United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-98-013 November 1998

R.E.D. FACTS

PROPACHLOR

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 (0177), propachlor.

Use Profile

Propachlor is a herbicide used to control grasses and broadleaf weeds in the first season (growth establishment phase). Propachlor is used on grain sorghum (milo), field corn, hybrid seed corn, silage corn, and for onion seed in Washington and Oregon.

Formulation types registered include: manufacturing product (93% and 96.5% a.i.); a flowable concentrate (31.5% and 42% a.i. formulated with atrizine); and a granular (20% a.i.).

Propachlor can be applied with groundboom sprayers, tractor-drawn broadcast spreaders, and granular row planters.

Application rates vary from 3.0 to 6.0 pounds of active ingredient per acre depending upon the application scenario.

Regulatory History

Propachlor was first registered as a pesticide in the U.S. in 1964. EPA issued a Registration Standard for propachlor in December, 1984. A September, 1991 Data Call-In (DCI) required additional generic and product-specific chemistry data for the Monsanto 96.5% Technical. Currently, eight propachlor products are registered.

Human Health Assessment

Toxicity

In studies using laboratory animals, propachlor is highly toxic to the eyes. The Agency has placed propachlor in Toxicity Category I (the highest of four categories) for this effect.

[NOTE: For acute oral, dietary, mammalian/avian/aquatic toxicity:

Category I = very highly or highly toxic

Category II = moderately toxic

Category III = slightly toxic

Category IV = practically non-toxic]

Sufficient data are available to assess the acute, subchronic, chronic toxicity and carcinogenic potential of propachlor. Propachlor has been classified as a "**Likely**" human carcinogen, based on the (a) rare stomach tumor in male Fischer 344 rats; (b) thyroid tumors in male and ovarian granulosa/theca cell tumors in female Sprague-Dawley rats at doses that were not adequate to assess carcinogenicity; c) hepatocellular tumors in male CD-1 mice; (d) in vitro clastogenic activity; and (e) tumors observed at one or more of the same sites with three structurally-related chloroacetanilide compounds.

Dietary Exposure

People may be exposed to residues of propachlor through the diet. Tolerances or maximum residue limits have been established for propachlor (see 40 CFR 180.211). EPA has reassessed the propachlor tolerances and updated a list of raw agricultural and processed commodities and feedstuffs derived from crops. Due to these changes, some commodity definitions must be corrected. In addition, tolerances for which there are currently no registered uses of propachlor are being proposed for revocation.

EPA has assessed the acute dietary risk posed by propachlor. MOE's (food and drinking water exposure combined) for adult males and females range from 17,000 to 53,000. Given the magnitude of the calculated Margins of Exposure, cancer risk does not seem to be of concern.

For the overall U.S. population, chronic exposure from all current propachlor tolerances represents less than 1% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. Therefore, it appears that chronic dietary risk is minimal.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to propachlor in agricultural settings during and after normal use of the pesticide.

The Agency has determined that there are potential exposures to mixers, loaders, applicators, and other handlers during usual use-patterns associated with propachlor. Based on the use patterns, five major exposure scenarios were assessed for propachlor:

(1) mixing/loading liquids for groundboom application;

(2) mixing/loading dry flowables for groundboom application;

(3) loading granulars for tractor-drawn spreader application;

(4) applying sprays with groundboom equipment; and

(5) applying granulars with a tractor-drawn spreader.

For worker protection, the Agency will require the use of additional personal protective equipment (chemical resistant gloves, apron, and chemical resistant shoes) and engineering controls under certain conditions.

Human Risk Assessment

The Agency considers propachlor to be classified as a likely human carcinogen. The Agency's Cancer Review Assessment Review Committee has classified propachlor as a "**Likely**" human carcinogen, based on (a) the observance of multiple tumors at multiple sites, including the rare stomach tumor in a male Fischer 344 rat, thyroid tumors in male and ovarian granulosa/theca cell tumors in female Sprague-Dawley rats, and hepatocellular tumors in CD-1 mice; (b) in vitro clastogenic activity; (c) tumors observed at one or more of the same sites with three structurally-related chloroacetanilide compounds (alachlor, acetochlor, and butachlor); (d) lack of data on mode of action; and (e) the relevance of the observed tumors to human exposure.

Because dietary exposure to propachlor residues in foods is extremely low. The acute, chronic, and cancer exposure risk is also low to the general population.

There is concern for the risk posed to propachlor handlers, particularly mixers/loaders/applicators, and field workers who come into contact with treated areas following application of this herbicide. Exposure and risk to workers will be mitigated by the use of Personal Protective Equipment (PPE) required by the WPS, supplemented by additional PPE and closed systems as required by this RED. Post-application reentry workers will be required to observe a 48-hour Restricted Entry Interval, the basis for this decision being that propachlor is classified as a toxicity category I (severe) for eye irritation potential and is also classified as a strong dermal sensitizer.

FQPA Considerations

Determination of safety includes consideration of special sensitivity to children, potential cumulative effects with pesticides that have a common mode of toxicity and aggregate risks resulting from exposure to dietary residues, residues in drinking water, and residential sources.

The database for developmental and reproductive toxicity of propachlor is considered to be complete at this time. A developmental neurotoxicity study was not required. There is no unique or special sensitivity for pre- or post-natal exposure. Based on these three factors, the Agency has concluded that there is not a basis for retaining the additional 10X safety factor from FQPA. An uncertainty factor of 100 will adequately protect infants and children.

The Agency has determined that consideration of a common mode of toxicity with other chemicals such as acetochlor, butachlor, metolachlor, and alachlor is not appropriate at this time. Tolerance reassessments have occurred in the RED as a result of new data on the concentrations of propachlor residues present in food. As a result, the existing and unsupported tolerances will be revoked in conjunction with this RED.

There are no residential uses of propachlor. The aggregate risk assessment from exposure to propachlor in food and water, does not result in aggregate risk that exceeds the Agency's level of concern.

Thus, the agency concludes that there is a reasonable certainty of no harm to infants and children, and adults from consuming potential residues of propachlor. This conclusion encompasses residues from aggregate exposure (food and water).

Propachlor is a member of the acetanilide class of herbicides. It is structurally similar to acetochlor, butachlor, metolachlor, and alachlor.

Section 408(b)(2)(D)(v) of FQPA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also policies and methodologies for conducting cumulative risk assessments. For most pesticides, the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances.

However, at this time the Agency does not have the methodology to resolve the scientific issues concerning common mechanism of toxicity in a meaningful way. The Agency has begun a pilot process to study this issue further through the examination of particular classes of pesticides. Hopefully, the results of this pilot process will enable the Agency to develop and apply policies for evaluating the cumulative effects of chemicals having a common mechanism of toxicity. At present, however, the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments. Exceptions include pesticides that are toxicologically and structurally dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case the metabolite must be assessed as part of a common mechanism assessment).

In making individual tolerance decisions, the Agency will determine whether:

1) it has sufficient information to determine that a pesticide does not appear to share a common mechanism of toxicity with other substances;

2) it is unable to conclude that a pesticide does not share a common mechanism of toxicity with other substances; or

3) it is able to conclude that a pesticide does share a common mechanism of activity with other substances.

Due to the structural similarities with acetochlor, metolachlor, butachlor, and alachlor, propachlor may fall into the second category. However, at this time the Agency has not yet made a final decision concerning a possible common mechanism of toxicity for these five chemicals to scientifically apply that information to the tolerance decision. The process has begun, but is not yet completed. Therefore, for the purposes of this decision document, the tolerance decision will be reached based upon the best available and useful information for propachlor only. The risk assessment has been performed for propachlor only assuming that no common mechanism of toxicity exists. However, these decisions will be reexamined after methodologies and procedures for integrating information concerning common mechanism of toxicity into risk assessments are developed by the Agency.

Environmental Assessment

Environmental Fate

The environmental fate assessment for propachlor shows that:

- The three major degradates appear to be very mobile and persistent due mainly to its low affinity to adsorb soil.
- While highly mobile, propachlor is not expected to persist substantially on the soil surface under most conditions.
- The major routes of dissipation for the parent propachlor are aerobic soil metabolism and, in the absence of an active microbial population, leaching. A half life of <3 days is observed with 50% field dissipation rate occurring within 1 to 6 days.
- Propachlor may be more persistent in low moisture conditions, in soils with low microbial activity, or under anaerobic conditions.
- Due to its high solubility and low affinity for adsorption, propachlor is likely to dissipate rapidly from plant and soil surfaces.

Water Resources Assessment

The water resources assessment concludes that:

- The Agency has determined that the parent propachlor does not pose a significant threat to ground-water quality under most conditions. However, the three acid degradates have a high potential to leach and to persist in ground water.
- Detections of propachlor and/or its metabolites have been reported (0.02-3.5 ppb) in some wells, suggesting that this chemical or its degradates reach ground water under certain conditions.
- Propachlor is most likely to reach ground water in soils which have little microbiological activity, high permeability, and a shallow water table.
- Based upon limited fate data, the three major acid degradates of propachlor appear to be available for runoff longer than the parent, moving primarily by dissolution in runoff water.

Ecological Effects

The available toxicity of propachlor suggest that:

- Moderately toxic to birds on both an acute oral and chronic basis.
- Practically non-toxic to mammals on an acute oral basis.
- Practically non-toxic to bees on an acute oral basis and a subacute dietary basis.
- Moderately to highly toxic to freshwater fish on an acute basis. The technical grade material (TGAI) is more toxic to rainbow trout than the formulated product however, the formulated product is more toxic to bluegill sunfish than the technical grade material.

- No aquatic invertebrate studies have been performed however, a comparative analysis yielded a Risk Quotient (RQ) factor which does not trigger the need for any further testing for freshwater fish.

Environmental Risk Characterization

An evaluation of the risk to nontarget organisms from the use of propachlor products, combining toxicity data with potential exposure, indicates that:

- The overall toxicological spectrum for propachlor suggests that it is slightly to moderately toxic to most non-target organisms (the Agency has no reported incidences of adverse impacts on non-target organisms from the use of propachlor.
- The granular formulations pose the greatest risk to non-target organisms.
- The potential for chronic (long-term) exposure of non-target organisms to propachlor is reduced because it is not persistent under most conditions and because the pesticide is only applied once in a growing season.

Risk Mitigation

To lessen the human health, ecological, water and food quality risk posed by propachlor, EPA is requiring mitigation measures that will: protect non-target species, control surface water and ground water contamination, and protect workers.

Additional Data Required

EPA is requiring the following additional generic studies for propachlor to confirm its regulatory assessments and conclusions:

- 72-3 (a) Acute toxicity to estuarine and marine fish
- 72-3 (b) Acute toxicity to estuarine and marine mollusks
- 72-3 (c) Acute toxicity to esturarine and marine shrimp
- 123-2 Aquatic Plant Growth on four of the five required species is still outstanding: *Lemna gibba, Skeletonema costatum, Anabaena flos-aquae, and freshwater diatom.*
- 162-1 Aerobic Soil Metabolism. An additional study is needed to better characterize the rate of dissipation of propachlor.
- 162-4 Aerobic Aquatic Metabolism
- 165-1 Limited Field rotational Crop

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

All propachlor end-use products must comply with EPA's current pesticide product labeling requirements and with the following. For a

Changes Required

comprehensive list of labeling requirements, please see the propachlor RED document.

- Ground water advisory language must be placed on all propachlor labels.
- Surface water advisory language must be placed on all propachlor labels.
- Advisory statement for the Environmental Hazards of toxicity to terrestrial and aquatic plants, fish and aquatic invertebrates for both manufacturing use and end use products.
- Advisory statement for toxicity to non-target organisms for granular products.
- Spray Drift labeling Language.
- Product labels for all uses must be amended include a skin sensitization statement.
- The label for the Personal Protective Equipment for the mixing/loading for all liquid products containing propachlor must include

  -Chemical resistant gloves.
- For the mixing/loading of granular products, the label must reflect the following Personal Protective Equipment:

  -Long-sleeved shirt, long pants

  -Chemical-resistant apron

  -Chemical resistant footwear

  -Chemical resistant gloves
- For the applicator Personal Protective equipment for all propachlor granular products, the label will reflect:

  -Long-sleeved shirt, long pants

  -Chemical resistant apron

  -Chemical resistant footwear

  -Chemical resistant gloves
- Labels referring to the engineering controls for application of all liquid formulations must specify:

  -A closed system
- Labels for all products must contain User Safety Requirements for the cleaning and maintenance of Personal Protective Equipment.
- Each label must have an Environmental Hazard Statement in reference to fish, aquatic invertebrate, and wildlife toxicity.
- An Environmental Hazard Statement for granular formulations must be included requiring that spilled granules must be covered or incorporated.
- Rotational crop label amendment stating that only crops for which there are registered propachlor uses may be rotated to treated fields.
- A 48 hour restricted entry interval (REI) is required for uses within the scope of WPS. This is based on he acute toxicity of the active ingredient

(category I for primary eye irritation). Personal protective Equipment required for early entry is:

-Protective eyewear

Regulatory Conclusion

EPA has determined that the reassessed tolerances for propachlor meet 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 propachlor residues. The use of currently registered products containing propachlor in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the use of the liquid and granular formulations of propachlor are eligible for reregistration provided labeling changes described in the RED are followed. Propachlor products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by the EPA. The use of currently registered products containing propachlor in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all liquid and granular uses of these products are eligible for reregistration.

The Agency had concerns for the occupational risk posed to mixers/loaders of the dry flowables. The registrant has agreed to voluntarily cancel their formulation of the dry flowable product.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for propachlor 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 Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the propachlor 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 propachlor RED, or reregistration of individual products containing propachlor, 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 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.