United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | EPA 738-F-05-012 October 6, 2005

EPA R.E.D. FACTS

Pyrazon

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA (the Agency), 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 (FQPA) 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 registers pesticides that meet current health and safety standards 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 with the Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document.

Use Profile

Pyrazon [5-amino-4-chloro-2-phenyl-3(2H)-pyridazinone], also known as chloridazon, is an herbicide belonging to the pyridazinone class of pesticides. It works as an herbicide by blocking electron transport in photosystem II in green plants, thereby inhibiting photosynthesis. Pyrazon is registered for pre-plant, pre-emergence, and early post-emergence use on sugar beets and red table beets to control certain weeds. Approximately 10% of the U.S. sugar beet crop and 50% of the U.S. table beet crop are treated with pyrazon annually. Pyrazon is also registered for commercial use on ornamentals, including bulb crops and roses.

Human Health Assessment

Toxicity

Pyrazon is considered to be of low toxicity without highly specific responses in mammals. Pyrazon has low (category III/IV) acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not an eye or skin irritant (category IV) and does not cause dermal sensitization. In longer-term studies, reduced body weight associated with reduced food consumption appears to be the most significant effect of pyrazon exposure in laboratory animals. At higher doses, conditions such as poor general appearance and some motor effects considered to be associated with poor nutrition are noted in rats. No systemic effects resulted from dermal exposure to pyrazon. Pyrazon is classified as "not likely to be a carcinogen in humans."

Dietary Risks

EPA determined that there is reasonable certainty that no harm to any population subgroup will result from aggregate exposure to pyrazon when considering dietary (food and water) exposure.

An acute dietary assessment was not conducted because an endpoint of concern attributable to a single dose was not identified. Therefore, only a chronic dietary assessment was conducted. According to the assessment, estimated exposures from pyrazon residues in food represent less than 0.1% of the cPAD for all population subgroups.

The drinking water assessment for pyrazon and desphenyl pyrazon, the major degradate, showed that estimated exposures from drinking water are well below the Agency's level of concern, representing 25% or less of the cPAD for all population subgroups.

Residential and Other Non-Occupational Risks

There are currently no pyrazon products registered for homeowner use, and no residential exposure is expected from commercial uses of pyrazon; therefore, a residential risk assessment was not conducted.

FQPA Considerations

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide up to an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures. EPA chose to waive the FQPA safety factor (i.e., reduce it to 1X) based on a conclusion of no increased pre- and/or post-natal susceptibility and no residual uncertainty for pre- and/or post-natal toxicity.

EPA did not perform a cumulative risk assessment for pyrazon because unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for pyrazon and any other substances, and pyrazon does not appear to produce a toxic metabolite produced by other substances.

Worker Risks

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Nine occupational scenarios were assessed for mixers, loaders, applicators, and flaggers supporting applications of pyrazon via aerial, groundboom, low pressure handwand sprayer, and backpack sprayer equipment. Dermal toxicity endpoints were not identified in existing studies; therefore, only inhalation risks to workers were assessed. Long-term exposures (greater than 6 months) are not expected from use of pyrazon. There were no risks of concern identified for handlers when baseline PPE is worn.

Post-application exposure was not assessed because there is no dermal endpoint of concern and post-application inhalation exposure is expected to be negligible. However, the Worker Protection Standard requires a 12-hour restricted entry interval (REI) for chemicals classified as Toxicity Category III or IV. Pyrazon is classified in Toxicity Category III for acute oral and dermal Toxicity Category IV for acute inhalation and primary eye and skin irritation; therefore, the current REI of 12 hours is appropriate and will remain on labels.

Environmental Assessment

Environmental Fate

Available fate date indicate that pyrazon is mobile in a variety of soil types and is persistent in soil and in aquatic environments. On soil, the photolysis half-life is 69 days, with an aerobic soil metabolism half-life of 90-152 days, and an anaerobic soil metabolism half-life of 307 to 607 days, depending on the soil texture tested. The most significant route of degradation of pyrazon in water appears to be photolysis, with a half-life of 12.5 days. Pyrazon is stable to hydrolysis at pH 5, 7 and 9.

Ecological Risks

The screening level ecological risk assessment for aquatic organisms resulted in no acute risks of concern for freshwater fish and invertebrates. Chronic risks to freshwater fish and invertebrates could not be assessed, due to the lack of available data. Some pyrazon may be used in coastal areas in California; thus, estuarine/marine organisms may be exposed. However, due to the lack of available toxicity data estuarine and marine organisms, risks to these organisms could not be assessed. Also, there are no risks of concern for non-listed aquatic plants, but are several RQs that exceed the level of concern (LOC) for listed threatened or endangered species.

The screening level assessment for terrestrial organisms resulted exceedances of the Agency's endangered species acute LOC for birds and mammals. Chronic risks were not assessed for birds, because chronic toxicity data were not available. EPA does not expect pyrazon to pose chronic risks of concern to mammals.

Based on modeled EECs and the available toxicity data, RQ values for all uses of pyrazon and all application scenarios exceed the LOC for listed and non-listed non-target terrestrial plants and terrestrial plants in semi-aquatic areas.

Risk Mitigation

As with most herbicides, risks of concern associated with pyrazon were identified for listed and non-target terrestrial and semi-aquatic plants, and in some scenarios, endangered aquatic plants. Additionally, acute risks of concern, if exposures occur, were identified for endangered species of birds and mammals. Given that the pyrazon ecological risk assessment is a screening level analysis, EPA is not imposing any mitigation at this time. Should EPA's endangered species specific assessment indicate that use of pyrazon "may affect" listed species, the registered uses of pyrazon may need to be modified (see section on "Endangered Species Concerns)".

Pyrazon is persistent and mobile in many types of soil, and therefore, has the potential to enter surface and ground water. Label statements regarding drift, runoff, and leaching, as well as chemigation prohibitions and plant-back restrictions are to be added to the labels.

Additional Data Required

The generic database supporting the reregistration of pyrazon has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory and are listed below.

Toxicology:

- 870.5550 – Unscheduled DNA Synthesis in Mammalian Cells in Culture

Residue Chemistry:

- 860.1340 - Independent Laboratory Validation (ILV) study for Method A9202
- 860.1900 – Field Accumulation in Rotational Crops Study

Ecological effects:

- None (72-3A) – Estuarine/marine Fish Acute Toxicity Test
- 850.1020 – Gammarid Acute Toxicity Test
- 850.1025 – Estuarine/marine Mollusk (Oyster) Acute Toxicity Test (Shell Deposition)
- None (72-3F) – Estuarine/marine Myside Acute Toxicity Test
- 850.1045 – Penaeid Acute Toxicity Test
- 850.1300 – Daphnid Chronic Toxicity Test
- 850.1350 – Mysid Chronic Toxicity Test
- 850.1400 – Early-life Stage, Freshwater Fish
- 850.1450 – Early-life Stage Estuarine Fish
- 850.1500 – Fish Life Cycle Study

- 850.2300 – Avian Reproduction Test, Bobwhite Quail
- 850.2300 – Avian Reproduction Test, Mallard Duck

Regulatory Conclusion

The use of currently registered products containing pyrazon in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment if the label changes outlined in the RED are implemented. Therefore, all uses of these products are eligible for reregistration. These products will be reregistered once the required product specific data, confidential statements of formula (CSFs), and revised labeling are received and accepted by EPA. Products that contain ingredients in addition to pyrazon will be reregistered when all of their other active ingredients also are reregistered.

For More Information

To obtain a copy of the pyrazon 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 pyrazon RED and all supporting documents are also available on the Agency's electronic docket at http://www.epa.gov/edocket.

For more information about EPA's pesticide reregistration program or the pyrazon RED, please contact the U.S. EPA, OPP, Special Review and Reregistration Division (7508C), 1200 Pennsylvania Avenue, NW, Washington, DC 20460, 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. The NPIC internet address is http://www/npic.orst.edu.