United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-05-007 September 2005

R.E.D. FACTS

Chloroneb

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 generally 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 chloroneb (Chemical Code 027301 and Case No. 0007).

Use Profile

Chloroneb (1,4-dichloro-2,5-dimethoxybenzene) is a fungicide currently registered for use on a wide variety of food crops but is primarily used for pre-plant cottonseed treatment as well as on commercial turf and ornamentals. The markets for chloroneb seed treatment uses include: sugar beets, soybeans, cotton, and beans.

Treated cottonseed are used in the cotton growing states of CA, AZ, MS, LA, AR, TX and KS with lower use in AL, GA, SC, TN and NC. Turf uses are primarily in midwestern and northeastern states as well as FL for use on golf courses. Chloroneb can be applied as a seed treatment, foliar spray, chemigation, ground spray, drip, and soil drench.

Human Health Assessment

Acute Toxicity

Chloroneb has been shown to have low dermal, oral and inhalation toxicity. It is classified as Toxicity Category IV for oral ingestion, dermal toxicity, and inhalation toxicity, and Toxicity Category III for eye irritation. Chloroneb is a dermal sensitizer.

The category ratings are:

Category I = very highly or highly toxic

Category II = moderately toxic

Category III = slightly toxic

Category IV = practically non-toxic

Dietary Exposure and Risk

EPA has assessed the dietary risk (food and drinking water) posed by chloroneb. No acute dietary assessment was performed since an endpoint attributable to a single exposure was not identified from the available database. Chronic (non-cancer) risks from combined food and water are below the Agency's level of concern and the Agency concluded that chloroneb is unlikely to pose a dietary cancer risk.

Residential and Occupational Exposure and Risk

There is a potential risk from postapplication exposure (dermal and incidental oral) in residential settings, such as recreational areas, golf courses, and home lawns resulting from entering areas previously treated with chloroneb. There is also a potential risk from occupational exposure from the application of chloroneb on both food and non-food use sites resulting from handling chloroneb products (i.e., mixer/loaders and applicators) and for occupational postapplication exposure resulting from entering areas previously treated with chloroneb.

FQPA Considerations

The Environmental Protection Agency (EPA) has concluded its reregistration eligibility decision for chloroneb and determined that the chemical is eligible for reregistration provided that: (1) current data gaps and additional data needs are addressed; (2) the risk mitigation measures outlined in this document are adopted; and (3) label amendments are made to implement these measures. The 24 tolerances for chloroneb are now considered reassessed as safe under section 408(q) of FFDCA, as amended by FQPA.

The Agency concluded that the toxicology data base for chloroneb is not complete, since an acceptable 2-generation reproduction study is not available and therefore an FQPA 10X database uncertainty factor has been retained. In addition, the Agency is requiring other studies for the reregistration of chloroneb.

Potential exposures from food, drinking water, and residential scenarios were considered, and aggregated for chloroneb. The pathways for adults lead to exposure via the oral (dietary) and dermal (residential) routes. The pathways for children lead to exposure via the oral (dietary) and, dermal and incidental oral (residential) routes. The aggregate risks from residential exposure alone (excluding dietary exposure), all had risks of concern.

EPA has found no information indicating chloroneb shares a common mechanism of toxicity with other substances. Chloroneb does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of tolerance reassessment and a decision on reregistration eligibility, EPA is not assuming that chloroneb shares a common mechanism of toxicity with other compounds. In the future, if additional information suggests chloroneb shares a common mechanism of toxicity with other compounds, additional testing may be required and a cumulative assessment may be necessary.

Environmental Assessment

The assessment of the fate and transport properties of chloroneb is based upon an incomplete data set. Therefore, there are uncertainties associated with the fate and transport behavior of chloroneb and its major degradates. Based on available data, chloroneb is expected to leach to ground water under sandy soils, as degradation would be expected to slow down when chloroneb leaches below the root zone. Chloroneb is mobile and is expected to be transported to surface water, through runoff.

For ecological risks, there are exceedences of the level of concern (LOC) for endangered species, or no data to dismiss the concern for endangered species, in the following taxa: avian, mammal, freshwater fish and invertebrates, and estuarine/marine organisms. For avian and freshwater organisms, the risk quotients

exceeded the endangered species acute LOC, and no chronic data are available. For mammals and estuarine/marine organisms, no relevant acute or chronic data are available to dismiss the concern for endangered species.

Risk Mitigation

To mitigate residential and occupational risks to chloroneb and to reduce potential exposures to wildlife, the registrant has agreed to:

- voluntarily cancel the use of chloroneb on residential lawns and turf, as well as on lawns and turf at parks and schools;

- amend its label to remove ornamentals, all other turf, bedding plants, ferns, and on-farm seed treatment from its label pending the Agency receipt, review, and acceptance of a 21-day dermal toxicology study and reevaluation of risk; and,

- voluntarily amend labeling for turf uses as follows, if the revised risk assessment based on the dermal toxicity study indicates (see above) acceptable risks:

    - restrict use on turf to golf course tees, greens, collars, aprons, and spot treatment of fairways, as well as, professional athletic turf (football, baseball fields, etc.)

    - limit the number of applications on golf courses to 6 per year; 4 applications at 7 lb ai/A and 2 applications at 16 lb ai/A

    - limit maximum use per year on golf courses to 60 lb ai/acre/year

    - require a minimum retreatment interval of 14 days for golf course tees, greens, and aprons, and professional athletic fields;

- replace the wettable powder formulation with the use of water soluble packaging for commercial seed treatment, and require a closed loading system when loading/applying liquid for commercial seed treatment.

Additional Data Required

EPA is requiring confirmatory data for chloroneb. These include: (1) the 2-generation reproduction data in the rat; (2) oncogenicity data in the mouse; and (3) combined chronic toxicity/oncogenicity data in the rat. In addition, the Agency is requiring other studies for the reregistration of chloroneb. For a complete listing of

required studies with corresponding guideline number, see Section V. of the chloroneb RED document.

Product Labeling Changes Required

The chloroneb end-use product must comply with EPA's pesticide product labeling requirements summarized in the RED. For a comprehensive list of labeling requirements, please see Section V. of the chloroneb RED document.

Regulatory Conclusion

EPA has concluded its reregistration eligibility decision for chloroneb and determined that the chemical is eligible for reregistration provided that: (1) current data gaps and additional data needs are addressed; (2) the risk mitigation measures outlined in this document are adopted; and (3) label amendments are made to implement these measures.

For More Information

EPA is making the Reregistration Eligibility Decision (RED) document and all supporting documents for chloroneb available, as announced in a Notice of Availability published in the *Federal Register* November 16, 2005. To obtain a copy of the RED document, please contact the Pesticide Docket, Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805. Please refer to EPA Docket number OPP-2004-0369.

Electronic copies of the RED and this fact sheet are available on the Internet. See http://www.epa.gov/pesticides/reregistration/status.htm.

For more information about EPA's pesticide reregistration program, the chloroneb RED, or reregistration of individual products containing chloroneb, please contact the Special Review and Reregistration Division (7508C), 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 Pesticide Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm 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.