

SEPA R.E.D. FACTS

Mitin FF

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 <u>re</u>registered 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 3097, Mitin FF.

Use Profile

Mitin FF is used to moth-proof wool. It is used in the textile industry as an 80 percent active ingredient formulated fine powder applied to wool during the dyeing/manufacturing process.

Regulatory History

Mitin FF was first registered as a pesticide in the U.S. in 1948. EPA issued a Data Call-in for Mitin FF in October 1992 requiring the registrant to provide appropriate product chemistry, toxicological, environmental fate and ecological effects data on this active ingredient to support reregistration. Currently, one Mitin FF product is registered.

Human Health Assessment

Toxicity

In acute toxicity studies using laboratory animals, Mitin FF has been shown to be low to moderately 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.

The current use of Mitin FF does 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 Mitin FF in commercial and industrial settings, the Agency believes that the handler exposures associated with the application of Mitin FF product will not pose an adverse risk to workers. There is no identified toxicological endpoint of concern and the worker exposure (inhalation) is assumed to be low.

Human Risk Assessment

The toxicology database, although limited in its scope, suggests Mitin FF has low mammalian toxicity. Technical Mitin FF has low acute and subchronic toxicities from dermal and inhalation exposure; was negative for developmental effects; and, Mitin FF did not cause mutagenic effects in a battery of studies.

Ecological Effects and Environmental Fate

Mitin FF is slightly acutely toxic to birds, moderately to slightly toxic to mammals and moderately acutely toxic to fish and aquatic invertebrates. It appears to be stable to hydrolysis. Exposure to the environment is expected to be low, and is regulated under the NPDES permitting program of the Agency's Office of Water.

Risk Mitigation

EPA is not requiring active ingredient based risk mitigation measures. General user safety requirements and recommendations, application restrictions, and use directions must be included on product labeling. NPDES statements are also required to address potential environmental risks.

Additional Data Required

EPA is not requiring additional generic studies for Mitin FF to confirm its regulatory assessments and conclusions.

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

Regulatory

The use of the currently registered product containing Mitin FF, in accordance with approved labeling, will not pose unreasonable risks or

Conclusion

adverse effects to humans or the environment. Therefore, all uses of this product are eligible for reregistration.

Mitin FF products will be reregistered once the required productspecific 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 Mitin FF during a 60-day time period, as announced in a Notice of Availability published in the <u>Federal Register</u>. 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 Mitin FF 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 Mitin FF RED, or reregistration of individual products containing [name], please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone703-308-8000. 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.