United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-98-016 November 1998

R.E.D. FACTS

DICOFOL

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 0021, dicofol.

Use Profile

Dicofol is an organochlorine miticide/pesticide used for foliar applications, mostly on cotton, apples, and citrus crops. Other crops include: strawberries, mint, beans, peppers, tomatoes, pecans, walnuts, stonefruit, cucurbits, and non-residential lawns/ornamentals. Formulations registered for use on food/feed crops include emulsifiable concentrates, and wettable powder formulations. These formulations may be applied as concentrated or dilute sprays using aircraft, duster, groundboom, and sprayer.

Regulatory History

Dicofol was first registered as a pesticide in the U.S. in 1957. EPA issued a Registration Standard for dicofol on December 30, 1983. Data Call-Ins on September 30, 1991, March 3, 1995, and October 13, 1995 required additional residue and ecological effects data.

Currently, 32 dicofol products are registered, including end use and manufacturing use products.

Human Health Assessment

Toxicity

Exposure to pesticidal residues of dicofol to the U.S. population can occur via diet through its usage on a wide array of crops, such as apples and citrus. Occupational exposure to dicofol occurs to pesticide workers via its agricultural application.

The Agency has calculated the chronic dietary reference dose (RfD) for dicofol, the amount of pesticide believed not to cause adverse effects if consumed daily over a 70 year lifetime, at 0.004 mg/kg/day based on hormonal toxicity seen in both sexes of an oral chronic dog study.

EPA has calculated an acute dietary reference dose for dicofol, the amount of a pesticide which can be consumed in one day and believed not to cause adverse effects, of 0.05 mg/kg/day based on neurotoxic effects observed after a single oral dose in a rat acute neurotoxicity study.

For the purpose of determining short-term and intermediate term worker risk, the endpoints of concern were selected for developmental and hormonal toxicity observed in rabbit and rat studies.

For the purposes of precautionary language for the registered product labels, dicofol has been found to be toxicity category III (the second lowest of four categories) for acute oral toxicity, acute dermal toxicity, acute eye irritation, and acute dermal irritation. Dicofol has been found to be toxicity category IV (lowest category) for acute inhalation.

Dietary Exposure

People may be exposed to residues of dicofol through the diet. Tolerances or maximum residue limits have been established for dicofol. (See 40 CFR §180.163). The raw agricultural commodity tolerances listed under 40 CFR §180.163 are currently expressed in terms of dicofol *per se*, with no animal tolerances established. The dicofol RED recommends that the listing of tolerances for residues in/on plant commodities be designated 40 CFR §180.163(a), and that a new section, 40 CFR §180.163(b), be provided for the listing of animal tolerances expressed in terms of the combined residues of dicofol and its metabolite FW-152.

The dicofol RED recommends that dicofol tolerances be revised as follows: 1 tolerance level is recommended to be revoked, 4 tolerances are recommended to remain unchanged, 3 tolerances are recommended to be raised, 45 new tolerances are recommended to be established, and 33 tolerance levels are recommended to be moved to a crop grouping. In most cases, tolerance levels being moved to a crop grouping are also having their tolerance levels lowered, based on new field trial data.

Chronic dietary food exposure is calculated at 38% of the RfD in the most at-risk population (children, 1-6 years), not enough to cause concern. Acute dietary exposure estimates, while higher (90% of RfD in the most at-risk

population, non-nursing infants, less than 1 years old), still do not exceed the Agency's Level of Concern.

When possible exposure to pesticidal residues of dicofol through drinking water, taken from conservative modeling estimates, are included in the dietary assessment, the Agency still does not have a risk concern for any population subgroup with either acute or chronic dietary exposure.

Occupational and Residential Exposure

The risk assessment in this RED raises some strong concerns for dicofol mixers/loaders/applicators, and field workers. The endpoint of concern is hormonal and developmental toxicity. At the present time, most short term and all intermediate term scenarios result in Margin of Exposures (MOEs) which exceed the Agency's level of concern, even with engineering controls. However, the Agency believes that the default assumptions used to arrive at this conclusion may have led to an overestimation of that risk (i.e. the default assumption of 100% dermal absorption and a initial Dislodgeable Foliar Residue (DFR) level at 20% of the application rate and assuming residue dissipation of 10% per day). To improve our estimation of dicofol risk, the registrants have initiated a dermal toxicity study, which is due to the Agency on December 31, 1998. In addition, as a result of a Data Call In from October 13, 1995, the registrants are also completing a DFR study, due in October, 1998. EPA will consider results of these studies in a revised risk assessment. In the interim, while this data is being developed and evaluated, the registrants have agreed to undertake risk mitigation measures (described in the Risk Mitigation section of this Fact Sheet) to address the occupational risks identified in this RED.

EPA will revise the Restricted Entry Interval (REI) based upon results of the dermal toxicity study and DFR study.

Because all residential uses are being voluntarily canceled by the registrants, residential risk is not a concern.

FQPA Considerations

EPA conducted additional risk analyses using available data in response to the new FQPA requirements. Based upon data evaluated by the Agency, the 10X FQPA safety factor is being reduced to 3X for all population subgroups for both chronic and acute dietary risk.

The Agency has not made a determination whether dicofol or any other pesticide has a common mechanism of toxicity for either cancer or non-cancer effects and require a cumulative risk assessment. For the purposes of this RED, EPA has considered only the risks from dicofol. If required, cumulative risks will be assessed when methodologies for determining common mechanism of toxicity and for performing cumulative risk assessments are finalized.

Environmental Assessment

Environmental Fate

Dicofol has a short to intermediate half-life (days to months) in laboratory studies. Major routes of dissipation are hydrolysis in neutral and alkaline environments and microbial-mediated degradation. Dicofol is likely to be more persistent in acidic than neutral or alkaline soils or waters and in drier conditions. Laboratory and field data suggest that dicofol is not very mobile, and neither leaching nor volatility are expected to play an important role in the dissipation of dicofol.

Ecological Effects

Dicofol is moderately to slightly toxic on an acute basis to terrestrial animals and slightly toxic to honey bees. Dicofol has also been shown to cause reproductive effects in avian and mammalian species. For avian species, laboratory studies suggest that reproductive sensitivity varies greatly, with raptors apparently the most sensitive. Dicofol is highly to very highly toxic to all aquatic organisms tested, including fish, invertebrates, and estuarine/marine organisms.

Ecological Effects Risk Assessment

Acute risks to non-target mammals from exposure to dicofol may occur for citrus, apples, pears, nuts, and quince uses from exposure to short grass food sources. Because many small mammal species primarily feed on short grass, acute hazard from these use patterns is possible. For avian species, exposure to dicofol in short grass exceeds the Level of Concern (LOC), based on current uses. Since few if any avian species feed solely or even primarily on short grass, the acute hazard from this use does not present an unacceptable risk.

Chronic hazard, in the form of reproductive impairment to mammalian and avian species, can occur for all currently registered use patterns.

For certain avian species, numerous reproductive parameters may be adversely affected by exposure to dicofol. Greatest risk appears to be from citrus. Laboratory data suggest that, for certain avian species, numerous reproductive parameters may be adversely affected by exposure to dicofol, based on present uses.

In aquatic environments, fresh and salt water fish, shellfish, and invertebrates are potentially at risk from direct contamination of dicofol to the water. Indirect contamination is also a concern

Labeling and other risk mitigation measures recommended in Chapters 4 and 5 of the dicofol RED are sufficient to address these environmental risk concerns.

Risk Mitigation

To address risks to homeowners, residents, and children:

(All residential uses have been eliminated from labels and will be voluntarily canceled.

To address risks to handlers:

(Mixers/loaders/applicators must wear additional personal protective equipment (PPE), as specified in the labeling specifics in Chapter 5 of the RED, and use enclosed cabs and cockpits.

(All wettable powder formulations produced after December 31, 1998 must be produced in water soluble packaging (WSP).

(Application with handheld equipment is eliminated for liquid formulations.

(Liquid formulations produced after December 31, 1998 must bear labeling requiring closed mixing systems for dry beans.

To address risks to workers (persons entering treated areas following applications of dicofol):

(A revised REI will be set, based on DFR data being submitted in October, 1998, and on a dermal toxicity study being submitted in December, 1998.

To protect the environment and wildlife:

Dicofol applications are limited to no more than one per year. Previously, for some uses, the number of applications allowed per year was either unrestricted or limited to 2 or 3 applications per year.

Dicofol applications on citrus will not exceed 3 pounds a.i./acre per year. This has been reduced from 8 pounds a.i./acre per year.

Dicofol applications on strawberries will not exceed 2 pounds a.i./acre per year. This has been reduced from 2.4 pounds a.i./acre per year.

Additionally, as a result of previous agreements with the registrants, applications will not exceed:

3 lb ai/acre for apples and pears (reduced from 4 lb ai/acre);

2 lb ai/acre for pecans and walnuts (reduced from 4 lb ai/acre);

1.5 lb ai/acre for cotton (reduced from 1.6 lb ai/acre);

1.3 lb ai/acre for grapes (reduced from 1.5 lb ai/acre);

0.63 lb ai/acre for cucurbits (reduced from 1.5 lb ai/acre);

0.75 lb ai/acre for tomatoes and peppers (reduced from .8 lb ai/acre)*;*

1.5 lb ai/acre for stonefruits;

1.5 lb ai/acre for beans; and

0.55 lb ai/acre for nonresidential lawns and ornamentals.

- **#** A spray drift and Runoff Caution Statement is being added to the label. Also, a statement prohibiting application directly to water is being added to the label.

Additional Data Required

All dicofol products must comply with EPA's current pesticide product labeling requirements. For a comprehensive list of labeling requirements, see Chapter 5 of the dicofol RED document.

EPA is requiring the following additional generic studies for dicofol to confirm its regulatory assessments and conclusions: a UV/visible absorption study, DFR study, dermal toxicity study, and postnatal developmental neurotoxicity study in addition to other confirmatory studies listed in Chapter 5 of the dicofol RED.

The Agency also is requiring product-specific data including revised Confidential Statements of Formula (CSFs) and revised labeling for reregistration. In addition, the Agency is requiring certain confirmatory data, as detailed in Chapter 4 of the dicofol RED document.

Product Labeling Changes Required

All dicofol end-use products must comply with EPA's current pesticide product labeling requirements. For a comprehensive list of labeling requirements, please see the dicofol RED document, chapter 5.

Regulatory Conclusion

EPA has determined that products containing dicofol may be eligible for reregistration, as specified in the dicofol RED, contingent upon results of a dermal toxicity study due to the Agency in December 1998.

The registrants have agreed to a voluntary cancellation of all dicofol products, which will go into effect if, after a review of the dermal toxicity study, MOEs remain unacceptable. In addition, the registrants have agreed to the risk mitigation measures discussed in the Risk Mitigation section of this Fact Sheet. Moreover, a restricted entry interval (REI) will be set, based on the dermal toxicity study and a DFR study to be submitted to EPA in October 1998.

If results of the dermal toxicity study and DFR study show dicofol to be acceptable, based upon review by the Agency's science peer review committees and EPA management approval, dicofol products will then be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to dicofol will be reregistered when all of their other active ingredients also are eligible for reregistration.

While the current occupational risk assessment indicates possible unacceptable risk levels, EPA has found that it is not appropriate to declare dicofol ineligible at this time. One key consideration is the fact that the registrants are submitting a study which may be a more appropriate study for regulatory purposes but which the Agency has not yet received. Although the Agency would not normally delay a decision for a study voluntarily conducted by a registrant outside the RED timeframe, two factors make this appropriate here. First, the registrants have committed to significant risk mitigation measures to be implemented immediately. Second, the registrants have committed to a process that would result in automatic and voluntary cancellation of any use which continues to have unacceptable risk after EPA completes its review of the incoming new study, in a timeframe that is comparable or more rapid than what EPA could achieve through its own regulatory process.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for dicofol 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 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 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 dicofol RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone (703) 605-6000.

For more information about EPA's pesticide reregistration program, the dicofol RED, or reregistration of individual products containing dicofol, 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 Pesticides Telecommunications Network (NPTN). Call toll-free (800) 858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.