



R.E.D. FACTS

Pesticide Reregistration

Metalaxyl

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 for reregistration Case 0081, metalaxyl.

Use Profile

Metalaxyl is a systemic fungicide used to control plant diseases caused by the Oomycetes or water-mold fungi. It is used on many food and feed crops, and on non-food, residential and greenhouse crops such as tobacco, ornamental plants, trees, shrubs and vines, and lawns and turf.

Formulations include a dust, granular, wettable powder, emulsifiable concentrate, flowable concentrate, crystalline and ready-to-use liquid. Metalaxyl may be applied by foliar application, soil incorporation, surface spraying, drenching, sprinkler or drip irrigation, soil mix or seed treatment. Use practice limitations on current product labeling prohibit use of treated seed for feed, food or oil; feeding clippings, crop waste or vines to livestock; or grazing treated areas. Preharvest interval restrictions also apply.

Regulatory History

Metalaxyl was first registered as a pesticide in the U.S. in 1979. EPA issued Registration Standards for metalaxyl in June 1981 (NTIS #PB82-172297) and September 1988 (NTIS #PB89-128979). A June 1991 Data Call-In (DCI) required additional aquatic plant growth and field rotational crop studies.

Currently, 81 metalaxyl products are registered; 35 of these are full Federal registrations and 46 are State special local need registrations. These

products contain metalaxyl as the sole active ingredient or in combination with other active ingredients.

Human Health Assessment

Toxicity

Metalaxyl generally is of low acute toxicity but is a moderate eye irritant and has been placed in Toxicity Category II (indicating the second-highest degree of acute toxicity) for eye irritation effects.

In a subchronic feeding study using rats, reduced food consumption and liver cell effects were noted at the highest dose tested. In a dermal study using rabbits, no treatment-related effects were observed.

In a chronic toxicity study using beagle dogs, blood serum enzyme effects and increased liver weights were noted in the highest dose group. A study using rats resulted in liver effects.

Cancer studies using rats and mice raised concerns about the incidence of thyroid, adrenal and liver tumors. EPA reviewed this issue in 1985 and concluded that the studies demonstrated that metalaxyl did not have carcinogenic potential in laboratory animals. In December 1985, EPA classified metalaxyl as a Group E carcinogen; that is, a chemical that does not show evidence of carcinogenicity for humans.

A developmental toxicity study using rats resulted in maternal toxicity and fetotoxicity at the higher dose levels. However, no treatment-related developmental effects were noted in a study using rabbits. Metalaxyl does not cause reproductive toxicity or mutagenicity. A tobacco smoke inhalation study using rats indicates that toxicological effects beyond those associated with heavy cigarette smoking are unlikely.

Dietary Exposure

People may be exposed to residues of metalaxyl through the diet. Tolerances or maximum residue limits have been established for well over 100 raw agricultural commodities, processed foods and feed (please see 40 CFR 180.408(a), (b) and (c); 40 CFR 185.4000(a), (b) and (d); and 40 CFR 186.4000(a), (b) and (d)). EPA has reassessed the metalaxyl tolerances and found that numerous revisions are necessary. These revisions will be handled administratively.

Numerous international Codex maximum residue limits (MRLs) have been established for metalaxyl. Harmonization of Codex MRLs and U.S. tolerances for metalaxyl is not possible at this time as Codex and U.S. tolerance definitions are incompatible.

EPA has assessed the dietary risk posed by metalaxyl. For the overall U.S. population and 22 population subgroups, exposure from all current metalaxyl tolerances represents 16% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The exposure level of the most highly exposed subgroup, children ages 1 through 6, represents 31% of the RfD.

Information on the percent of crop actually treated with metalaxyl was included to more accurately estimate the dietary exposure of the same population groups. The resulting Anticipated Residue Contribution (ARC) for the overall U.S. population represents 8% of the RfD, and the ARC for children is 15% of the RfD. When proposed metalaxyl tolerance changes are considered, the exposure estimates for the overall U.S. population and all subgroups are below the RfD. Therefore, it appears that chronic dietary risk is minimal.

Occupational and Residential Exposure

Based on current use patterns, workers may be exposed to metalaxyl both during and after applications in agricultural and other settings. However, neither an application nor a post-application exposure assessment is required because metalaxyl does not pose sufficient toxicity concerns.

Based on a reevaluation of eye irritation data (Toxicity Category II), the 12-hour Restricted Entry Interval (REI) imposed by the Worker Protection Standard (WPS) is being increased to 24 hours to better protect workers. A protective eyewear requirement also is being added to the Personal Protective Equipment (PPE) previously required for early entry.

Human Risk Assessment

Metalaxyl generally is of low acute toxicity but is an eye irritant. It has been classified as a Group E carcinogen; that is, a chemical showing evidence of non-carcinogenicity for humans.

Although people may be exposed to residues of metalaxyl in many food commodities, the chronic dietary risk from all uses is minimal. Application and post-application risks to workers and others also are minimal because metalaxyl has no toxicological endpoints of concern. Since metalaxyl can irritate the eyes, a 24-hour restricted entry interval (REI) is being imposed and use of personal protective equipment (PPE) including protective eyewear is required.

Environmental Assessment

Environmental Fate

Metalaxyl is moderately stable under normal environmental conditions. It is photolytically stable in water when exposed to sunlight, with a half-life of 400 days, and is stable to photodegradation in soil. In aquatic systems, metalaxyl degrades moderately rapidly. Very little of the chemical is lost to volatilization.

Metalaxyl is persistent and mobile, and both metalaxyl and its major degradate readily leach in many soils. Monitoring data demonstrate that metalaxyl and its primary degradate have the potential to reach groundwater. Metalaxyl has been detected in ground water in five states at levels typically reaching up to 3 parts per billion (ppb). Concentrations as high as 236 ppb have been found, but are not likely the result of normal field use.

In order to reduce the possibility of groundwater contamination, EPA is requiring a groundwater label advisory for metalaxyl end use products. The

registrant also has agreed to conduct a user education program if levels of metalaxyl are detected in groundwater at or above 400 ppb.

Ecological Effects

Metalaxyl is used in numerous sites, and exposure to non-target organisms may result from direct application, spray drift and/or runoff from treated areas.

Metalaxyl is practically non-toxic to birds on a dietary basis, and slightly toxic on an acute, single dose basis. The risk to birds from granular metalaxyl is minimal. Avian reproduction studies still are needed. Metalaxyl is practically non-toxic to honeybees, and is not expected to present a risk to small mammals. Minimal risks are posed to freshwater and estuarine organisms. Metalaxyl is not expected to adversely affect aquatic plants.

Ecological Effects Risk Assessment

Metalaxyl poses minimal if any risks to birds, small mammals, fish and estuarine species, honey bees and aquatic plants. The registered uses of metalaxyl do not present an acute hazard to endangered terrestrial and aquatic animals or plant species.

Additional Data Required

EPA is requiring the following additional generic data for metalaxyl to confirm its regulatory assessments and conclusions: product chemistry, animal metabolism, analytical method validation for additional metabolites, storage stability, magnitude of the residue in plants for a newly registered formulation, residue data for cotton gin byproducts, magnitude of the residue in processed tomato products, and avian reproduction studies.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSF) and revised labeling for reregistration.

Product Labeling Changes Required

All metalaxyl end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Worker Protection Standard - The following entry restrictions are required:
Non-WPS Occupational Uses

For liquid applications: "Do not enter or allow others to enter the treated area until sprays have dried."

For dry applications: "Do not enter or allow others to enter the treated area until dusts have settled."

Homeowner Products

For liquid applications: "Do not allow people or pets to enter the treated area until the sprays have dried."

For dry applications: "Do not allow people or pets to enter the treated area until dusts have settled."

Other Occupational/Residential Requirements

Application Restrictions: "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Engineering Controls: "When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240 (d) (4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements: "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, 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."

Environmental Hazard Statement - The following language is required:

"For terrestrial uses, do not apply to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Do not contaminate water when disposing of equipment wash water or rinsate."

Groundwater Advisory - The following language is required on all end-use products:

"This chemical is known to leach through soil into groundwater under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination."

Regulatory Conclusion

The use of currently registered products containing metalaxyl in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of all products containing the active ingredient metalaxyl are eligible for reregistration.

These metalaxyl products will be reregistered once the confirmatory generic data, 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 metalaxyl 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.

Following the comment period, the metalaxyl RED document 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 metalaxyl RED, or reregistration of individual products containing metalaxyl, 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 8:00 am and 6:00 pm Central Time, Monday through Friday.