United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-97-008 August 1997

R.E.D. FACTS

Diflubenzuron

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. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that 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 0144, diflubenzuron.

Use Profile

Diflubenzuron is an acaricide/insecticide (insect growth regulator) used to control many leaf eating larvae of insects feeding on agricultural, forest and ornamental plants (e.g. gypsy moths, mosquito larvae, rust mites). Diflubenzuron is used primarily on cattle, citrus, cotton, mushrooms, ornamentals, standing water, forestry trees and in programs to control mosquito larvae and gypsy moth populations. Formulations include a soluble concentrate, flowable concentrate, wettable powder and a pelleted/tableted. Diflubenzuron is applied by airblast, aircraft and hydraulic sprayers.

Regulatory History

Diflubenzuron was first registered as a pesticide in the U.S. in 1976. EPA issued a Registration Standard for diflubenzuron in September 1985 (PB86-176500). A November 1991 Data Call-In (DCI) required additional residue chemistry and ecological effects data. Currently, 29 diflubenzuron products are registered.

Human Health Assessment

Toxicity

In studies using laboratory animals, diflubenzuron generally has been shown to be slightly toxic on an acute basis. It is absorbed by the dermal route and has been placed in Toxicity Category III (the second lowest of four categories). It has also been placed in Toxicity Category IV (the lowest of four categories) for ingestion by the oral and inhalation routes.

Dietary Exposure

People may be exposed to residues of diflubenzuron through the diet. Tolerances or maximum residue limits have been established for diflubenzuron (please see 40 CFR 180.377). All tolerances for diflubenzuron residues are currently expressed in terms of diflubenzuron *per se* [40 CFR §180.377(a) and (b) and §186.2000]. The Agency has concluded that the tolerance expression should be changed to address combined residues of diflubenzuron and metabolites convertible to parachloroaniline (PCA), expressed as diflubenzuron. EPA has reassessed the diflubenzuron tolerances and found that data for cotton gin by-products, cottonseed, grass forage, liver, milk, mushrooms, pasture grass hay, soybeans and walnuts are required for the continued registration of diflubenzuron.

EPA has assessed the dietary risk posed by diflubenzuron. For the overall U.S. population and 22 subgroups, exposure from all current diflubenzuron tolerances represents less than 1% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The exposure level of the most highly exposed subgroup, children (aged 1-6), represents 1% of the RfD. Therefore, it appears that chronic dietary risk is minimal.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to diflubenzuron during and after normal use of applications in agricultural and other settings. The Agency is establishing a short-term (1 to 7 days) toxicological endpoint of sulfhemoglobinemia and intermediate-term (1 week to several months) toxicological endpoint of methemoglobinemia.

Human Risk Assessment

Diflubenzuron generally is of low acute toxicity, but affects the hemoglobin of animal in studies. Although the Agency has determined that there is no evidence of carcinogenicity for diflubenzuron *per se* (Group E); p-chloroaniline (PCA), a metabolite of diflubenzuron, is a probable human

carcinogen (Group B2). The Agency has also determined that p-chlorophenylurea (CPU), a metabolite of diflubenzuron that is closely related to PCA but has no adequate carcinogenicity data, is considered as having the same carcinogenicity potential (Q1*) as PCA. The total cancer risk estimate for PCA and related metabolites for the overall U.S. population is 1 X 10^{-6}. The Rfd is 0.02 mg/kg/day, based on the NOEL of 2.0 mg/kg/day in the 52-week chronic oral study in dogs with a safety factor of 100 to account for interspecies extrapolation and intraspecies variability.

Of greater concern is the risk posed to diflubenzuron handlers, particularly mixers/loaders/applicators. The risk for short-term occupational exposure is acceptable for handlers wearing long-sleeved shirts, long pants and chemical-resistant gloves. The risk for intermediate-term occupational exposure is also acceptable, provided dust/mist respirators (TC-21C) are required for mixers, loaders and applicators when working with diflubenzuron for certain higher risk application methods. Post-application reentry workers will be required to observe a 12-hour Restricted Entry Interval, as set by the WPS.

Under the Food Quality Protection Act of 1996, the Agency has determined that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to diflubenzuron. The total dietary cancer risk for the published tolerances for the overall U.S. population is approximately 1 x 10^{-6}. Since there are no detections of diflubenzuron in ground water, dietary risk from drinking water are expected to be negligible. Based on very low residues detected in forestry dissipation studies, a low dermal absorption rate, and extremely low dermal and inhalation toxicity, occupational uses of diflubenzuron in residential locations, parks, or forests treated with diflubenzuron are expected to result in insignificant risk.

Environmental Assessment

Environmental Fate

Diflubenzuron appears to be relatively non-persistent and immobile under normal use conditions. The major route of dissipation appears to be biotic processes (half-life of approximately 2 days for aerobic soil metabolism). Diflubenzuron is stable to hydrolysis and photolysis. Available data indicate that it is unlikely that diflubenzuron will contaminate ground water or surface water. Additional data are needed to confirm this conclusion.

Ecological Effects

Diflubenzuron is practically non-toxic to avian species, small mammals, freshwater fish and marine/estuarine fish on an acute oral dietary basis, while it is slightly toxic to avian species on a subacute dietary basis.

Diflubenzuron is non-toxic to bees. The results indicate that diflubenzuron is very highly toxic to freshwater aquatic invertebrates, including marine/estuarine crustacea, while it is highly toxic to marine/estuarine mollusks. The results indicate that diflubenzuron affects reproduction, growth and survival in freshwater invertebrates as well as reproduction in marine/estuarine invertebrates.

Ecological Effects Risk Assessment

The risk assessment conducted using available data indicates that levels of concern are not exceeded for avian species, mammals, insects or freshwater fish. Although the use of diflubenzuron is expected to cause some adverse chronic effects to estuarine/marine fish at the highest application rate (forestry), these effects are not as widespread as those associated with freshwater and estuarine/marine invertebrates. The use of diflubenzuron is expected to cause adverse acute and chronic effects to both freshwater and estuarine/marine invertebrates, including endangered species.

The risk to aquatic invertebrates is also expected to be substantial when diflubenzuron is applied to control mosquito larvae. Since this use involves direct application to water and/or near water, no mitigation is currently proposed.

Risk Mitigation

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

- row crops and orchard uses must include a 150 foot buffer zone for aerial applications and a 25 foot vegetative buffer strip to decrease runoff in all cases (buffer strip will also serve as a buffer zone for spray drift from ground applications);
- aerial applications must include the most current spray drift language; and
- all products must bear a hazards statement warning about possible adverse effects to aquatic organisms.

Additional Data Required

EPA is requiring the following additional generic studies for diflubenzuron to confirm its regulatory assessments and conclusions: ecological effects, toxicity, residue chemistry, and occupational and residential exposure.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All diflubenzuron end-use products must comply with EPA's current pesticide product labeling requirements. For a comprehensive list of labeling requirements, please see the diflubenzuron RED document.

Regulatory Conclusion

The use of currently registered products containing diflubenzuron in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Diflubenzuron products will be reregistered once the required product specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for diflubenzuron during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the diflubenzuron RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the diflubenzuron RED, or reregistration of individual products containing diflubenzuron, please contact the Special Review and Reregistration Division (7508W), 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 Pesticides Telecommunications Network (NPTN). Call toll-

free 1-800-858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.