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

R.E.D FACTS

Dimethipin

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 (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 dimethipin (Chemical Code Number: 118901).

Use Profile

Dimethipin is registered for use as a cotton growth regulator and desiccant. In addition, it is an herbicide that is used post-emergence for selective control of weeds. Dimethipin is registered for use on cotton and nonbearing apple nursery stock.

Annual domestic dimethipin usage is approximately 100,000 pounds. For dimethipin, rates per application and rates per year are generally less than 0.31 lbs ai/A and 0.56 lbs ai/A respectively. Dimethipin is used predominantly in Georgia, Mississippi, and Alabama. Dimethipin is used alone and is also used as tank mix with other plant growth regulating chemicals.

Regulatory History

Dimethipin has been registered in the United States since 1982. Several data call-ins (DCIs) have been issued for dimethipin. 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 1989, 1991, and 1995.

Human Health Assessment

Toxicity

In acute studies, dimethipin has moderate acute toxicity (Toxicity Category II) via the oral and inhalation routes, and low (Toxicity Category III) acute toxicity via the dermal route of exposure. Dimethipin is not an eye or skin irritant, nor a skin sensitizer.

In longer-term studies, dimethipin is toxic to the liver, kidneys, and lungs. In rats, the lowest observed adverse effect levels (LOAELs) are based on decreased body weight gains and body weight. The no observed adverse effect levels (NOAELs) are based on cardiovascular toxicity in the gastrointestinal tract for female rats and toxicity in the gastrointestinal tract for male rats.

Dimethipin has been classified as a Category C chemical, or possible human carcinogen. However, a quantification of carcinogenic risk was not recommended, based on the weight-of-evidence evaluation of available data.

There are no signs of neurotoxicity or developmental toxicity following exposure to dimethipin.

Dietary Exposure and Risk

The dimethipin dietary risk assessment considered only chronic risks from residues in food based on field trials because no acute endpoint was identified. The chronic dietary (food) risk is estimated at less than 1% of the Chronic Population Adjusted Dose (cPAD) for all population subgroups, and is not of concern.

The Agency estimates potential surface water and ground water pesticide contamination using models and monitoring data. The maximum surface water modeling concentration of 7.3 parts per billion (ppb), or micrograms per liter (ug/l), was used to estimate the surface water EDWC. The ground water EDWC and chronic drinking water exposure value is based on a ground water monitoring value of 99 ppb. Both the surface water and ground water EDWC values are below the drinking water level of concern (DWLOCs) of 762 ppb for chronic exposure, and are 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). Dimethipin has no residential uses, thus the aggregate risk included food and water only. Additionally, there were no acute endpoints identified therefore only chronic aggregate risk was calculated. The chronic aggregate risk does not exceed the Agency's level of concern.

The DWLOC method was used to assess the aggregate risk of dimethipin. A DWLOC is the portion of the chronic PAD (cPAD) remaining after estimated dietary (food only) exposures have been subtracted and the remaining exposure has been converted to a concentration (ug/liter or ppb). This concentration value (DWLOC) represents the available or allowable exposure through drinking water.

Chronic (non-cancer) aggregate risk. The chronic DWLOCs range from 218 ppb to 762 ppb with the most sensitive population being infants. The EDWCs, which range from 7.3 to 99 ppb, are less than the DWLOCs which means that the risks are not of concern. In addition, the chronic aggregate risks are not of concern because they are estimated at less than 1 percent of the cPAD.

Occupational Exposure and Risk

Based on current use patterns, occupational handlers (mixers, loaders, and applicators) may be exposed to dimethipin during normal use. The Agency identified 7 handler scenarios resulting from mixing/loading and applying dimethipin to crops. For the occupational use of dimethipin, EPA is concerned with any MOE less than 100, which incorporates uncertainty factors of 10x for interspecies variation and 10x for intraspecies variation.

The majority of short and intermediate term scenarios had inhalation MOEs that exceeded the target of 100 with baseline PPE: no respirator, long sleeve shirt, pants, shoes and socks. Aerial application requires a closed cockpit to achieve the target MOE of 100. Long term worker exposure is not expected for dimethipin and thus was not assessed. There are no post-application risks to workers because there were no dermal endpoints identified.

FQPA Considerations

The Agency has concluded that the FQPA Safety Factor for dimethipin should be reduced (equivalent to 1X) based on a complete database for FQPA consideration. The toxicity database for dimethipin includes acceptable developmental and reproductive toxicity studies. Developmental toxicity studies were conducted in rats and rabbits with no evidence of susceptibility. There is evidence of decreased body weight and decreased body weight gains for females in the 2-generation reproduction study in rats. There were no body weight changes for males.

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 no evidence of developmental neurotoxicity, the Agency has determined that a developmental neurotoxicity (DNT) study is not required for dimethipin. 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 dimethipin meet the FQPA safety standards for the U.S. population and sensitive populations, including infants and children. There are

seventeen tolerances that were reassessed in the dimethipin RED, and of these seventeen 11 are proposed for revocation. The tolerances are for cotton seeds and hulls, cattle, horse, goat, and sheep meat and byproducts, as well as the fat of horses, goats, sheep, and cattle. EPA found that there is a reasonable certainty of no harm to the general population and any subgroup from the use of dimethipin.

Environmental Assessment

Environmental Fate

Dimethipin is persistent in most environmental conditions with biodegradation, hydrolysis, and photolysis all occurring slowly. Half-lives for dimethipin range from a few weeks to several months. Dimethipin is not expected to absorb in solids and sediments, and thus has potential for leaching to groundwater or run-off to surface water. Dimethipin does not bioaccumulate in aquatic organisms, and no major degradates were identified in the environmental fate studies.

A complete database has been assembled for dimethipin. The dissipation of dimethipin is dependent on the site-specific properties of the soil to which it is applied. Data indicate that dimethipin is practically insoluble in water and stable to hydrolysis and photolysis in soil. The aqueous photolysis half-lives are 60, 224, and 72 days at pH levels of 5,7, and 9 respectively.

According to laboratory mobility studies, dimethipin is highly mobile in all soils. Dimethipin has been detected in soil at depths of 90 cm below the soil surface.

Ecological Toxicity

Dimethipin is considered to be practically non-toxic to birds on an acute basis with mortality as the endpoint. There is no chronic avian data thus chronic avian risk cannot be precluded. Dimethipin 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 dimethipin is practically non-toxic to the honey bee. There were no data available on terrestrial plants; however, dimethipin is expected to be toxic to terrestrial plants as it is an herbicide.

Acute toxicity studies on dimethipin show that it is slightly toxic to aquatic invertebrates, freshwater fish, and estuarine fish. In addition, dimethipin is acutely toxic to freshwater plants.

Risks to Terrestrial and Aquatic Organisms

The Agency conducted a screening-level ecological risk assessment to determine the potential impact of dimethipin use on non-target terrestrial and aquatic organisms. The Agency used modeling to evaluate ecological risks for dimethipin.

The majority of ecological risk quotient (RQ) values do not exceed the Agency's level of concern (LOC), with the following exceptions: for acute restricted use, the RQ exceeds the LOC (0.2) for a 15g mammal feeding on short grass, and for endangered species, the RQs for 15g mammals feeding on short grass, tall grass, broadleaf plants, and small insects exceed the acute endangered risk LOC of 0.1.

Risk Mitigation

There was no mitigation needed for dimethipin as there are no human health risks of concern, and there were very few ecological risks of concern.

Additional Data Required

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

Ecological Data Requirements

EPA is requiring data on seedling germination and seedling emergence (Tier II) and a vegetative vigor (Tier II) study. In addition, avian reproduction tests, early-life stage freshwater fish, and fish life cycle studies must be submitted to fulfill guideline requirements.

Toxicity Data Requirements

The EPA is not requiring registrants to submit additional toxicity studies. However, there is clarification needed on three existing toxicity studies: the test material stability, homogeneity, and concentration in the dosing medium.

Chemistry Data Requirements

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

Product Labeling Changes Required

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

Regulatory Conclusion

EPA has determined that all products containing dimethipin as the active ingredient are eligible for reregistration, provided changes specified in the dimethipin 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.epa.gov/edockets.

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