

EPA Metiram Facts

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 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 summarizes the information in the RED document for the pesticide metiram, case number 0644.

Regulatory History

Metiram was first registered in the United States in 1948 for use on food and ornamental crops to prevent crop damage in the field and to protect harvested crops from deterioration in storage or transport. Metiram is a member of the ethylene bisdithiocarbamate (EBDC) group of fungicides, which includes the related active ingredients mancozeb and maneb. The EBDCs share the common degradate ethylenethiourea (ETU). EPA has considered aggregate risk from ETU from all sources as a part of the RED.

The EBDCs have been the subject of two Special Reviews. In 1977, the Agency initiated a Special Review for products containing EBDCs based on evidence suggesting that the EBDCs and ETU, a contaminant, metabolite and degradation product of these pesticides, posed potential risks to human health and the environment. In 1982, the Agency concluded this Special Review by issuing a Final Determination (PD 4) which required risk reduction measures to prevent unreasonable adverse effects pending development and submission of additional data needed for improved risk assessment.

The Metiram Registration Standard Document was issued on September 8, 1986, an Addendum to the Registration Standard on January 13, 1987, and an Update to the Metiram Registration Standard on August 11, 1992. In 1987, EPA issued a second Notice of Initiation of Special Review of the EBDC pesticides because of health concerns caused by ETU, including potential carcinogenic, developmental and thyroid effects. Subsequent Data Call-Ins (DCIs) were issued in 1988 and 1995 which included standard and worker exposure data requests, respectively. The Special Review's Preliminary Determination (PD 2/3) was published on December 20, 1989 (54 FR 52158) and the Final Determination (PD 4) on March 2, 1992 (57 FR 7484). The Agency concluded that the dietary risks of EBDCs exceeded the benefits for the following food/feed uses for which one or more of the EBDC pesticides were registered: apricots, carrots, celery, collards, mustard greens, nectarines, peaches, rhubarb, spinach, succulent beans, and turnips. Accordingly, EPA canceled all metiram and other EBDC products registered for use on the above-listed food/feed crops. Currently, the only food/feed uses of metiram eligible for continued registration are apples and potatoes, provided the label revisions are submitted.

Uses

- Metiram is used on apples, potatoes, and ornamental plants (leatherleaf ferns) in nurseries and greenhouses. Metiram was previously registered for use on tobacco seedlings and roses, but these uses have since been voluntarily cancelled. There are no residential labels, and no agricultural uses that could result in exposure to metiram in residential settings.
- Approximately 900,000 pounds of metiram are used for about 125,000 acres treated on an annual basis.
- Metiram is not a Restricted Use Pesticide (RUP)

Health Effects

- Similar to other EBDCs and ETU, the thyroid is the target organ for metiram. Thyroid effects observed in subchronic studies in rats include increased thyroid weights, increased thyroid stimulating hormone (TSH) and decreased T₄ (serum thyroxin) values.

Risks

- Acute, chronic, and cancer dietary (food only) risk from metiram, metiram-derived ETU, and ETU from all sources are low and below the Agency's level of concern.
- The drinking water exposure assessment for metiram addresses concentrations of ETU only, since metiram is not expected to remain in drinking water long enough to reach a location that would supply water for human consumption, whether from surface or groundwater sources. Estimated concentrations of ETU, for both surface and ground water sources of drinking water, are low and not of concern.

- There are no registered residential uses of metiram, thus no residential risks were assessed.
- Acute, short-term, and chronic (non-cancer) aggregate risks are low and not of concern. Aggregate cancer risk estimates are within a negligible risk range
- EPA has risk concerns for some workers who mix, load, and/or apply metiram to agricultural sites, and workers who enter treated areas.
- Chronic risks exceed the Agency's level of concern for some terrestrial species. Also, there is a potential concern for acute and chronic effects on some listed terrestrial and aquatic endangered species, should exposure actually occur.

Risk Mitigation

To address assessed risks of concern, the following mitigation measures will be implemented:

- Add a PF5 respirator to label PPE for some worker scenarios: mixer/loaders of dry flowables for aerial/chemigation applications; airblast applicators to apples; and flaggers,
- Add the use of engineering controls to labels for aerial applicators (enclosed cockpits),
- Reduce apple pre-bloom maximum application rate from 4.8 to 3.6 lbs ai/A,
- Reduce maximum number of applications for apples from 4 to 3 per year,
- Reduce maximum number of applications for potatoes from 7 to 6 per year,
- Limit the number of applications to leatherleaf ferns to 1 per week and 10 per year, and
- Metiram use on roses and dust and wettable powder formulations have been voluntarily cancelled prior to completion of the RED. Further, as a result of the voluntary cancellation of the dust formulation by the technical registrant and risks associated with this formulation, the end-use registrant has requested voluntary cancellation of their active potato seed treatment fungicide product registration.

Regulatory Conclusion

The Agency has determined that metiram containing products are eligible for reregistration provided that the risk mitigation measures are adopted and labels are amended to reflect these measures.

For More Information

Electronic copies of the Metiram RED and all supporting documents are available in the public docket OPP-2005-0177 located on-line in the Federal Docket Management System (FDMS) at <http://www.regulations.gov>.

For more information about EPA's pesticide reregistration program, the Metiram RED, or reregistration of individual products containing metiram, please contact the Special Review and Reregistration Division (7508C), Office of Pesticide Programs, 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 Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 am Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. The NPIC internet address is <http://npic.orst.edu>.