed in Toxicity Category III for oral, inhalation and dermal toxicity, and in Toxicity Category IV, indicating the lowest degree of acute toxicity, for skin effects. A dermal sensitization study must be submitted as confirmatory data.

A subchronic toxicity study using rats showed skin reactions in males and females at all dose levels, with more severe reactions in females.

A developmental toxicity study using rats showed a developmental no observed effect level (NOEL) greater than the highest dose tested. A maternal NOEL and LOEL were established based on reduced body weight gain and food consumption, as well as gastrointestinal abnormalities.

This chemical shows some weak evidence of mutagenicity, and two additional mutagenicity studies are being required as confirmatory data.

Dietary Exposure

2-[hydroxymethyl]amino]ethanol has no registered food or feed uses. Therefore, no dietary exposure is expected to result from its use as a pesticide.

Occupational and Residential Exposure

2-[hydroxymethyl]amino]ethanol pesticides are added to industrial products during the manufacturing process using pour liquid and pump liquid application methods. During these processes, exposure to workers is expected. Further, 2-[(hydroxymethyl)amino]ethanol degrades over time to form ethanolamine and formaldehyde; the latter poses worker exposure concerns. However, exposure to the parent compound is low, and the conditions and likelihood of degradation so slight that exposure to mixers/loaders/applicators and post-application workers would be minimal.

Human Risk Assessment

No food uses of 2-[(hydroxymethyl)amino]ethanol are registered; therefore no dietary risks are posed. The potential for occupational exposure and risk are minimal, provided that protective eyewear and chemical resistant gloves are used, as required by this RED. The industrial preservative uses, which involve pouring and pumping application methods, could involve worker exposure to formaldehyde, a degradation product of concern. However, based on the conditions of use and the low exposure associated with the parent compound, exposure of workers or the general public to formaldehyde is not expected.

Environmental**Environmental Fate**

Assessment

The results of a hydrolysis study indicate that 2-[(hydroxymethyl)amino]ethanol rapidly degrades in aqueous solutions to ethanolamine and formaldehyde. Therefore, environmental exposure to the parent compound is expected to be minimal. This study must be repeated, however, as confirmatory data.

Ecological Effects

2-[(hydroxymethyl)amino]ethanol is slightly toxic to upland game birds, bobwhite quail, on an acute oral and a dietary basis. The chemical is slightly toxic to fish and aquatic invertebrates.

Ecological Effects Risk Assessment

2-[(hydroxymethyl)amino]ethanol is only slightly toxic to avian and aquatic organisms, and it rapidly degrades in the environment. When this chemical is used according to the label, minimal exposure to the environment from the parent compound or its degradates should occur. Therefore, risk to nontarget organisms is expected to be minimal.

**Additional Data
Required**

EPA is requiring additional dermal sensitization, mutagenicity and hydrolysis studies as confirmatory data. The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSF), and revised product labeling for reregistration of products containing 2-[(hydroxymethyl)amino]ethanol.

**Product Labeling
Changes Required**

The labeling of all end-use and manufacturing use products containing 2-[(hydroxymethyl)amino]ethanol must comply with EPA's current pesticide labeling requirements. In addition:

- **Personal Protective Equipment (PPE) Requirements**

Since mixers/loaders/applicators could be exposed during pouring and pumping application methods, PPE (goggles, eye shield or face shield and chemical resistant gloves) is required to prevent eye irritation.

- **Environmental Hazard Statements**

The following effluent discharge statements must appear on product labels: "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters, including near marine or estuarine habitats, 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. 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 registered industrial preservative products containing 2-[(hydroxymethyl)amino]ethanol will not pose unreasonable risks or adverse

effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration. These products will be reregistered once the required confirmatory generic data, product-specific data, 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 2-[(hydroxymethyl)amino]ethanol 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.

Following the comment period, the 2-[(hydroxymethyl)amino]ethanol RED document 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 2-[(hydroxymethyl)amino]ethanol RED, or reregistration of individual products subject to this RED, 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, 8:00 am to 6:00 pm Central Time, Monday through Friday.