United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-03-003 May 29, 2003

EPA R.E.D. FACTS

Dinocap

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 number 2200, dinocap.

Use Profile

Dinocap is a foliar fungicide/miticide used to control powdery mildew. Dinocap is applied to apples and grapes outside of the U.S., mainly in Europe, the Middle East and northern Africa. There are currently no registered dinocap products in the U.S. Dow AgroSciences, LLC (DAS), the registrant of dinocap, intends to support tolerances for dinocap residues in/on apples and grapes to permit legal importation of these commodities into the U.S., in the absence of a U.S. registration.

Regulatory History

Dinocap, a List B chemical, was the subject of a Phase 4 Review dated January 30, 1991 and a Data-Call-In Notice (DCI) issued on September 10, 1991. At that time, the current registrant Rohm and Haas Company (R&H) had indicated that they intended to amend registrations to drop all food/feed uses for end-use products (EPs). The registrant subsequently requested that the Agency retain dinocap tolerances for apples and grapes as import tolerances. Following cancellation by R&H of all dinocap food/feed uses registered in the U.S., the

Agency revoked all dinocap tolerances, except those for apples and grapes (63 FR 206, October 26, 1998).

The registration for dinocap was transferred from R&H to DAS on September 21, 2001. On February 12, 2002, DAS requested voluntary cancellation pursuant to Section 6(f) of FIFRA of all U.S. product registrations for dinocap. The Agency announced its receipt of the above-mentioned cancellation requests in the Federal Register on April 26, 2002 [OPP-2002-0013; FRL-6833-8]. The Agency did not receive any comments specific to these cancellations; therefore, the cancellation order was effective on October 24, 2002. Because dinocap products have not been marketed in the U.S. for several years, existing stocks are expected to be negligible.

Human Health Assessment

Dietary Exposure

The FQPA committee recommended that the FQPA safety factor for the protection of infants and children be retained at 10x for all population subgroups when assessing acute and chronic exposure to dinocap. The reasons are: (1) there is concern for the quantitative and qualitative increase in susceptibility observed in fetuses following *in utero* exposure in the prenatal developmental studies in mice and rabbits; and (2) there is a data gap for the developmental neurotoxicity study in rats.

The acute reference dose (aRfD) is 0.04 mg/kg/day and the acute population adjusted dose (aPAD) is 0.004 mg/kg/day. The chronic reference dose (cRfD) is 0.0038 mg/kg/day and the chronic population adjusted dose (cPAD) is 0.00038 mg/kg/day. The population adjusted dose is the reference dose divided by the FQPA safety factor.

The Agency has classified dinocap as a Group E "not likely" carcinogen. It was negative for inducing mutations in all studies of the standard mutagenicity battery except the Ames test. In Ames studies, dinocap was weakly positive at best and only at high doses.

The dietary risk assessment was conducted two ways, using the current tolerances of 0.1 ppm and using Maximum Residue Limits (MRLs) recommended by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). There are European data which have been reviewed by the JMPR. The JMPR proposes MRLs for individual pesticides in different food and feed items, and provides advice on the acceptable levels of pesticide residues in food moving in international trade. Residues of dinocap in the European trials were <0.05 (ND) to 0.09 ppm in apples and <0.05 to 0.67 ppm in grapes. In 1988, JMPR recommended MRLs of 0.2 for apples and 1 ppm for grapes.

Irrespective of the residue data used (i.e., current U.S. tolerances or MRLs), acute and chronic dietary risk estimates are well below the Agency's level of concern for all supported dinocap food uses. Acute dietary risk is <1% of the aPAD for the only subpopulation of concern, females, 13-50 years old. Chronic dietary risk is <1% of the cPAD for the U.S. general population and all subpopulations.

There are currently no Codex MRLs established for residues of dinocap. However, in 1988, JMPR recommended dinocap MRLs of 0.2 for apples and 1 ppm for grapes. Harmonization of the tolerance expression/definition and tolerances between Codex MRLs and U.S. tolerances cannot be achieved until the outstanding metabolism and residue data have been submitted.

Additional Data Required

The Agency is requiring the following confirmatory data requirements for supporting the apple and grape tolerances for import purposes: Acute Neurotoxicity Screening Battery, Rat; Subchronic Neurotoxicity Study, Rat; Developmental Neurotoxicity Study, Rat; Nature of the Residue, Plants & Livestock; Storage Stability, Plants; Crop Field Trials (Apple & Grapes); and Processed Food (Apple & Grapes). These data requirements are consistent with EPA's "Guidance on Pesticide Import Tolerances and Residue Data for Imported Food," (65 FR 106; 35069-350-90, June 1, 2000). The Agency will attempt to harmonize with international standards to the extent possible.

Regulatory Conclusion

The Agency has completed its reregistration eligibility decision for the fungicide/miticide, dinocap, which consists of a voluntary cancellation of all U.S. product registrations. Because the registrant has indicated their intention to retain the existing tolerances for apples and grapes for import purposes, EPA has conducted a dietary risk assessment for dinocap. Although there are Data Gaps, the Agency has used protective assumptions including a 10x safety factor and tolerance level residue values to determine that dietary risk is minimal, less than 1% of the acute and chronic PADs for all population subgroups. EPA finds that there is a reasonable certainty that no harm will result from dinocap use on apples and grapes imported into the U.S. Confirmatory data are required as outlined in the previous section.

For More Information

To obtain a copy of the dinocap RED document, please contact the OPP Public Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460-0001, telephone: (703) 305-5805. Electronic copies of the dinocap RED and all supporting documents are also available on the Agency's website at *http://cfpub.epa.gov/oppref/rereg/status.cfm?show=rereg*.

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

The dinocap RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161-0001, telephone: 1-800-553-6847; fax: 703-605-6000.

For more information about EPA's pesticide reregistration program or the dinocap RED, please contact the US EPA, OPP, Special Review and Reregistration Division (7508C), Washington, DC 20460-0001, telephone: 703-308-8000.

For more 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 *http://ace.orst.edu/info/nptn/.*