



R.E.D. FACTS

4,4- Dimethyloxazolidine

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 the chemical 4,4-dimethyloxazolidine, found in reregistration case 3095.

Use Profile

4,4-Dimethyloxazolidine is used as an antimicrobial to control bacteria and fungi in oil recovery drilling muds, packer fluids, secondary oil recovery injection water, adhesives, metalworking cutting fluids, latex paints, resin emulsions, wet-end additives and industrial processing chemicals or in specialty industrial products. Formulations include soluble concentrated solids and ready-to-use liquids. Products containing 4,4-dimethyloxazolidine are added to systems and industrial products using pouring and pumping methods. Product labeling restrictions include National Pollutant Discharge Elimination System (NPDES) permit requirements.

Regulatory History

4,4-Dimethyloxazolidine was first registered as a pesticide in the U.S. in 1982. In 1987 the Agency issued the Antimicrobial Data Call-In Notice imposing subchronic toxicity and occupational exposure data requirements for this and other antimicrobial chemicals. Another Data Call-In Notice was issued in September 1992 for 4,4-dimethyloxazolidine requiring

additional data in support of reregistration. Currently, there are six products containing 4,4-dimethyloxazolidine that are eligible for reregistration.

Human Health Assessment

Toxicity

In acute toxicity studies using laboratory animals, 4,4-dimethyloxazolidine has been shown to be slightly toxic by the acute oral, dermal and inhalation routes and has been placed in Toxicity Category III (the second lowest of four categories) for these effects. 4,4-Dimethyloxazolidine has been placed in Toxicity Category I (the highest of four categories) for its effects as a severe eye irritant. 4,4-Dimethyloxazolidine is not a skin sensitizer. The overall results of mutagenicity studies with 4,4-dimethyloxazolidine suggest that mutagenicity health hazards from its expected usage are minimal. 4,4-Dimethyloxazolidine does not cause developmental effects.

Reproductive toxicity, metabolism, chronic toxicity, and carcinogenicity studies are not required because there are no expected chronic occupational/residential exposures, and the current use pattern scenarios of 4,4-dimethyloxazolidine will not result in significant human exposure over a significant portion of the human life span.

Dietary Exposure

Current uses of 4,4-dimethyloxazolidine do not include any food or feed uses. Exposure through the diet therefore is not anticipated and a dietary exposure and risk assessment is not necessary.

Occupational and Residential Exposure

While there are potential application and post-application exposures from the use of 4,4-dimethyloxazolidine in commercial, industrial, and residential settings, the Agency has decided that an occupational/residential mixer/loader/applicator exposure analysis is not warranted at this time due to the absence of toxicological endpoints of concern.

Human Risk Assessment

4,4-Dimethyloxazolidine is a severe eye irritant but otherwise is of relatively low acute toxicity. This particular effect is most appropriately addressed at the individual product level where formulation and dilution affect the degree of irritation and necessity for eye protection. Long term exposure effects are not of concern because use of 4,4-dimethyloxazolidine does not result in significant exposure over the course of people's lives and subchronic toxicological endpoints are not of concern. EPA has also considered the potential hazard of exposure to formaldehyde as a degradate of 4,4-dimethyloxazolidine. Post-application settings are addressed for formaldehyde by the Occupational Safety and Health Administration. OSHA has a comprehensive workplace standard for formaldehyde for the protection of workers in the industrial setting due to formaldehyde-release in the workplace.

Environmental Assessment

Environmental Fate

EPA requires only a hydrolysis study to characterize the environmental fate of 4,4-dimethyloxazolidine, due to its current use patterns. From the results of this study, 4,4-dimethyloxazolidine was found to dissipate so rapidly that no degradation rate or half-life could be determined. Only minor amounts of the parent 4,4-dimethyloxazolidine were present soon after solution preparation. The hydrolysis products were formaldehyde and 2-amino-2-methyl-1-propanol(AMP); AMP remained stable throughout the length of the study (30 days).

Ecological Effects

4,4-Dimethyloxazolidine is slightly to moderately toxic to birds on an acute basis and slightly toxic on a subacute basis. It demonstrates slight toxicity to both cold and warm freshwater fish, and is slightly toxic to freshwater invertebrates on an acute basis. Acute toxicity testing with estuarine and marine organisms resulted in practically non-toxic effects on estuarine fish and shrimp species, while moderate toxicity was observed among eastern oysters.

Ecological Effects Risk Assessment

EPA requires only a limited set of ecotoxicology and environmental fate studies for microbiocides. While the hazard to aquatic organisms from 4,4-dimethyloxazolidine has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments from these uses are regulated under the National Pollution Discharge Elimination System (NPDES) permitting program of EPA's Office of Water. EPA does not anticipate any exposure of concern to fish or wildlife, providing that all 4,4-dimethyloxazolidine products are handled and applied as specified in the product labeling and discharges to the environment comply with all federal disposal laws and the NPDES program.

Risk Mitigation

To protect handlers of 4,4-dimethyloxazolidine from potential eye irritation hazards, end use products in Toxicity Categories I or II for eye irritation potential must require use of protective eyewear on their labeling. Other minimum work attire or personal protective equipment (PPE), including use of a long-sleeved shirt, long pants, and socks and shoes during application, is also required for all handlers of products containing 4,4-dimethyloxazolidine. General user safety requirements and recommendations, application restrictions, and use directions must be included on product labeling. NPDES statements also are required to address potential environmental risks.

Additional Data Required

The Agency 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 4,4-dimethyloxazolidine end-use products must comply with EPA's current pesticide product labeling requirements and with the following.

PPE/Engineering Control Requirements for Pesticide Handlers

For sole-active-ingredient end-use products that contain 4,4-dimethyloxazolidine, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain 4,4-dimethyloxazolidine, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

Minimum (Baseline) PPE/Engineering Control Requirements

Because of the lack of special toxicity endpoints of concern, EPA is not requiring any active-ingredient-based PPE/engineering control beyond the minimum (baseline) PPE/engineering control requirements for 4,4-dimethyloxazolidine end-use products that are intended primarily for occupational use. Any additional PPE for each 4,4-dimethyloxazolidine occupational end-use product will be established on the basis of the end-use product's acute toxicity. NOTE: All end-use products will be required to specify a long-sleeved shirt, long pants, socks and shoes as minimum work attire for all handlers. If the end-use product is classified as toxicity Category I or II for eye irritation potential, protective eyewear is also required.

Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Other Labeling Requirements

The Agency is requiring the following precautionary labeling statements to be located on all end-use products containing 4,4-dimethyloxazolidine.

Application Restrictions

"Do not use this product in a way that will contact workers or other persons."

User safety requirements

If gloves and/or protective eyewear are required PPE for the use of the end-use product, add:

"Follow manufacturers' instructions for cleaning/maintaining personal protective equipment. If no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry."

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."

If gloves are required PPE for the use of the end-use product, add:

"Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible wash thoroughly."

Directions for Use

Registrants must specify on labeling the complete directions for use for each use pattern: site of application, type of application, timing of application, equipment used for application, and the rate of application (dosage).

Effluent Discharge Labeling Statements

To reduce environmental risk from 4,4-dimethyloxazolidine discharge and disposal, product labels must continue to have the statements pertaining to effluent discharge under the National Pollutant Discharge Elimination System (NPDES) permitting system (refer to PR Notice 93-10 or 40 CFR 152.46(a)(1)) and disposal under any applicable federal laws.

Regulatory Conclusion

The use of currently registered products containing 4,4-dimethyloxazolidine in accordance with labeling as required herein will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Products containing 4,4-dimethyloxazolidine will be reregistered once EPA receives and accepts the required product-specific data, revised Confidential Statements of Formula, and revised labeling.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for 4,4-dimethyloxazolidine 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, D.C. 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 4,4-dimethyloxazolidine 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 4,4-dimethyloxazolidine RED, or reregistration of individual products containing 4,4-dimethyloxazolidine, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, D.C. 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 a.m. and 7:30 p.m. Eastern Standard Time, Monday through Friday.