United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-96-006 March 1996

R.E.D. FACTS

Desmedipham

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 2150, desmedipham.

Use Profile

Desmedipham is a selective postemergence herbicide used to control various annual weeds. Desmedipham is Federally registered for use on sugar beets. There is one Special Local Needs registration granted to the State of Washington for use on table beet and Swiss chard seed production uses. Formulations include emulsifiable concentrates and wettable powders. Desmedipham is applied in spring by band treatment or broadcast method by aircraft or groundsprayer. There is a 75 day preharvest interval.

Regulatory History

Desmedipham was first registered as a pesticide in the U.S. in 1974. Currently, there are 10 Federally registered desmedipham products. Data Call-Ins (DCI) were issued in 1991 and 1992 requiring data in support of reregistration. An additional DCI for re-entry protection data and mixer/loader/applicator exposure monitoring data for desmedipham products was issued in March 1995.

Human Health Assessment

Toxicity

In studies using laboratory animals, desmedipham generally has been shown to be practically non-toxic for acute oral toxicity, inhalation toxicity and

dermal irritation, and has been placed in Category IV (the lowest of four categories) for these effects . It is slightly toxic for dermal exposure and has been placed in Toxicity Category III for this effect. Desmedipham is moderately toxic for eye irritation and has been classified as Category II.

Desmedipham is not considered a developmental toxicant or a mutagen. Its cancer classification is Group E (evidence of non-carcinogenicity for humans) pending receipt and evaluation of confirmatory data.

Dietary Exposure

People may be exposed to residues of desmedipham through the diet from processed sugar and sugar products derived from sugar beets. Tolerances have been established of .2 ppm in/on sugar beet roots and tops (please see *40 CFR 180.353*). EPA has reassessed these desmedipham tolerances and found them acceptable.

AgrEvo has petitioned the Agency to establish a tolerance for sugarbeet tops at 15 ppm. The Agency must receive acceptable field trial data prior to acceptance of this proposal. Available data indicate that residues of desmedipham do not concentrate in processed food or feed; therefore, no food or feed additive tolerances are established or required at this time. No international Codex Maximum Residue Levels (MRLs) have been established or proposed for desmedipham.

EPA has assessed the dietary risk posed by desmedipham. The Anticipated Residue Concentration (ARC) for the overall U.S. general population represents about 0.1 % of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The most highly exposed subgroup, non-nursing infants less than one year old, has an ARC which represents 0.41% of the RfD. This low fraction of the allowable RfD is considered to be an acceptable dietary exposure risk.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to desmedipham during and after normal use of formulations during application in agricultural settings. The Margins Of Exposure for dermal exposure are of concern for occupational mixers/loaders. EPA is requiring chemical-resistant gloves for all mixers and loaders. In addition, a dust/mist respirator will be required for mixers/loaders of wettable powder formulations who are supporting groundboom applications. To adequately mitigate risks to mixers/loaders of wettable powder formulations who are supporting aerial applications, EPA is requiring that the product must be formulated in water-soluble packaging, or application rates must be limited to no more than 0.5 lb of active ingredient per acre on no more than 350 acres treated per day. The Agency believes that implementation of the above measures will adequately mitigate the potential risk identified in the risk assessment.

Human Risk Assessment

Desmedipham generally is of low acute and chronic toxicity. It poses a very low risk from dietary exposure. The potential risk to handlers from exposure may be adequately mitigated by appropriate use of Personal Protective Equipment or engineering controls. Post-application reentry workers will be required to observe a 24-hour Restricted Entry Interval.

Environmental Assessment

Environmental Fate

Although the environmental fate database is not complete, there is sufficient acceptable and supplemental environmental fate information for the Agency to conclude that desmedipham will not persist in the environment. The primary degradation pathway for desmedipham is hydrolysis to ethyl-(3-hydroxyphenyl) carbamate (EHPC) and aniline, with further degradation by microbial processes to carbon dioxide. Photodegradation, volatilization, and bioaccumulation in fish do not appear to contribute significantly to the dissipation of desmedipham. Desmedipham and EHPC have a low potential to leach to ground water in most soils. It is expected that desmedipham residues which reach surface water by either spray drift or runoff will be rapidly degraded.

Ecological Effects

The Agency has concluded that risk from desmedipham to aquatic plants and animals is minimal, as is the acute risk to insects, birds, and mammals. The Agency believes that chronic risk to mammals is also minimal, and that a chronic risk to birds exists but is low to moderate. Effects are expected to be limited in extent, and the impact to the environment should be signifcant only on the local level. Risk to terrestrial and semiaquatic plants could not be assessed because of lack of testing using a typical end-use product. To be conservative, desmedipham is assumed to pose risk to these plants through exposure from drift, however this risk is low and is addressed by labelling changes.

Additional Data Required

EPA is requiring additional information to upgrade the following supplemental submissions for desmedipham to confirm its regulatory assessments and conclusions: General Metabolism, Hydrolysis, Anerobic soil metabolism, Anaerobic aquatic metabolism, Terrestrial field dissipation, Rotational crops (confined), Magnitude of the residue in plants (sugar beet tops).

In addition, new studies using a typical end-use product are being required for seedling emergence testing and a vegetative vigor test. 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

The minimum PPE for occupational uses of desmedipham end-use products is long-sleeved shirt and long pants, chemical-resistant gloves, shoes plus socks for all formulations. In addition, for wettable powder formulations, a dust/mist filtering respirator must be used. Wettable-powder formulated products must be contained in water-soluble packaging when applied aerially (unless the application rate used is no more than 0.5 pounds active ingredient per acre, assuming aerial applications of up to 350 acres per day). A 24-hour restricted-entry interval is required. For early entry into a treated field, workers must wear coveralls, chemical-resistant gloves, shoes plus socks, and protective eyewear.

Regulatory Conclusion

The use of currently registered products containing desmedipham 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.

Desmedipham products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA. The use of eligible desmedipham products in accordance with labeling specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required confirmatory generic data, product specific data, CSFs, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to desmedipham will be reregistered when all of their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for desmedipham 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 desmedipham 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 desmedipham RED, or reregistration of individual products containing desmedipham, 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.