United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-97-009 August 1997

R.E.D. FACTS

PROPOXUR

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.

Under the Food Quality Protection Act of 1996, EPA must consider the increased susceptibility of infants and children to pesticide residues in food, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with a common mechanism of toxicity in establishing or reassessing tolerances.

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 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 2555, propoxur.

Use Profile

Propoxur is a carbamate insecticide used to control ants, roaches and hornets in and around residences and commercial food handling establishments. The formulations include aerosols, baits, emulsifiable concentrates, wettable powders formulated into aerosol cans, dusts and powders, pest strips, shelf paper, ready-to-use solutions, granular baits, containerized baits, and pet flea collars.

Regulatory History

Propoxur was first registered as a pesticide in the U.S. in 1963. In December, 1987, the Agency issued a DCI to call in data needed to support the continued registration of propoxur products. The DCI required additional data to support the outdoor uses of propoxur as well as studies to examine potential risks to applicators and persons living in treated buildings. None of the companies, including Bayer, the basic producer of propoxur,

committed to support all of the uses registered at that time. In 1987, propoxur was registered for outdoor use as a premise spray, use on turf, and for adult mosquito control. These uses were not supported and were deleted from labels.

In 1988, the Agency issued a preliminary notification (Grassley-Allen) letter to Bayer indicating its decision to consider propoxur for Special Review because of the potential carcinogenic risks to pest control operators and the general public during indoor and outdoor applications and risks to occupants of buildings treated with propoxur products.

In 1989, a DCI was issued to end-use producers after Bayer decided not to support the outdoor uses. None of the end-use producers elected to support the outdoor uses.

In 1990, a Notice of Intent To Suspend (NOITS) was issued for certain propoxur registrations for which Bayer failed to provide acceptable data. This was after they committed to provide exposure data for all uses except the fogger, which they declined to support. These exposure data were eventually provided and the suspensions lifted.

In January, 1995, the Agency issued a notice (60 FR 3210) proposing not to initiate a Special Review of the insecticide propoxur. The Agency had received and evaluated new exposure and carcinogenicity data on propoxur and determined that the uses which posed the greatest concern had been eliminated through voluntary cancellation or label amendment. Therefore, the Agency believed that the estimated risks did not warrant initiation of a Special Review. The Agency issued a final decision not to initiate a Special Review in February, 1996 (61 FR 7508). Currently, 173 propoxur products are registered.

Human Health Assessment

Toxicity

In studies using laboratory animals, propoxur generally has been shown to be of moderate acute toxicity. It has been placed in Toxicity Category II (the second highest of four categories) for effects via the oral route of exposure, and Toxicity Category III for the dermal and inhalation routes. Propoxur has been classified as a Group B_2, probable human carcinogen, with a Q_1* of 3.7×10^{-3}. Propoxur shows little if any genotoxic activity. The Agency has calculated a reference dose (RfD), the amount of pesticide believed not to cause adverse effects if consumed daily over a 70-year lifetime, of 0.005 mg/kg/day, based on a human study with a LOEL of 0.15 mg/kg, the lowest dose tested. An uncertainty factor of 10 was applied to account for intra-species variability and an additional factor of 3 was applied to compensate for the lack of a NOEL.

Dietary Exposure

People may be exposed to residues of propoxur through the diet. However, exposure is likely to be limited because the only use of propoxur

that could result in residues in food, is for crack and crevice treatments in food handling establishments and food processing plants. Sufficient data are available to support the proposed tolerance of 0.2 ppm in/on all foods. The anticipated residue contribution (ARC) for the overall US population is 1.84% of the RfD. For the most highly exposed sub-group, non-nursing infants < 1 year old, the ARC is 7.23 % of the RfD. These low fractions of the allowable RfD (100%) are well within the range of acceptable dietary risk.

The cancer dietary risk estimate for incidental residues of propoxur on food in food handling establishments for the overall US population is 3.4×10^{-7}. EPA considers dietary cancer risks less than 1×10^{-6} to be minimal.

Because of very limited outdoor use of propoxur, no residues are anticipated in drinking water.

Occupational and Residential Exposure

Professional pest control operators (PCOs) as well as residents and residential applicators (RAs) can be exposed to propoxur during and after applications in and around the home, and in commercial and industrial settings. Combined application and post-application cancer risks to resident applicators range from 2.3×10^{-8} for pet flea and tick collars to 4.5×10^{-7} for crack and crevice applications. EPA considers residential cancer risks of less than 1×10^{-6} not to be of concern.

Propoxur has an estimated cancer risk to workers of 7.7×10^{-6}. The Agency's policy for worker risk is that risk should be as close to negligible (i.e., 1×10^{-6}) as possible. EPA is requiring personal protective clothing, including long-sleeved shirt, long pants, chemical resistant gloves, and shoes plus sox, for professional applicators applying propoxur to cracks and crevices. The Agency believes that there are no other reasonable measures that could be imposed to further reduce risk.

Risk assessments for chronic (non-cancer) and short-term, dermal and inhalation exposure to propoxur have not been conducted because no adverse effects were seen at the highest dose tested of 1000 mg/kg/day in a dermal study and the vapor pressure of propoxur is low.

FQPA Considerations

EPA conducted additional risk analyses using available data in response to the new FQPA requirements. The Agency found that the propoxur data base for pre- and post-natal effects is complete based on current requirements. Because these reliable data indicate no special sensitivity of young organisms to propoxur, the Agency has concluded that an additional uncertainty factor need not be applied to the NOELs used in the propoxur risk assessments.

EPA has considered the potential for aggregate exposure from various sources of propoxur to residents including children. Dietary exposure is possible from incidental residues of propoxur used as a crack and crevice treatment in food handling establishments and food processing plants.

Exposure to homeowners is also anticipated during applications of propoxur in and around the home and to both homeowners and children after such applications. Becasue of the limited outdoor use of propoxur for structural perimeter applications and spot treatments to wasp nests and ant hills, little or no post application exposure is anticipated to residents or children and no residues are expected in drinking water. When dietary and residential risks are combined, the aggregate cancer risk from propoxur ranges from 3.6×10^{-7} to 7.9×10^{-7}, well within acceptable limits.

The Agency has not made a determination whether propoxur and any other pesticide have a common mechanism of toxicity for either cancer or non-cancer effects and require cumulative risk assessment. For the purposes of this RED, EPA has considered only the risks from propoxur. 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

For the currently registered uses of propoxur, the Agency typically requires an abbreviated set of environmental fate data on hydrolysis, metabolism, and mobility. Only supplemental data are available for propoxur. While shortcomings in the studies preclude a comprehensive assessment of the environmental fate of propoxur, a general assessment can be made.

Based on supplemental data, propoxur is likely to be moderately persistent (the metabolic half-life is on the order of several months), mobile, and may potentially leach to groundwater. It is apparently hydrolytically stable at acid to neutral pHs (3 to 7) but degrades rapidly at alkaline pH values. The parent chemical appears susceptible to photolysis in water but not on soil. However, the intensity of light in the studies did not reflect that of natural sunlight. Aerobic and anaerobic soil metabolism half-lives are on the order of several months. Degradate characterization was incomplete in these studies. Laboratory mobility studies indicate that propoxur is very mobile (K_d values less than 1). Propoxur exhibits fate and transport characteristics similar to chemicals that are known to leach to groundwater.

Well-designed, scientifically-valid studies could result in changes in the overall assessment, particularly in relation to persistence. For instance, photolysis may play a role in degradation of propoxur applied outdoors. However, considering the nature of the current outdoor uses, additional studies are not required at this time. The limited data available only support the uses discussed in this document. Any additional uses will require data to support them.

Ecological Effects/Risk

Although calculated acute avian risks exceed the LOCs, the Agency believes risks to birds from the limited outdoor bait applications are not

excessive. There are no reported bird poisoning incidents from propoxur according to Agency records. Potential exposure to birds has been greatly reduced since the 1992 deletion of broadcast uses on lawns/turf.

Outdoor applications are limited to exteriors of buildings, on and immediately around patios, sidewalks and building foundations, and boat mooring lines, water lines and utility supply lines. Exposure of propoxur to avian and mammalian wildlife species with the current outdoor uses results in slight exposures, if any.

Minimal aquatic exposure from runoff or drift is expected from propoxur outdoor bait products. Although the toxicity is high, the aquatic risk does not exceed the Agency's LOCs. Based on the limited outdoor bait applications of propoxur, minimal to no risk is expected to aquatic organisms.

Risk Mitigation

To lessen the occupational and residential risks posed by propoxur, EPA is requiring the following risk mitigation measures:

- Personal protective equipment (PPE) including long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks for PCOs applying propoxur as a crack and crevice treatment
- Areas treated are not to be entered until the sprays have dried and the dusts have settled.

Additional Data Required

EPA 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 propoxur end-use products must comply with EPA's current pesticide product labeling requirements and with additional reentry specifications to their labels. The following labeling changes are required.

For products intended for occupational and homeowner use:

- For liquid applications to surfaces other than on pets: "Do not allow people or pets to enter the treated area until sprays have dried."

For products which have applications to surfaces other than on pets:

- "Do not apply this product in a way that will contact any person or pet, either directly or indirectly. Keep people and pets out of the area during application."

User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

- "Users should remove protective clothing and equipment immediately after handling this product. Wash the outside of gloves before removing. Keep and wash protective clothing and equipment separately from other laundry."

For products with residential outdoor uses:

- This product is toxic to wildlife and aquatic invertebrates. Birds and small mammals feeding on treated bait may be killed. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes.
- "Birds and small mammals feeding on treated bait may be killed"
- "Do not apply as a landscape treatment (to lawns, shrubs or trees, garden plants)"

For a comprehensive list of labeling requirements, please see the propoxur RED document.

Regulatory Conclusion

EPA has determined that the proposed tolerance for propoxur meets the safety standard under the FQPA, and that there is a reasonable certainty that no harm will result to infants and children or to the general population from aggregate exposure to propoxur residues. The use of currently registered products containing propoxur in accordance with approved labeling will not pose unreasonable risks of adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Propoxur products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA. These products will be reregistered once any 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 propoxur 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 propoxur 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 and External Affairs 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 by 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 propoxur 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 propoxur RED, or reregistration of individual products containing propoxur, 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.