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

R.E.D. FACTS

Ametryn

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 reregistration case 2010, ametryn.

Use Profile

Ametryn is an herbicide used to control broadleaf and grass weeds in fields planted with field corn, popcorn, pineapple, and sugarcane. There is only one formulation, an 80% water dispersible granule. Ametryn is applied mainly by groundboom but also by aerial application in Florida.

Regulatory History

Ametryn was first registered as a pesticide in the U.S. in 1964. Several Generic Data Call-Ins (DCIs) were issued that required a full range of testing on ametryn's chemistry, toxicology, and environmental fate.

Currently, only one ametryn end use product is registered. EPA has received requests for voluntary cancellation of all other products.

Human Health

Acute Toxicity

Assessment

Ametryn has been shown to have low acute dermal, oral, and inhalation toxicity. It is classified as a Toxicity Category III for oral ingestion and dermal toxicity and Category IV for inhalation toxicity. Ametryn is non-irritating to the eye (Category III) and skin (Category IV) and did not demonstrate sensitization. The category ratings are:

Category I = very highly or highly toxic

Category II = moderately toxic

Category III = slightly toxic

Category IV = practically non-toxic

Based on the available data, acute and chronic toxicity is expected to be low. Cancer is not expected to be a concern as tumors only occurred in oncogenicity studies when the maximum dose tolerated was exceeded.

Dietary Exposure and Risk

People may be exposed to residues of ametryn through the diet. Established tolerances or maximum residue limits for field corn, popcorn, pineapple, and sugarcane (please see 40 CFR §180.258) have been reassessed and set at lower levels. All other tolerances are to be revoked. No new tolerances were established for ametryn.

EPA has assessed the dietary risk (food and drinking water) posed by ametryn. Acute and chronic dietary (food only) risk from ametryn from all sources are low and below the Agency's level of concern. Estimated concentrations of ametryn and its metabolites, in groundwater and surface water sources of drinking water, are low resulting in risks below EPA's level of concern.

Occupational and Residential Exposure and Risk

Based on current use patterns, occupational handlers (mixers, loaders, and applicators) may be exposed to ametryn during normal use. Estimated risk to handlers with baseline personal protective equipment (pants, long sleeve shirt, shoes, and socks) are low and not of concern. Post application exposure is not expected for the registered use patterns of ametryn. Also, there are no residential uses of ametryn and no anticipated exposures in or around homes and recreational areas.

FQPA Considerations

EPA has determined that the reduced tolerances for ametryn, with amendments and changes as specified in the RED, meet the safety standards under the FQPA amendments to §408(b)(2)(C) of the FFDCA, and that there is a reasonable certainty of no harm for infants and children.

EPA considered the aggregate exposure from food and drinking water (there are no residential uses) and determined that the risks were well below the Agency's level of concern.

EPA reduced the ametryn FQPA safety factor to 1X based on the following: (1) there are no concerns and no residual uncertainties with regard to developmental toxicity studies and the reproduction study; (2) there were no indications of immunotoxicity or direct neurotoxicity in the standard studies, (3) the good quality of the dietary exposure data (crop field trial data); and (4) the conservatism in the drinking water models which are also considered adequately protective to infants and children.

EPA has determined that there is no known mechanism of toxicity that would support grouping ametryn with chloro-s-triazines (atrazine, simazine, propazine and their chloro-s-triazine metabolites) for a cumulative risk assessment. Ametryn has a different functional group attached to the triazine ring, i.e., thiomethyl versus chloro. Moreover, ametryn does not exhibit the same toxicity profile as the chloro-s-triazines. Further, the Agency has found no information indicating ametryn shares a common mechanism of toxicity with other substances, nor does ametryn appear to produce a toxic metabolite produced by other substances.

Environmental Assessment

For terrestrial species, short-term or acute ametryn risks are low to mammals, birds, and non-target insects. However, the screening-level ecological risk assessment for terrestrial species indicates some exceedance of the chronic levels of concern (LOCs), especially to mammals that rely on grasses and broadleaf plants/insects for their diet and birds that rely on short grasses. In aquatic species, acute and chronic risks are low, with the exception of the chronic risk for estuarine/marine invertebrates.

Consistent with its chemical use as an herbicide, ametryn is toxic to plants, including dicots which are much more sensitive to ametryn than monocots. The LOCs for dicot plants are exceeded for uses of ametryn in all exposure scenarios (adjacent areas, semi-aquatic, and spray drift). The LOCs for monocots exceed for almost all uses in adjacent area and semi-aquatic exposure scenarios. Similarly, for aquatic plants, although based on limited data, the LOCs are exceeded for both vascular and non-vascular plants for uses of ametryn.

Risk Mitigation

To lessen the environmental risks posed by ametryn, EPA is requiring the following risk mitigation measures:

- reduce the maximum single application rate and maximum annual rate for all remaining crops;
- limit aerial application to sugarcane in Florida only;
- eliminate use on bananas, plantain, and non-cultivated areas; and

- measures to control spray drift to reduce the risk of ametryn to non-target organisms.

Additional Data Required

EPA is requiring several general and confirmatory data requirements for ametryn. These include product and residue chemistry studies, environmental fate and effects studies, and a mutagenicity study. EPA will be calling in one new study, a modified foliar dissipation study to determine ametryn's half-life on leaves. For a complete listing of required studies with corresponding guideline number, see Section V. of the ametryn RED document.

Product Labeling Changes Required

The remaining ametryn 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 ametryn RED document.

Regulatory Conclusion

EPA has determined that all products containing ametryn as the sole active ingredient are eligible for reregistration, provided changes specified in the ametryn RED are incorporated into the label.

For More Information

EPA is making the Reregistration Eligibility Decision (RED) document and all supporting documents for ametryn available, as announced in a Notice of Availability published in the *Federal Register* September 21, 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-2004-0411.

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 ametryn RED, or reregistration of individual products containing ametryn, 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.