United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-05-002 September 2005

EPA R.E.D FACTS

Ferbam

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 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 (FQPA) 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 current human health and safety standards and can be used without posing unreasonable risks to human health and 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 ferbam (Chemical Code Number: 034801). Ferbam is a part of the dimethyldithiocarbamate case number 2180, which includes ziram, sodium dimethyldithiocarbmate, and potassium dimethyldithiocarbamate.

Use Profile

Ferbam is a fungicide registered for use on citrus, pome and stone fruits, cranberries, and tobacco.

Annual domestic ferbam usage is approximately 150,000 pounds. Ferbam rates per application and rates per year are generally less than 6.0 lbs ai/A and 60 lbs ai/A respectively. Major ferbam use areas are in Florida, Massachusetts, and New Jersey.

Regulatory History

Ferbam has been registered in the United States since 1948. Several data call-ins (DCIs) have been issued for ferbam. In 1989, the Agency conducted a review of the scientific data base underlying pesticide registrations and identified missing or inadequate studies. Subsequent Data Call-Ins (DCIs) were issued in 1991, 1995, and 1996.

Human Health

Toxicity

Assessment

In acute studies, ferbam has low acute toxicity (Toxicity Category III) via the oral and dermal routes, and moderate (Toxicity Category II) acute toxicity via the inhalation route of exposure. Ferbam is a slight eye or skin irritant, and weak dermal sensitizer. A substantially complete database has been assembled for ferbam as a result of bridging of data from the ziram and thiram databases.

In longer-term studies, ferbam is toxic to the liver, kidneys, and lungs. Lowest observed adverse effect levels (LOAELs) observed in rat studies are based on slower observed response time.

The thiram developmental neurotoxicity (DNT) NOAEL of 1.4 mg/kg/day was used to establish a dietary reference dose for females ages 13 - 49. In addition, the thiram DNT endpoint was used for the short-term and intermediate-term dermal endpoints in the ferbam occupational assessment.

There were no tumor effects observed in the ferbam studies; therefore, no cancer assessment was done. Based on information from the thiram DNT study, the Agency concluded that a ferbam DNT study is not required.

Dietary Exposure and Risk

The ferbam dietary risk assessment considered acute and chronic risks from residues in food based on field trials, and modeled drinking water residue values. The highest acute dietary (food and water) exposure is for children 1-2 years old at 68% of the Acute Population Dose (aPAD), and is not of concern. The greatest chronic exposure is for children age 1- 2 years old at 5% of the Chronic Population Adjusted Dose (cPAD), and is not of concern.

Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water pathways), as well as exposures from non-occupational sources (e.g., residential uses). Ferbam has no residential uses, thus the aggregate risk included food and water only. The chronic and acute aggregate risk does not exceed the Agency's level of concern.

Occupational Exposure and Risk

Based on current use patterns, occupational handlers (mixers, loaders, and applicators) may be exposed to ferbam during normal use. For the occupational use of ferbam, EPA is concerned with any MOE less than 100, which incorporates uncertainty factors of 10x for interspecies variation and 10x for intraspecies variation.

The Agency identified 10 handler scenarios resulting from mixing/loading and applying ferbam to crops. The majority of short and intermediate term scenarios had MOEs that exceeded the target of 100 with baseline PPE: long sleeve shirt, pants, shoes and socks. To achieve the target MOE of 100, airblast applicators must wear chemical resistant-gloves, double layers, and a PF5 respirator. Long-

term worker exposure is not expected for ferbam and thus was not assessed. Five post-application scenarios were assessed, and there were risks of concern for pome fruits, mangos, and grapes. These risks were mitigated by decreased application rates.

FQPA Considerations

The Agency has concluded that the FQPA Safety Factor for ferbam should be reduced (equivalent to 1X) based on a complete database for FQPA consideration. The toxicity database for ferbam was bridged with thiram and ziram to satisfy the guideline data requirements. Developmental toxicity studies were conducted in rats and rabbits with no evidence of susceptibility. However, there is evidence of decreased body weight and body weight gains for females in the 2-generation reproduction study in rats.

After establishing developmental toxicity endpoints to be used in the risk assessment with traditional uncertainty factors (10x for interspecies variability and 10x for intraspecies variability), the Agency has no residual concerns for the effects seen in the developmental toxicity studies. Therefore, the 10X FQPA special safety factor was reduced to 1X.

Based on limited evidence of developmental neurotoxicity, the Agency has determined that a developmental neurotoxicity (DNT) study is not required for ferbam. The developmental and two generation reproduction studies were complete. Therefore, the Agency determined that a database uncertainty factor (UF_{DB}) is not needed.

Tolerance Reassessment

The tolerances for ferbam meet the FQPA safety standard for the U.S. population and sensitive populations, including infants and children. EPA found that there is a reasonable certainty of no harm to the general population and any subgroup from the use of ferbam.

Environmental Assessment

Environmental Fate

The major degradate of ferbam identified in the environmental fate studies is thiram. Ferbam is not persistent in the environment because it degrades rapidly via hydrolysis, photodegradation, and aerobic soil metabolism to thiram. Ferbam's half-life ranges from as little as 31 minutes in water to several hours in soil. Ferbam is not expected to leach into groundwater or run-off to surface water.

Ecological Toxicity

Ferbam is considered to be slightly to practically non-toxic to birds on an acute basis. The chronic avian data indicate that chronic dietary exposure results in adverse effects for several reproductive parameters, including decreased egg production, and hatchling survival and growth.

Ferbam is classified as moderately toxic to small mammals on an acute oral basis with decreased body weight as the affected endpoint.

A honey bee acute toxicity study indicated that ferbam is practically non-toxic to the honey bee.

Acute toxicity studies on ferbam show that it is highly toxic to estuarine/marine aquatic invertebrates, estuarine/marine fish, and freshwater invertebrates. No data are available to assess the chronic toxicity of thiram or ferbam to freshwater fish or aquatic invertebrates.

Risks to Terrestrial and Aquatic Organisms

The Agency conducted a screening level ecological risk assessment to determine the potential impact of ferbam use on terrestrial and aquatic organisms.

The majority of ecological risk quotient (RQ) values do not exceed the Agency's level of concern (LOC), with the following exceptions: for freshwater fish and estuarine marine fish the RQs exceeded the LOC of 0.5. The RQs ranged from 0.15 - 1.14 for freshwater fish and 1.8 - 14.3 for estuarine and marine aquatic invertebrates. Freshwater fish and estuarine/marine invertebrates RQs exceeded the acute endangered species level of concern (0.05) for all crop scenarios.

The acute RQs for mammals ranged from 0.01 - 1.5, and the chronic mammalian RQs ranged from 1.5 - 137 and exceeded the LOC for all scenarios assessed. The acute RQs for birds ranged from 0.01 - 1.0, and the chronic avian RQs ranged from 5 - 400 and exceeded the LOC for all scenarios.

Risk Mitigation

There were several mitigation measures taken to reduce occupational and ecological risks of concern identified for ferbam. The registrant will voluntarily cancel use on rough lemon nursery stock, conifers, and flowering plants. The maximum single application rate will be decreased on several crops, the total number of applications per season will decrease to three on most crops, and aerial application will be prohibited on all crops. The deletion of aerial application decreases risk to aquatic organisms from spray drift and it eliminates a handler exposure scenario with MOEs below the target of 100. The addition of double layer PPE and a PF5 respirator will provide sufficient protection to workers during airblast applications. The decrease in several application rates will decrease the exposure levels to aquatic organisms, non-target mammals, and workers.

Additional Data Required

EPA is requiring confirmatory data requirements for ferbam. For a complete listing of required studies with corresponding guideline numbers, see Section V of the ferbam RED document.

Ecological Data Requirements

EPA is requiring data on freshwater fish, aquatic invertebrate life-cycle, and freshwater fish life-cycle.

Toxicity Data Requirements

EPA is not requiring any additional toxicity data.

Chemistry Data Requirements

The Agency has identified several product and residue chemistry requirements. Crop field trial data, field accumulation in rotational crops, and storage stability data is required.

Product Labeling Changes Required

All ferbam products must comply with EPA's current pesticide product labeling requirements and with the labeling changes set forth in Section V of the ferbam RED document.

Regulatory Conclusion

EPA has determined that all products containing ferbam as the active ingredient are eligible for reregistration, provided changes specified in the ferbam RED are incorporated into the label and additional data identified in Section V of the RED confirm this conclusion.

For More Information

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

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