

US EPA ARCHIVE DOCUMENT



R.E.D. FACTS

Methoprene

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 from pesticide producers and reviews a complete set of studies showing 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 Document, or RED. This fact sheet summarizes the information in the RED for methoprene.

Methoprene

Methoprene, which is sold under the trade name Altosid, is an insect growth regulator. It is considered a biochemical pesticide because rather than controlling target pests through direct toxicity, methoprene interferes with an insect's life cycle and prevents it from reaching maturity or reproducing. Methoprene is used in the production of a number of foods including meat, milk, eggs, mushrooms, peanuts, rice and cereals. It is also used in aquatic areas to control mosquitoes and several types of flies, moths, beetles and fleas. All pesticide products that contain methoprene as the sole active ingredient are eligible for reregistration except the briquette or slow-release formulation.

Regulatory History

Methoprene was first registered by EPA as a conventional, chemical pesticide in 1975. EPA issued a Registration Standard for methoprene in February 1982. Subsequently, the Agency reclassified methoprene as a biochemical pesticide.

Health Effects

Methoprene is a biochemical pesticide, and its health-related data base consists mainly of a group of screening studies designed to show its toxicity and developmental effects in people and other nontarget organisms. If these studies indicated potential adverse effects, further studies on environmental fate, ecological effects and food residues would have been required.

The results of these screening tests and other available studies on methoprene indicate that it is of low toxicity and poses little risk to people and other nontarget species, with one exception. Methoprene is highly acutely toxic to estuarine invertebrates. Use of the briquette or slow-release formulation of methoprene in aquatic environments could pose an undue risk to these species. Further study of this formulation is being required, as described further below.

Methoprene showed no significant adverse toxicological effects in any human health effects screening studies. The pesticide has very low acute oral and inhalation toxicity potential, and is not an eye or skin irritant (it has been placed in toxicity category IV, the least toxic category, for these effects). It also is not a human skin sensitizer. Methoprene is of low acute dermal toxicity (it has been placed in toxicity category III).

In subchronic studies, methoprene showed some evidence of causing increased liver weights in test animals, at high dose levels. However, in chronic effects and oncogenicity studies, no effects were observed even at the highest dose levels. Other studies show that methoprene does not cause developmental or reproductive effects, is not mutagenic, and metabolizes rapidly and completely in mammals.

Routes Of Exposure**Through the Diet**

People may be exposed to small amounts of methoprene through the food supply. However, the amount of methoprene in the U.S. consumer's diet is well below the level at which any adverse health effects could occur.

Tolerances, or legal residue limits, have been established for residues of methoprene in or on a number of raw agricultural commodities (also see 40 CFR 180.359). Several international Codex Maximum Residue Levels (MRLs) and Canadian tolerances also have been established, as listed below:

Methoprene Tolerances

Canadian Commodity	U.S.	Codex	
	Tolerance (ppm) (ppm)	MRL (ppm)	Tolerance
Cattle, fat	0.3		
Cattle, meat	0.1		
Cattle, meat byproducts	0.1		
Eggs	0.05	0.05	
Goats, fat	0.3		
Goats, meat	0.1		
Goats, meat byproducts	0.1		
Hogs, fat	0.3		
Hogs, meat	0.1		
Hogs, meat byproducts	0.1		
Horses, fat	0.3		
Horses, meat	0.1		
Horses, meat byproducts	0.1		
Milk	0.05		
Mushrooms	1.0	0.2	0.1
Peanuts	2.0	2.0	
Peanut hulls	40.00		
Poultry, fat	0.5		
Poultry, meat	0.5		
Poultry, meat byproducts	0.5		
Sheep, fat	0.3		
Sheep, meat	0.1		
Sheep, meat byproducts	0.1		
Meat, fat		0.1	
Cattle milk		0.05	
Edible offal (mammalian)		0.1	

EPA has reassessed the existing tolerances and finds that they are set at appropriate levels. Although the U.S. tolerances for mushrooms and meat fat are higher than the Codex and Canadian limits, EPA is not lowering the U.S. tolerances at this time. These tolerances are set at levels that accommodate current methoprene use practices in this country. No changes are needed to adequately protect the public health.

No new tolerances are required to cover the existing methoprene uses. (Please note that a petition is pending to establish additional methoprene tolerances for cereal grains, grain milled fractions and rice hulls.)

During Application

People can be exposed to methoprene while mixing, loading or applying the pesticide, and while working among treated crops. However, since methoprene is of such low acute toxicity, and poses no risk of oncogenic, reproductive, developmental or neurotoxic effects, EPA is satisfied that methoprene poses no risks to people who are occupationally exposed to the pesticide.

Environmental Hazards

All the environmental fate data requirements for methoprene are satisfied. The information available to EPA indicates that methoprene will not result in unreasonable adverse effects to the environment. However, the ecological effects studies on methoprene suggest that use of the briquette or slow-release formulation in estuarine areas may cause undue risks to estuarine invertebrates, since the pesticide is highly acutely toxic to these organisms. EPA is therefore requiring further study of this methoprene use.

Environmental Fate

Methoprene degrades rapidly in sunlight, both in water and on inert surfaces. The pesticide also is metabolized rapidly in soil and does not leach. Thus, it should not persist in soil or contaminate ground water.

Ecological Effects

Methoprene has been shown to be practically non-toxic to mallard ducks, and had no effect on quail reproduction. However, the pesticide is moderately toxic to warm water, freshwater fish, and is slightly toxic to cold water, freshwater fish.

Methoprene is very highly toxic to freshwater invertebrates, as seen in studies with crayfish and Daphnia magna. The pesticide also can be very highly acutely toxic to estuarine and marine invertebrates, as seen in studies with grass shrimp and mud-crabs. Marine organisms are not likely to be exposed to methoprene, but estuarine organisms are likely to be exposed as a result of the use of methoprene as a mosquito larvicide.

Methoprene degrades rapidly in water so the use of most formulations in estuaries is not of concern. However, the slow-release briquette formulation is of concern to EPA because it causes estuarine organisms to be exposed to methoprene over an extended period of time. An estuarine invertebrate life cycle toxicity study is being required to adequately characterize the chronic toxicity of methoprene to estuarine organisms.

**Additional Data
Required**

EPA has a sufficient battery of studies to support the reregistration of most uses of methoprene. The only use of concern is the aquatic, mosquito larvicide use involving the briquette formulation. An estuarine invertebrate life cycle study is being required to determine whether long term exposure of these species to methoprene through the briquette formulation poses adverse effects. In addition, an octanol/water partition coefficient study is being required to complete the product chemistry data base for methoprene.

**Product Labeling
Changes Required**

End-use products containing methoprene must bear a statement warning the applicator that improper use could harm aquatic invertebrates. These products also must bear an updated water contamination warning. Please see the Reregistration Eligibility Document for a detailed list of labeling requirements.

**Regulatory
Conclusion**

* The studies available to EPA indicate that the biochemical insect growth regulator methoprene is of low toxicity and poses very little hazard to people and most other nontarget species.

* Methoprene is highly acutely toxic to estuarine invertebrates, however, and these organisms may be exposed to sufficient amounts of methoprene through its aquatic, slow-release, briquette formulation to experience adverse effects. An estuarine invertebrate life cycle toxicity study must be completed before the briquette formulation of methoprene will be eligible for reregistration.

* All other registered methoprene products can be used without causing unreasonable adverse effects in people or the environment. Therefore, all pesticide products containing methoprene as the sole active ingredient, except the briquette formulation, are eligible for reregistration.

* EPA will reregister individual products containing methoprene once product specific data and revised product labeling are submitted to and accepted by the Agency.

**For More
Information**

EPA requests public comments on the Reregistration Eligibility Document for methoprene, and will consider comments received during the next several months. To obtain a copy of the RED, or to submit written comments, please contact the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, U.S. EPA, Washington, D.C. 20460. Call 703-557-4436, or FAX to 703-557-1884.

To obtain a copy of the Registration Standard for methoprene, please contact the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA. 22161. Call 703-487-4650, and request document #PB87-109443.

For more information about methoprene or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (7508W), Office of Pesticide Programs, U.S. EPA, Washington, D.C. 20460. Call 703-808-8000, or FAX your request to 703-308-8005.

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, 24 hours a day, seven days a week, or FAX your inquiry to 806-743-3094.