United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-03-002 September 2003

EPA R.E.D. FACTS

Propanil

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 humans 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 propanil (Chemical Code No. 028201; Case No. 0226).

Use Profile

Propanil is a selective post-emergent use herbicide registered to control broadleaf and grass weeds on rice. It is also registered (but not currently marketed) for turf use at commercial sod farms. The small grain use was voluntarily cancelled. There are no residential uses of propanil. EPA estimates that approximately seven million pounds of active ingredient are used annually on rice.

Regulatory History

Propanil was the subject of a Reregistration Standard Guidance Document that was issued on December 23, 1987. In addition to the data requirements imposed in the 1987 Guidance Document, a Data Call-In (DCI) notice dated June 9, 1989, required the registrant to analyze their propanil products for halogenated dibenzo-p-dioxin and dibenzofuran contaminants. Based on the submitted data, the Agency does not expect any potential for the formation of halogenated dibenzo-p-dioxin and dibenzofuran contaminants in measurable quantities during the manufacture of propanil. The Agency issued subsequent DCIs for propanil on July 1, 1994 and October 13, 1995. These data received in response to the DCIs were used to reach the reregistration eligibility conclusions for propanil that are presented in this RED.

On June 5, 2002, EPA published its tolerance reassessment decision on propanil in the *Federal Register* and released the human health and ecological risk assessments for public comment [OPP-2002-0033; FRL-7179-4]. Subsequent to the tolerance reassessment, the use of propanil on the small grains was voluntarily cancelled by the technical registrants.

Human Health Assessment

Toxicity

Propanil has low acute toxicity, with toxicity categories of III (oral) and IV (dermal, inhalation and primary skin irritation). No dermal sensitization was observed; however, primary eye irritation was observed in rabbits. Propanil is considered neither carcinogenic nor mutagenic.

Dietary Risks

The tolerance reassessment decision on propanil concluded that acute and chronic dietary risk for food and drinking water did not exceed the Agency's level of concern for all population subgroups.

Worker Risks

The risk to occupational handlers of propanil is potentially of concern for several of the aerial exposure scenarios, even with maximum personal protective equipment (PPE) and engineering controls. To reduce these risks initially, the following mitigation measures are needed: (1) Spray drift management practices consistent with best management practices for rice; (2) Require engineering controls including closed cabs and closed mixing/loading systems; and (3) Maintain a reentry interval of 24 hours for rice. In addition, propanil/rice-specific worker exposure (bio-monitoring) data for the liquid formulation were developed by the Propanil Task Force II.

The following mitigation will be needed unless EPA determines, based on the bio-monitoring data currently under review, that lesser or no mitigation is warranted: (1) Reduce maximum seasonal application rate to 6 lbs. a.i./acre on rice; and (2) Reduce maximum number of acres treated to 500 per day for aerial applications of propanil on rice.

Long-term handler exposure is not expected for propanil. All post-application worker risks associated with the rice use of propanil met or exceeded the target MOE of 300, and thus, are not of concern at the current restricted entry interval (REI) of 24 hours.

To address sod farm worker risk, the registrant has agreed to **reduce the maximum application rate to 5 lbs. a.i./acre.** In order to further mitigate the Agency's remaining concerns, a REI of 34 days at the reduced maximum application rate is required for transplanting sod. Further, a REI of 1 day following application at the reduced maximum application rate is required for activities such as aerating, fertilizing, irrigating, scouting and mechanical harvesting and weeding.

Residential and Other Nonoccupational Risks

There are no residential or other nonoccupational risk concerns because propanil does not have any residential uses.

FQPA Considerations

FQPA requires that the Agency consider the "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency does not have sufficient information at this time concerning common mechanism issues to determine whether or not propanil shares a common mechanism of toxicity with other substances, including other acetanilides. Therefore, for the purposes of this risk assessment, the Agency has assumed that propanil does not share a common mechanism of toxicity with any other chemicals.

Available data indicates that 3,4-DCA is a major metabolic degradate of propanil. 3,4-DCA is also a metabolite of two other pesticides, linuron and diuron, but to a much lesser extent. The Agency's MARC does not recommend aggregating residues of 3,4-DCA for the propanil, linuron and diuron risk assessments. 3,4-DCA is a degradate of these three pesticides; however, it is only a significant residue of concern for propanil. 3,4-DCA is assumed to be of equal toxicity to the parent.

More detailed information can be found in the technical supporting documents for propanil referenced in the RED document.

Environmental Assessment

Ecological Risks

Propanil use on rice may cause adverse ecological effects at the current maximum seasonal application rate of 8 lbs. a.i./acre/yr (from two 4 lbs. a.i./acre applications) in areas where rice is produced. Acute risks are estimated for birds, small mammals, freshwater invertebrates and nontarget aquatic plants although RQs are relatively low. Chronic risks are potentially a concern for small mammals and freshwater fish and invertebrates.

The potential use of propanil on turf at the current maximum application rate of 10 lbs. a.i./acre may pose a risk to aquatic vascular/nonvascular plants and terrestrial plants in semi-aquatic areas, and acute risk to birds, small mammals, freshwater fish and invertebrates and estuarine/marine fish and invertebrates. Chronic risks are a concern for small mammals at the current label rate. To reduce the above risks, the following mitigation measures are needed:

- Reduce the maximum application rate for propanil use on turf from 10 lbs. a.i./acre to 5 lbs. a.i./acre and eliminate aerial applications to mitigate concerns for avian and mammalian species, and nontarget terrestrial, semi-aquatic and aquatic plants.
- Establish a 7-day water holding (discharge) interval for rice in the Mississippi Delta (Arkansas, Mississippi, Missouri & Northern Louisiana) and California; a 10-day discharge interval along the Gulf Coast (Texas); and a 15-day discharge interval in Southern Louisiana to address aquatic species concerns, including those for endangered species.

- Reduce the maximum application rate for propanil use on turf; eliminate aerial applications to turf; and label language specifying best management practices for spray drift to address concerns for nontarget terrestrial and semi-aquatic plants, including those for endangered species.

Currently, the Agency does not have data to determine the risk from propanil use on rice to terrestrial nontarget plants. In addition, no acceptable chronic avian data were available, so chronic risks for avian species could not be assessed. Data are required to address these gaps in the ecological assessment.

Summary

This Fact Sheet explains the Agency's decision regarding the reregistration eligibility of the registered uses of propanil. This document also presents the Agency's tolerance reassessment decision for propanil, which includes the consideration of risk to infants and children for any potential dietary, drinking water, dermal, inhalation or oral exposures. The Agency's 2002 tolerance reassessment decision for propanil was based on the data required for reregistration, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that the current uses of propanil on rice and turf are eligible for reregistration, provided the changes specified in the RED are made to the labels. The small grain use has been voluntary cancelled.

Additional Data Required

EPA is requiring the following confirmatory data requirements for propanil to confirm its regulatory assessments and conclusions and to further characterize the toxicity of propanil and 3,4-DCA:

- 835.1240: Sediment and Soil Adsorption/Desorption on 3,4-DCA
- 835.2120: Hydrolysis on 3,4-DCA
- 835.2240: Photodegradation (Water) on 3,4-DCA
- 850.1010: Freshwater Invertebrate Acute Toxicity on 3,4-DCA
- 850.1035: Mysid Acute Toxicity on 3,4-DCA
- 850.1075: Freshwater and Estuarine/Marine Fish Acute Toxicity on 3,4-DCA
- 850.1300: Early-Life Stage in Freshwater and Estuarine/Marine Fish on 3,4-DCA
- 850.1350: Life Cycle in Freshwater and Estuarine/Marine Invertebrates on 3,4-DCA
- 850.2200: Avian Subacute Dietary Toxicity - Bobwhite Quail on 3,4-DCA
- 850.2300: Avian Reproduction - Bobwhite Quail for Parent Propanil and 3,4-DCA
- 850.2300: Avian Reproduction - Mallard Duck for Parent Propanil and 3,4-DCA
- 850.4100: Seedling Emergence (Tier 1) on 3,4-DCA
- 850.4150: Vegetative Vigor (Tier 1) on 3,4-DCA
- 850.4250: Vegetative Vigor (Tier 2) on Propanil - TEP
- 870.3465: 90-Day Inhalation - Rat
- 870.6200: Acute Neurotoxicity Screening Battery - Rat
- 870.7800: Immunotoxicity Study - Rat
- 875.1100: Estimation of Dermal Exposure at Outdoor Sites

Product Labeling Changes Required

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

Regulatory Conclusion

EPA has determined that all products containing propanil as the active ingredient for use on rice and turf are eligible for reregistration, provided changes specified in the propanil RED are incorporated into the label and additional data identified in Section V of the RED confirm this conclusion.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for propanil during a 60-day time period, as announced in a Notice of Availability published in the *Federal Register*. To obtain a copy of the propanil 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 propanil RED and all supporting documents are also available on the Agency's website at *http://www.epa.gov/pesticides/reregistration/status.htm*.

Printed copies of the propanil 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: (800) 490-9198; fax: (513) 489-8695.

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

For more information about EPA's pesticide reregistration program or the propanil RED, please contact the U.S. 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 Information Center (NPIC). Call toll-free (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://www.npic.orst.edu*.