United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-00-007 September, 2000

R.E.D. FACTS

Diclofop-Methyl

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 2160, Diclofop-Methyl.

Use Profile

Diclofop-methyl is a restricted use herbicide used on wheat, barley, and golf courses (turf). Diclofop-methyl controls or suppresses various grass weed species. The total annual domestic usage of diclofop-methyl is approximately 750,000 pounds of active ingredient (a.i.).

Regulatory History

Diclofop-methyl was first registered in the United States in 1982 for the control or suppression of wild oats and annual grasses in wheat and barley. It is currently also registered for goose grass control on established golf courses. The use of diclofop-methyl on golf courses is authorized under Section 24(c) of FIFRA in 11 states.

Human Health Assessment

Toxicity

Toxicity Categories, which range from 1 (most toxic) to 4 (least toxic), placed diclofop-methyl in toxicity category II for the oral route of exposure, III by the dermal route, and IV via the inhalation route. In primary irritation studies, diclofop-methyl produced moderate eye irritation (toxicity category III) and slight dermal irritation (toxicity category IV).

Diclofop-methyl is classified as a likely human carcinogen based on laboratory studies in the rat and the mouse. The Agency used a linear low-dose approach (Q^*) to assess cancer risk to diclofop-methyl.

Dietary Exposure (food and water)

EPA's human health risk assessment for diclofop-methyl indicates few risk concerns. Food risks, as measured by both an acute and chronic Population Adjusted Doses (PAD), are well below the Agency's level of concern. When considering the carcinogenic potential of diclofop-methyl, the dietary (food) risk appears to be slightly above the level of concern (1.2×10^{-6}). Even though this cancer risk is slightly over the level of concern (10^{-6}), the Agency believes this overestimates the actual carcinogenic exposure to diclofop-methyl in the food supply. Drinking water risk estimates are based on surface and groundwater screening models. Limited monitoring data and a small scale prospective ground water (PGW) study also support the conclusion that diclofop-methyl is not likely to be found in drinking water. Drinking water risks are, therefore, not of concern to the Agency.

Non-Occupational Risks (Golfers)

The only non-occupational source of exposure to diclofop-methyl is residues on treated golf courses. Cancer risk for golfers is 2.2×10^{-6}. The Agency believes that the cancer risks associated with golfers on diclofop-methyl treated turf is an upper-bound estimate since the post-application risk assessment is based on protective assumptions related to golfer behavior and diclofop-methyl use practices. The risk is overestimated because the Agency assumes the golfer is exposed continuously during a round of golf (four hours, assuming the entire course is treated), two days per year, for 50 years. But because diclofop-methyl is usually applied as a spot treatment covering less than the entire course, the golfer would be exposed for a much shorter duration. A more likely duration of exposure is probably ½ hour rather than four hours. With ½ hour of exposure, the resulting cancer risk would be 2.7×10^{-7} and would not be of concern to the Agency. The odds of a golfer encountering diclofop-methyl treatment twice a year for a lifetime is also unlikely. The Agency is therefore not concerned with cancer risks to golfers exposed to residues of diclofop-methyl on treated turf.

Aggregate Risk

Under the Food Quality Protection Act, the Agency considers contributions to risk from various exposure sources, specifically food, drinking water, and non-occupational sources (e.g., golfers playing on treated courses). Four aggregate risk assessments were calculated for diclofop-methyl.

The short-and intermediate term as well as the chronic (non-cancer) aggregate are not of concern to the Agency. Although the cancer aggregate risk appears to be of concern, the Agency does not believe that exposure to residues of diclofop-methyl in food and drinking water contribute to an aggregate risk of concern for the general population. The food cancer risk is based on a number of protective exposure assumptions and the water cancer risk is based on screening level modeling estimates.

Golfers who play on diclofop-methyl treated courses may be at a greater aggregate cancer risk because the carcinogenic risk to golfers is 2.2×10^{-6}. Any aggregation of carcinogenic exposure to golfers with carcinogenic exposure from food and drinking water would ordinarily increase the risk further above the level of concern. In this case, golfer exposure to diclofop-methyl is probably much less than the assessment indicates. Because the cancer risk estimate to golfers is based on high-end assumptions and may possibly overestimate risk, aggregation with food and drinking water estimates does not result in a meaningful estimate of aggregate carcinogenic risk. Overall, the Agency concludes that there is neither an aggregate carcinogenic concern for the general population nor for golfers who play on diclofop-methyl treated courses.

Tolerances

Tolerances (refer to 40#CFR §180.385) or maximum residue limits are summarized below.

- Revoke 2 tolerances for lentils and dry peas. The registrant no longer supports these commodities.
- Establish 23 tolerances for the following: Barley hay, wheat forage, and wheat hay. Tolerances will also be established for the following: cattle fat, cattle meat, cattle meat byproducts (excluding kidney), cattle kidney, goat fat, goat meat, goat meat byproducts (excluding kidney), goat kidney, hog fat, hog meat byproducts (excluding kidney), hog kidney, horse fat, horse meat, horse meat byproducts (excluding kidney), horse kidney, milk, sheep fat, sheep meat, sheep meat byproducts (excluding kidney), and sheep kidney.

Occupational and Residential Exposure

The most significant human risk concern relates to handlers who mix, load, and apply diclofop-methyl to agricultural sites. Non-cancer risks do not exceed the Agency's level of concern. However, cancer risks associated with the use of diclofop-methyl are of concern to the Agency. Cancer risk for handlers incorporating both dermal and inhalation exposure range from $1.4x10^{-2}$ to $5.1x10^{-6}$ without the use of personal protective equipment, $8.4x10^{-5}$ to $6.0x10^{-7}$ with PPE, and $5.8x10^{-5}$ to $1.4x10^{-6}$ at the engineering controls level. The Agency's goal is to reduce worker cancer risks to 10^{-6} or less, although risks somewhat higher than 10^{-6} may be considered acceptable if measures to mitigate these risks are not available and benefits of continuing use are demonstrated. Thus, for risks that are greater than 10^{-6} and less than 10^{-4}, the Agency carefully examines risks in this range including the benefits of use, availability of alternatives, number of workers at risk, and will seek ways to further mitigate these risks. Because all of the worker scenarios described in Section III have cancer risk estimates in the range of 10^{-6} to 10^{-4}, the Agency considered whether additional worker mitigation measures were available.

FQPA Considerations

The FQPA Safety Factor is intended to provide up to an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food or to compensate for an incomplete database. The Agency reduced the FQPA Safety Factor to 1X after evaluating the hazard and exposure data for diclofop-methyl. The FQPA Safety Factor was reduced to 1X for the following reasons:

1. The toxicology database is complete for the assessment of the effects following *in utero* and/or postnatal exposure to diclofop-methyl;
2. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to diclofop-methyl in the available toxicity data;
3. The Agency determined that a developmental neurotoxicity study is not required for diclofop-methyl; and
4. Adequate monitoring data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary and non-occupational sources of exposure and to provide a screening level drinking water exposure assessment. The assumptions and models used in the assessments do not underestimate the potential risk for infants and children.

Environmental Assessment

Environmental Fate

Diclofop-methyl is not persistent in soil under aerobic conditions and has very low persistence in anaerobic soil or water. The residues that do reach surface

waters will likely be rapidly degraded by microbial metabolism. To better understand the environmental fate and transport of diclofop-methyl and its free acid metabolite in soil, soil water, and groundwater, a small scale prospective groundwater (PGW) study was undertaken by the registrant. The results of the PGW study indicated that neither diclofop-methyl or its acid degradate migrated to the ground water during the two- plus- year study in a worst case scenario application. When considering the existing environmental fate data, the Agency concludes that diclofop-methyl is unlikely to reach surface and ground water.

Ecological Effects

The Agency has identified certain ecological risks of potential concern. Although there are remaining uncertainties, diclofop-methyl poses a risk of reproductive toxicity to mammals on an acute basis and may also pose a chronic risk to mammals. Runoff and spray drift from diclofop-methyl pose a high risk to nontarget grasses and sedges. Toxicity data are lacking for risks to aquatic plant species and the Agency is requiring further studies to better characterize these risks. Revised label language on reducing spray drift will help to reduce exposure to non-target organisms.

Risk Mitigation

The Agency found that exposure to wheat and barley handlers could be substantially reduced by employing appropriate engineering controls, such as closed mixing/loading systems and enclosed application equipment. To minimize the occupational cancer risk to such handlers, the registrant has agreed to implement engineering controls to reduce exposure to all agricultural handlers.

Additional Data Required

In addition to certain chemistry data requirements, EPA is requiring the following additional generic studies for diclofop-methyl to confirm its regulatory assessments and conclusions:

- Dermal Exposure (§ 875.2400)
- Foliar Dislodgeable Residue Dissipation (§ 875.2100)
- Bioaccumulation Study in Fish (§ 850.1730)
- Aquatic Plant Toxicity (§ 850.4400 and 850.5400)

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 diclofop-methyl end-use products must comply with EPA's current pesticide product labeling requirements and with the specifications outlined in the RED. For a comprehensive list of labeling requirements, please see Table 11 the diclofop-methyl RED document.

The Agency finds that the currently registered uses of diclofop-methyl are eligible for reregistration, provided engineering controls for both aerial and groundboom handlers are required for diclofop-methyl containing products and reflected in product labeling,

Regulatory Conclusion

The use of currently registered products containing diclofop-methyl 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.

Diclofop-methyl 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 diclofop-methyl 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 Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet are available on the Internet. See http://www.epa.gov/REDs.

Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the diclofop-methyl RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the diclofop-methyl RED, or reregistration of individual products containing diclofop-methyl, 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 Telecommunications Network (NPTN). 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. Their internet address is ace.orst.edu/info/nptn.