



R.E.D. FACTS

Dimethoxane

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 3064, dimethoxane.

Use Profile

Dimethoxane is a fungicide, microbiocide/microbiostat used to preserve emulsions and water-based industrial processes.

This biocidal product is used in the manufacturing process to control spoilage microorganisms encountered in industrial emulsions and specialty industrial products, textiles, jet fuels, adhesives and leather processing liquors. Dimethoxane is a preservative used in industrial settings only.

Dimethoxane is formulated as a liquid soluble concentrate. It is applied by the open-pouring method and by closed delivery system.

Use practice limitations preclude combining dimethoxane with systems containing amides or amines, because dimethoxane products may cause discoloration in these systems.

Regulatory History

Dimethoxane was first registered as a pesticide in the U.S. in 1962. In 1987, an antimicrobial Data Call-In (DCI) required the submission of a variety of subchronic and chronic toxicology and occupational exposure studies. A Phase IV DCI was issued in 1992, which required product chemistry, ecological effects and environmental fate data. There is currently one product registered for the incorporation into emulsion paints, emulsion inks, jet fuels,

leather processing liquors, coatings, specialty industrial products, and use in textile and adhesive production.

Human Health Assessment Toxicity

In studies using laboratory animals, dimethoxane generally has been shown to be of minor acute toxicity. It is slightly toxic by the oral, dermal and inhalation routes and has been placed in Toxicity Category III (the second lowest of four categories) for these effects. It was found to cause mild eye irritation and was placed in toxicity category III for eye irritation. Dimethoxane caused only slight irritation in the dermal irritation study and was placed in toxicity category IV (the lowest of four categories). However, dimethoxane is a strong skin sensitizer.

In a subchronic toxicity test using rats, dermal irritation was observed in the highest dose levels. Other effects found at the highest dose levels include reduced body weight gains in males and increased incidence of liver changes in females.

The National Toxicology Program (NTP) conducted carcinogenicity studies on dimethoxane. The results indicated an increased incidence of tumors of the forestomach in the high dose male mice. NTP therefore concluded that there was equivocal evidence of carcinogenicity for male mice. However, there was no evidence of dimethoxane carcinogenicity in female mice or in male or female rats. The Agency has completed a qualitative assessment of exposure and cancer risk based on the NTP studies and conservative occupational exposure assumptions and concluded that there is no significant human cancer risk from the registered uses of dimethoxane.

In a developmental toxicity study using rats, dimethoxane produced some maternal toxicity effects at the highest dose level. Dimethoxane is not mutagenic.

Based on the toxicology data base for dimethoxane, neither short term (1 to 7 days) nor intermediate term (1 week to several months) toxicological endpoints for occupational/residential risk assessment were identified due to low toxicity and minor effects.

Dietary Exposure

There are no food uses of dimethoxane, therefore, people will not be exposed to residues through the diet.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to dimethoxane during and after application of the pesticide product in industrial settings. For those handlers using open pouring application methods, there is a potential for respiratory, dermal and eye exposure. Potential for exposure to handlers using closed delivery systems is expected to be significantly reduced. Due to the chemical properties of dimethoxane, including low vapor pressure, post-application inhalation

exposure to workers is expected to be minimal. Also, exposure to individuals who use dimethoxane products (such as paints) is possible; however, the amount of dimethoxane contained in these products is so small that resulting effects are expected to be negligible.

There are no residential uses of dimethoxane, so no exposure to the general public is expected.

Human Risk Assessment

Dimethoxane generally is of low acute toxicity. Based on a review of the data, the Agency has determined that there is no significant cancer risk from the registered uses of dimethoxane.

There are no food uses of dimethoxane, so people will not be exposed to the chemical through their diet. Dimethoxane is only used in industrial settings, so there is no exposure anticipated for the general public.

Dimethoxane handlers may be exposed to the chemical during open pouring application methods. Use of closed systems should significantly reduce handlers exposure. Based on dimethoxane's low toxicity and use patterns, risks to applicators are not believed to be significant.

All uses of dimethoxane are outside of the scope of the Agency's Worker Protection Standard and there are no special toxicological concerns about dimethoxane that warrant the establishment of active ingredient based personal protective equipment (PPE).

Environmental Assessment

Environmental Fate

The major route of degradation of dimethoxane is abiotic hydrolysis. Dimethoxane is highly unstable in water -- over 50% is hydrolyzed in two hours. It reacts with water to form acetic acid and dioxinol; the latter breaks down into acetaldehyde and aldol in 14 hours.

Ecological Effects

There is no direct use or application of dimethoxane outdoors. Any significant hazard would presumably result from a transportation accident, spill, or purposeful discharge into the environment. Any such environmental contamination would have minimal impact on avian and aquatic species, due to the low toxicity of dimethoxane to these species.

Dimethoxane was found to be slightly toxic to practically nontoxic to avian species on an acute oral and subacute dietary basis. Results from the acute freshwater fish studies indicated that dimethoxane is slightly toxic to both cold and warm water fish. The study submitted to the Agency indicating the effects of dimethoxane on freshwater invertebrates did not fulfill the guideline requirement. However, it did provide adequate information indicating that dimethoxane is only slightly toxic to freshwater invertebrates. This study is not required to be resubmitted due to the low level of toxicity to freshwater invertebrates and due to the fact that dimethoxane is only registered for indoor uses.

Ecological Effects Risk Assessment

Risk assessments are not conducted on nontarget organisms for microbiocides having indoor non-food uses without effluents. The preservative uses of dimethoxane in emulsion paints, emulsion inks, jet fuels, leather processing liquors, coatings, specialty industrial products, textiles and adhesives are expected to result in minimal to no exposure to the environment. The jet fuel use of dimethoxane, however, is associated with periodic releases into the environment based on purging of jet fuel storage tanks of "water bottoms" (small areas of condensation on the bottom of the tank, which if not removed could cause leakage from rust formation weakening the tank wall). The hazard to wildlife and aquatic organisms from these registered indoor non-food uses is expected to be minimal because dimethoxane is not more than slightly toxic to fish and aquatic invertebrates, and is slightly to practically nontoxic to birds.

Endangered Species

Limitations in the use of dimethoxane may be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. The jet fuel use of dimethoxane is associated with periodic releases into the environment based on purging of jet fuel storage tanks. The hazard to wildlife and aquatic organisms from this use is expected to be minimal because dimethoxane is not more than slightly toxic to fish and aquatic invertebrates, and birds. The Endangered Species Protection Program is expected to become final in the near future, at which time registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

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 dimethoxane end-use products must comply with EPA's current pesticide product labeling requirements, and with the following. For a comprehensive list of labeling requirements, please see the dimethoxane RED document.

The Agency is requiring that the following labeling statements be included on dimethoxane end-use products as appropriate, given the acute toxicity and use patterns of each product.

- Handler (Mixer, Loader, Applicator, Etc.) Personal Protective Equipment (PPE): The PPE for pesticide handlers will be based on the acute toxicity of the end-use product.

Application Restrictions:

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

Engineering Controls:

- "When handlers use closed metering systems, the handler requirements may be reduced or modified to long-sleeved shirt, long pants, shoes and socks."

Use Safety Requirements:

- "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washing, use detergent and hot water. Keep and wash PPE 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."

- "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."

Skin Sensitization Statement:

- "This product may cause skin sensitization reaction in some people."

Regulatory Conclusion

The use of currently registered products containing dimethoxane 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.

Dimethoxane 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 dimethoxane 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 dimethoxane 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 dimethoxane RED, or reregistration of individual products containing dimethoxane, 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.