



R.E.D. FACTS

Pesticide Reregistration

Piperalin

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 years ago 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. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 3114, piperalin.

Use Profile

Piperalin is a fungicide used to control powdery mildew on ornamental plants, shrubs, vines and trees grown in commercial green houses. It is formulated as a soluble concentrate/liquid, and is applied as a foliar spray using a high-volume high-pressure sprayer. Use practice limitations include a recommendation to use with three specific surfactants, and prohibitions against entering treated areas without personal protective equipment (PPE) for 12 hours, applying the pesticide through any type of irrigation system, applying directly to water or wetlands, and contaminating water, food or feed.

Regulatory History

Piperalin was first registered as a pesticide in the U.S. in 1964. Currently, only one product is registered which contains this active ingredient. The product contains 84.4% piperalin and is used only to control powdery mildew on ornamentals grown in commercial greenhouses.

Human Health Assessment

Toxicity

In studies using laboratory animals, piperalin generally has been shown to be of relatively low acute toxicity. It causes only slight dermal toxicity and has been placed in Toxicity Category IV (indicating the lowest degree of acute toxicity) for this effect. It also is not a skin sensitizer. Piperalin is slightly toxic through the oral and inhalation routes, causes mild eye irritation, and causes moderate to severe skin irritation; it has been placed in Toxicity Category III for each of these effects.

Piperalin caused no systemic toxicity in a subchronic dermal toxicity study using rabbits. In a developmental toxicity study using rats, piperalin caused excessive salivation, soiled fur, decreased body weight and decreased food consumption in the mothers. The lowest observed effect level (LOEL) was the highest dose tested, based on decreased fetal body weight. A third mutagenicity test is required to confirm the Agency's finding so far that piperalin is not mutagenic.

Dietary Exposure

Piperalin has no registered food uses, so dietary exposure is not a concern.

Occupational and Residential Exposure

Based on current use patterns, workers may be exposed to piperalin during and after application in greenhouses. However, piperalin is of sufficiently low toxicity that an exposure assessment was not conducted.

Human Risk Assessment

Piperalin has no registered food uses so no dietary risks are posed. Even though applicators can be exposed to significant amounts of piperalin, this pesticide poses little toxicity concern. Workers' exposure will be minimized through product labeling requirements.

Environmental Assessment

Environmental Fate

Piperalin hydrolyzes very rapidly at pH 9 forming two degradates, DCBA or dichlorobenzoic acid and 3-(2-methylpiperidino)propyl alcohol. Microbially-mediated and chemical hydrolysis are the most significant degradative processes. In soil metabolism studies, the parent compound decreased over time while the two degradates increased.

Piperalin is immobile in several types of soil. However, additional information is needed to confirm the identity and determine the leaching potential of piperalin's degradates.

Ecological Effects

While additional studies are needed to determine its acute toxicity to birds, piperalin is practically nontoxic to birds on a subacute dietary basis. Because piperalin is only used indoors (inside greenhouses), avian reproduction studies are not required. Piperalin is highly toxic to fish and moderately toxic to aquatic invertebrates.

Ecological Effects Risk Assessment

Piperalin is practically nontoxic to birds, highly toxic to fish, and moderately toxic to aquatic invertebrates. However, birds and mammals will not be significantly exposed to piperalin through consumption of insect and plant food containing residues of this pesticide. Exposure to fish and aquatic invertebrates also is not expected to occur since piperalin is used only inside greenhouses, and since labeling prohibits use practices that would contaminate water. No significant risks to birds, fish or aquatic invertebrates are expected. Similarly, no significant risks to endangered species are expected from the use of piperalin.

Additional Data Required

EPA is requiring the following additional generic data for piperalin to confirm its regulatory assessments and conclusions: an additional mutagenicity study, data confirming the identity of the major degradates, studies to determine the leaching potential of the two major hydrolytic degradates.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, a revised Confidential Statement of Formula (CSF) and revised labeling for reregistration.

Product Labeling Changes Required

The registered piperalin end-use product must comply with EPA's current pesticide product labeling requirements, and with the following:

Personal Protective Equipment (PPE) for Mixers/Loaders/ Applicators

There are no special toxicological concerns that warrant the establishment of active-ingredient-based PPE requirements for pesticide handlers.

Early Entry PPE

Since piperalin is of relatively low acute toxicity and the Agency has no special concerns about other adverse effects, the PPE required for early entry is coveralls, chemical-resistant gloves, shoes, and socks.

Restricted Entry Interval (REI)

The interim REI established for piperalin under the Worker Protection Standard (WPS) was 24 hours because data at that time indicated that piperalin was in Toxicity Category II for skin irritation potential. In reviewing the data, EPA determined that piperalin should be in Toxicity Category III for skin irritation potential. Therefore, piperalin must have only a 12-hour REI.

Environmental Hazard Labeling Statement

The following statement is required on end-use product labeling:

"This product is toxic to fish. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters."

Regulatory Conclusion

Use of the currently registered product containing piperalin in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of the product are eligible for reregistration.

This product will be reregistered once the required product-specific data, revised Confidential Statement of Formula and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for piperalin 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 Operations 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, and also can be reached on the Internet via *FEDWORLD.GOV* and EPA's gopher server, *EARTH1.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 piperalin 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 piperalin RED, or reregistration of individual products containing piperalin, 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 8:00 am and 6:00 pm Central Time, Monday through Friday.