US ERA ARCHIVE DOCUMENT



SEPA Mancozeb 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 mancozeb, case number 0643.

Regulatory History

Mancozeb was first registered in the United States in 1948 as a broad spectrum fungicide used in agriculture, professional turf management, and horticulture. Mancozeb is a member of the ethylene bisdithiocarbamate (EBDC) group of fungicides, which includes the related active ingredients maneb and metiram. The EBDCs share the common degradate ethylenethiourea (ETU), which has been considered in the Agency's assessments. 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.

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. 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 mancozeb and other EBDC products registered on the above-listed food/feed crops.

EPA issued the registration standard for mancozeb, "Guidance for the Reregistration of Pesticide Products Containing Mancozeb as the Active Ingredient," in April 1987. The Agency also issued a Generic Data Call In (DCI) requiring data needed to complete the reregistration of mancozeb in April 1987. EPA completed an update to the registration standard for product and residue chemistry data requirements in August 1992. Additional DCIs for mancozeb were issued in March and October 1995 to require data to evaluate exposure to pesticide handlers and re-entry workers.

Uses

- Mancozeb is used in agriculture, professional turf management, and horticulture. Mancozeb
 is used on a wide variety of food/feed crops, including tree fruits, vegetable crops, field crops,
 and grapes, ornamental plants, and sod farms. Other uses include greenhouse grown flowers
 and ornamentals, and seed and seed piece treatment.
- Approximately 5.6 million pounds of mancozeb are used annually, with the greatest use on potatoes and apples. Mancozeb is also used extensively on grapes, onions, pears, tomatoes, squash, and melons.
- Mancozeb is not a Restricted Use Pesticide.

Health Effects

• Similar to other EBDCs and ETU, the thyroid is the target organ for mancozeb. Thyroid effects were observed in multiple studies across species. Thyroid toxicity was manifested as alterations in thyroid hormones, increased thyroid weight, and microscopic thyroid lesions (mainly thyroid follicular cell hyperplasia), and thyroid tumors.

Risks

- Acute, chronic, and cancer dietary (food only) risk from mancozeb, mancozeb-derived ETU, and ETU from all sources are low and below the Agency's level of concern.
- The drinking water exposure assessment for mancozeb addresses concentrations of ETU only, since mancozeb 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.

- Mancozeb is registered for use in home vegetable gardens and on residential turf. However, a
 use restriction prohibiting homeowner use on sweet corn will effectively eliminate any risk
 concerns associated with the home garden use. In addition, registrants have agreed to
 voluntarily cancel all mancozeb use on residential lawns and turf and delete these uses from
 all product labels.
- Potential residential exposure to mancozeb may also occur from residues remaining on transplanted turf from sod farms. However, the reduced application rate and/or extended PHI, combined with the logistics of transplanting turf and installation restrictions, effectively reduced the potential contribution from this use pattern to a level not of concern to the Agency.
- 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 maneb to agricultural sites and for workers who re-enter treated areas.
- The Agency's screening level ecological assessment showed potential acute and chronic risk concerns for some terrestrial and aquatic species. These risk concerns have been mitigated to the extent practical and feasible by use restrictions. EPA has a potential concern for chronic effects on listed species of birds and mammals, acute and chronic effects on listed species of freshwater fish and freshwater invertebrates, and acute effects on listed species of estuarine/marine fish, should exposure actually occur. The risk mitigation measures described below will reduce the likelihood that endangeered and threatened species may be exposed to mancozeb at levels of concern.

Risk Mitigation

The following use restrictions and personal protective equipment (PPE) must be implemented for mancozeb to be eligible for reregistration. These mitigation measures are to be incorporated into all mancozeb labels.

Use Restrictions

Turf - All Formulations

- Establish a 3 day preharvest interval (PHI) on turf grown on sod farms
- For sod, restrict the amount that can be used to a maximum of 4 applications per year and reduce the maximum rate from 19 lbs ai/A to 17.4 lbs ai/A (69.6 lbs ai/A/season)

• Extend application interval from 7 to 10 days to 10 to 14 days

Turf - Wettable Powder (WP) Formulation

- Delete sod farm use from WP labels
- Use engineering controls (water soluble packs) for WP used on turf (golf courses & industrial parks)

Turf- Liquid Formulations

• Prohibit the application of liquids aerially to golf courses or sod farms, and prohibit the application of liquids in chemigation systems to golf courses

Papaya

• Reduce application rate from 4 to 2 lb ai/A

Cut Flowers/Greenhouse Grown Ornamentals

• Limit number of applications to 20 per year

Sweet Corn

• Prohibit homeowner use (remove from homeowner label)

Human Flaggers

• Prohibit human flaggers or require mechanical flaggers with aerial application

Personal Protective Equipment

WP Formulation, All Crops Except Turf

- Require single layer PPE, with PF 5 respirator and gloves (except pilots, groundboom applicators, and airblast applicators)
- Require single layer PPE for pilots, groundboom applicators, and airblast applicators

WP Formulation, Turf

- Delete sod farm use from WP labels
- Require use of engineering controls (water soluble packs) for WP used on turf (golf courses & industrial parks)

WP Formulation, Seed Treatment

- Require single layer PPE, with PF 5 respirator and gloves (all handlers except sewers and baggers)
- Require single layer PPE for sewers and baggers
- Require application as a liquid slurry or mist

Dry Flowable Formulation (All Crops) and Liquid Formulations (All Crops Except Turf)

- Require single layer PPE with gloves for all handlers except aerial, airblast, & groundboom applicators
- Require single layer, no gloves, for aerial, airblast, & groundboom applicators (to avoid contaminating cab)

Liquid Formulations (Turf)

- Require single layer PPE with gloves and a PF 5 respirator for handlers mixing and loading to support chemigation application to sod
- Prohibit the application of liquids aerially to golf courses or sod farms, and prohibit the application of liquids in chemigation systems to golf courses

Seed Treatment, Liquids

- Require single layer PPE, with gloves (all handlers except sewers and baggers)
- Require single layer PPE for sewers and baggers

Potato Seed-Piece Treatment, Dust Formulation

- Require engineering controls, i.e., dust collection equipment, for commercial loaders and applicators
- Require single layer PPE with gloves and a PF5 respirator for all on-farm handlers

Regulatory Conclusion

The Agency has determined that products containing the active ingredient mancozeb are eligible for reregistration provided that the risk mitigation measures are adopted and labels are amended to reflect these measures. The following uses of mancozeb are not eligible for reregistration and are being voluntarily canceled by registrants and deleted from all mancozeb labels: foliar use on cotton, use on pineapple seed pieces (for propagation), use on residential lawns/turf, use on athletic fields/turf, and use on pachysandra.

For More Information

Electronic copies of the Mancozeb RED and all supporting documents are available in Docket # EPA-HQ-OPP-2005-0176 at http://www.regulations.gov.

For more information about EPA's pesticide reregistration program, the Mancozeb RED, or reregistration of individual products containing mancozeb, 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.