

SEPA R.E.D. FACTS

Ethyl Parathion

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. To implement provisions of the Food Quality Protection Act (FQPA) of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and 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 serves as and explains the Agency's Reregistration Eligibility Decision for case 0155, ethyl parathion.

Use Profile

Ethyl parathion is a restricted use organophosphate insecticide/miticide used to control a broad spectrum of pests on alfalfa, barley, canola, corn, cotton, sorghum, soybeans, sunflowers, and wheat. It is formulated as a liquid and may be applied only using aerial equipment.

Regulatory **History**

Ethyl parathion was first registered as a pesticide in the U.S. in 1948. EPA issued a Registration Standard for ethyl parathion in December 1986 that stated the Agency planned to initiate a Special Review due to acute human and avian concerns. In 1991, the Agency and the registrants of ethyl parathion reached an agreement under which the registrants agreed to limit use sites and restrict application and post-application practices. This action was taken by the Agency to mitigate risk to workers exposed during application and post-application.(*Federal Register Notice Volume 56*, No. 240, November 13, 1991; and Volume 57, No. 19, January 29, 1992; and No. 34, February 20, 1992).

Since 1991, the use of ethyl parathion in the United States has been limited to nine crops: alfalfa, barley, canola (rapeseed), corn, cotton, sorghum, soybeans, sunflowers, and wheat. All of the technical ethyl parathion sold in the United States is produced by Cheminova Agro A/S, formulated at one location and sold under the Cheminova label. Two formulations of ethyl parathion are currently being sold in the United States: Parathion 8EC (emulsifiable concentrate) and Ethyl Methyl Parathion 6-3 EC. A third formulation, 4EC, is registered but is not currently marketed. Additionally, seven other registrants hold a total of 15 product registrations; none, however, are currently marketed.

Due to the high estimated risks based on the best information available to the Agency, and the registrants' decision not to support the data requirements for reregistration, the registrants have signed an agreement to voluntarily cancel their registrations. Cancellation of manufacturing use products is effective immediately, and end use products will be canceled effective December 31, 2002, with last legal use on October 31, 2003. Additionally, ethyl parathion end use product labels will be amended to delete use on corn grown for seed, the site with the highest potential risk to reentry workers, and add the last legal use date.

Human Health Assessment

Toxicity

Ethyl parathion is among the most highly toxic chemicals registered with EPA. It has been placed in Acute Toxicity Category 1 (most toxic) for acute eye, skin, and inhalation effects. It is a potent plasma, red blood cell and brain acetyl cholinesterase inhibitor. It is toxic by all routes of exposure and cholinesterase inhibition occurs following acute, subchronic and chronic exposures to low doses of ethyl parathion.

Dietary Exposure

People may be exposed to residues of ethyl parathion through the diet. Acute dietary risk estimates for the US population or US population subgroups, including infants and children, are equal to or less than 3% of the Agency established acute population adjusted dose (aPAD) for parathion. Chronic dietary risk estimates for the general US population, or population subgroups, are less than 1% of the chronic population adjusted dose (cPAD). The Agency considers dietary risk estimates of less than 100 percent of the aPAD or cPAD to be below the level of concern. Dietary risk is low since a low percentage of the crops are treated and the treated commodities are generally highly processed prior to consumption. Water modeling estimates predict that there may be a potential

dietary risk from ethyl parathion in drinking water. The Agency did not review any water monitoring data for ethyl parathion and with the phase-out of all ethyl parathion products, no monitoring data are being required.

Tolerances

Tolerances or maximum residue limits for ethyl parathion and its methyl homolog (methyl parathion) have been established for several commodities (please see 40 CFR 180.121). EPA anticipates publishing a notice which separates the tolerances into ethyl parathion tolerances and methyl parathion tolerances. This notice will propose revocation for commodities for which there has been no registered use of either parathion for a number of years. Tolerances for commodities from the nine crops for which the last legal use is October 31, 2003, will remain at the designated level until these commodities have cleared the channels of trade.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to unacceptable levels of ethyl parathion during and after normal use, even when workers have employed engineering controls and the maximum level of personal protective equipment. Margins of Exposure (MOEs) of 100 and greater are considered to be below the level of risk concern. For ethyl parathion, many of the MOEs were below 1.

Postapplication worker risk is also an issue with ethyl parathion, with estimated safe reentry intervals at greater than 40 days after application.

Human Risk Assessment

Ethyl parathion is of extremely high acute toxicity by causing cholinesterase inhibition. It has been classified as a Group C, possible human carcinogen, but cholinesterase inhibition is caused by doses far below those eliciting carcinogenic effects. However, dietary exposure to ethyl parathion residues in foods is extremely low, as is the cancer risk posed to the general population.

There are no residential uses of ethyl parathion. The main route for residential exposure would result from spray drift from agricultural applications. The method for assessing this exposure is still in development; therefore no residential exposure was considered for ethyl parathion.

Of greater concern is the risk posed to workers, particularly mixers/loaders/applicators, and field workers who come into contact with treated foliage and crops following ethyl parathion applications.

FQPA Considerations

Based on a weight of evidence of all submitted data, no increased susceptibility of rat and rabbit fetuses to ethyl parathion is observed. Therefore, the FQPA safety factor for special sensitivity was not used in the ethyl parathion dietary risk assessment.

No aggregrate assessment was conducted since no residential exposure was assessed.

Environmental Assessment

Use of ethyl parathion poses a high risk to nontarget organisms in terrestrial and aquatic environments.

Environmental Fate

Ethyl parathion degradation appears to be dependent on microbially mediated degradation, soil sorption, and to a small extent photodegradation. Ethyl parathion may be persistent in aerobic mineral soils with half-lives of up to 58 days, but degrades rapidly in aquatic environments.

Ecological Effects and Risk Characterization

Ethyl parathion is very highly toxic to birds, fish, aquatic invertebrates and small mammals, poses a high acute risk to birds, mammals and aquatic invertebrates, and also poses a high chronic and reproductive risk to birds. This high acute, chronic, and reproductive risk would also be expected to impact many endangered species in the ethyl parathion use area. Ethyl parathion is very highly toxic to pollinating insects such as bees and has a well documented history of beekill incidents.

Risk Mitigation

To lessen the worker and ecological risks posed by ethyl parathion use, EPA and the registrants have agreed to the following risk mitigation measures:

- N Immediately stop import of technical ethyl parathion.
- **N** Immediately cancel the registrations of all ethyl parathion manufacturing use products.
- N Immediately stop use on corn grown for seed.
- N Cancel end use product registrations effective December 31, 2002.
- N Stop sale and distribution of all ethyl parathion products by registrants by December 31, 2002.
- N Stop sale and distribution of all ethyl parathion products by retailers by August 31, 2003.
- N Stop all use of ethyl parathion products by October 31, 2003.

Additional Data Required

All previously issued Data-Call-Ins regarding ethyl parathion are considered to be unnecessary since all products are to be canceled. No additional data are required at this time.

Product Labeling Changes Required

All end-use products must comply with EPA's current pesticide product labeling requirements and must be modified to include the following:

- N Add "not for use on corn grown for seed" in the Directions for Use section for corn.
- N "It is unlawful to use this product after October 31, 2003. This container and any contents remaining after October 31, 2003 shall be disposed of in accordance with State and Federal law."

Regulatory Conclusion

The companies holding ethyl parathion product registrations have requested cancellation under FIFRA section 6(f), of all products containing ethyl parathion as an active ingredient. EPA intends to grant this cancellation request after a 30-day public comment period following the publication of the 6(f) notice in The Federal Register. EPA intends to initiate Notice of Intent to Cancel procedures for the registrations which were not requested for cancellation since there will be no legal source of technical product after the voluntary cancellations are granted.

For More Information

EPA is making this Reregistration Eligibility Decision (RED) Fact Sheet for ethyl parathion available, as announced in a Notice of Availability published in the <u>Federal Register</u>. To obtain a copy of the Fact Sheet or to submit written comments, please contact the Pesticide Docket, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of this RED Fact Sheet are available on the Internet. See http://www.epa.gov/REDs.

Printed copies of the RED fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the ethyl parathion RED Fact Sheet also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the ethyl parathion RED, or the status of individual products containing ethyl parathion, please contact the Special Review and Reregistration Division (7508C), 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 Pesticide Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. Their internet address is ace.orst.edu/info/nptn.