United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | EPA 738-F-05-XX August 2005

Maneb 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 maneb, case number 0642.

Regulatory History

Maneb was first registered in the United States in 1962 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. Maneb is a member of the ethylene bisdithiocarbamate (EBDC) group of fungicides, which includes the related active ingredients mancozeb and metiram. 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.

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

The Maneb Registration Standard dated August 22, 1986 required additional product chemistry data. Addendum No. 1 to the Maneb Registration Standard dated March 31, 1987 included a review of data not available at the time of the original registration standard and required additional product chemistry data. A comprehensive Data-Call-In (DCI) was issued April 1, 1987 to all registrants of maneb addressing product chemistry data requirements. The Product Chemistry Chapter of the Maneb Registration Standard Update dated May 13, 1988 included a review of data submitted in response to the April 1987 DCI with regard to adequacy in fulfilling product chemistry requirements. A Guidance Document for maneb was issued in October 1988. Product chemistry data submitted in response to the Guidance Document were reviewed in the Maneb Registration Standard Update dated August 11, 1992, and additional data were required for the registration of maneb.

Uses

- Maneb is used on a wide variety of food/feed crops, including fruit and nut crops, vegetable crops, field and forage crops, grapes, field crop seeds, and others; ornamental plants in nurseries and greenhouses; and sod farms. There are no residential uses, and no agricultural uses that could result in exposure to maneb in residential settings.

- Approximately 2.5 million pounds of maneb are used annually, mostly on almonds, lettuce, peppers, and walnuts.

- Maneb is not a Restricted Use Pesticide (RUP)

Health Effects

- Similar to other EBDCs and ETU, the thyroid is the target organ for maneb. Thyroid effects observed in multiple studies across species include changes in clinical chemistry parameters indicative of thyroid toxicity, increased thyroid weight, follicular (thyroid) cell hyperplasia, decreased T_4 (serum thyroxin), and increased incidence of diffuse follicular epithelial hypertrophy/hyperplasia.

Risks

- Acute, chronic, and cancer dietary (food only) risk from maneb, maneb-derived ETU, and ETU from all sources are low and below the Agency's level of concern.

- The drinking water exposure assessment for maneb addresses concentrations of ETU only, since maneb 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 currently registered residential uses of maneb. The only potential residential exposure to maneb is from residues remaining on transplanted turf from sod farms. 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 workers who enter treated areas.

- Acute and chronic risks exceed the Agency's level of concern for some terrestrial and aquatic species. Also, there is potential concern for acute and chronic effects on 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:

<u>Maneb-All Formulations</u>

- Sweet Corn - Cancel Use
- Grapes - Cancel Use
- Apples - Cancel Use
- Kadota Figs - Cancel Use
- Seed Treatment to Rice and Peanuts - Cancel Use
- Oats Seed Treatment - Reduce maximum application rate from 0.0031lb ai/lb seed to 0.0021 lb ai/lb seed
- Almonds- Reduce maximum seasonal rate from 25.6 to 19.2 lbs ai/acre/season and retain maximum application rate of 6.4 lbs ai/acre
- Sod Farm Turf - Reduce maximum application rate from 17.4 lbs ai/acre to 8.7 lbs ai/acre, limit maximum seasonal rate to 34.8 lbs ai/acre/season and add a 3 day pre-harvest interval. Handlers mixing/loading of dry flowables and liquids for aerial or chemigation application, add a PF5 Respirator.

- Cut Flowers - Limit number of applications per year to 20
- Commercial Potato Seed-Piece Treatment (dust) - require engineering controls (e.g. dust collector equipment)

Maneb- Wettable Powder Formulation Only

- Sod Farm Turf - Cancel Use
- Chemigation/Aerial Applications - Delete Application Method
- For mixing/loading all remaining uses add PF 5 Respirator.

Regulatory Conclusion

The Agency has determined that maneb containing products are eligible for reregistration provided that the risk mitigation measures are adopted and labels are amended to reflect these measures. The following uses of maneb are not eligible for reregistration and are being voluntarily canceled by registrants and deleted from all maneb labels: sweet corn, grapes, apples, kadota figs, and seed treatment use for peanuts and rice.

For More Information

Electronic copies of the Maneb RED and all supporting documents are available in the public docket OPP-2005-0178 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 Maneb RED, or reregistration of individual products containing maneb, 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.