

R.E.D. FACTS

Propionic Acid

Pesticide Reregistration

All pesticides sold or used 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, showing 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 undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for propionic acid.

Use Profile

Propionic acid is a fungicide and bactericide, registered to control fungi and bacteria in stored grains, hay, grain storage areas, poultry litter, and drinking water for livestock and poultry. It is formulated as a liquid and sprayed onto grain, hay, grain storage area surfaces, and poultry litter. It is added directly to drinking water for livestock and poultry.

Propionic acid is a colorless, oily, pungent liquid that occurs naturally in animals and dairy products. It also is a normal component of metabolism in the human body. People consume naturally-occurring propionic acid in common foods such as butter and cheese (swiss cheese may contain as much as one percent propionic acid), and as an added ingredient in other foods.

Regulatory History

Propionic acid was first registered as a pesticide in the early 1970's. In 1975, EPA first exempted propionic acid from certain tolerance, or legal residue limit, requirements. Currently, two manufacturing-use pesticide products are registered, as are 12 end-use products, each containing propionic acid as its sole active ingredient.

Human Health Assessment

Toxicity

Contact with concentrated solutions of propionic acid may cause damage to the eyes, skin and mucous membranes. Since it is corrosive, propionic acid has been placed in Toxicity Category I for acute eye and dermal irritation effects (Toxicity Category I indicating the highest degree of toxicity, and IV the lowest). However, propionic acid is of moderate to low toxicity taken orally or inhaled, and is placed in Toxicity Category III for acute oral, dermal and inhalation effects.

Subchronic studies using the related compounds calcium and sodium propionate showed some adverse effects in the high dose test animals, including lesions of the forestomach, reduced food consumption and growth depression. However, an adult male human fed sodium propionate showed no effects other than slightly alkaline urine.

In a chronic feeding study using propionic acid, the high dose rats had hyperplasia, ulcers and other effects in the forestomach. However, a similar study using calcium and sodium propionate showed no effects other than initial growth depression. No maternal, fetal or teratogenic effects have been observed. Propionic acid is not mutagenic.

Dietary Exposure

People may be exposed to residues of propionic acid by eating food crops, meat, milk or poultry. However, since propionic acid is metabolized by livestock and poultry, any residues in meat, milk or poultry are negligible. Further, propionic acid is a normal metabolite in the human body, and is utilized by most organs and tissues. Therefore, it has been exempt from tolerance, or legal residue limit, requirements when applied to growing crops or raw agricultural commodities after harvest (40 CFR 180.1001 (c)), and when used post-harvest on many grains (40 CFR 180.1023). EPA also intends to exempt residues occurring in livestock or poultry as a result of application to their drinking water and to poultry litter. Propionic acid is Generally Recognized as Safe, or GRAS, when used as a direct food additive (21 CFR 184.1081).

Applicator Exposure

Propionic acid is sprayed on grain, forage, poultry litter and grain storage areas, and is applied directly to livestock and poultry drinking water. Applicators and other workers in spray areas could be significantly exposed. To protect them from eye and skin hazards, the use of protective clothing is necessary. Appropriate product labeling, as specified in the RED, is being required for product reregistration.

Human Risk Assessment

Since propionic acid is a normal component of human metabolism, and is regularly consumed in dairy products and other foods without consequence, it is not subject to the usual pesticide toxicology data requirements. Risks from exposure to propionic acid through the diet are very low. Risks from occupational use also are considered low, with the exception of skin and eye exposure hazards. Therefore, to protect applicators, the use of protective clothing while applying concentrated propionic acid products, as specified in the RED, is being required for product reregistration.

Environmental Assessment

EPA does not foresee the potential for significant environmental risks associated with the registered uses of propionic acid. All environmental fate and ecological effects data requirements are waived, as explained below.

Environmental Fate

Propionic acid is registered for indoor use and limited outdoor use, only. Further, in the environment, it acts as a carbon source for various microbes and is metabolized to carbon dioxide and water. Therefore, since propionic acid has little outdoor use, and then is metabolized into simple, known byproducts, all environmental fate data requirements are waived.

Ecological Effects

The available ecotoxicity studies indicate that propionic acid is only slightly toxic to birds, fish, aquatic invertebrates and mammals. Since it has limited outdoor use and low toxicity, its hazard to nontarget organisms is expected to be minimal. Therefore, all ecological effects data requirements are waived.

Additional Data Required

While the generic data base for propionic acid is complete, product-specific acute toxicity and product chemistry data are required for reregistration. These requirements are specified in the Data Call-In Notice issued in conjunction with this RED.

Product Labeling Changes Required

The labels of end-use products containing propionic acid must comply with EPA's current pesticide labeling requirements. In addition,

- Products containing greater than 63% active ingredient must include the following protective clothing label requirements: "Wear chemical-resistant gloves, chemical-resistant aprons, chemical-resistant footwear and goggles or face shield when loading application equipment unless a closed loading system is used. Avoid working near high concentrations of spray mist/vapor. Use with adequate ventilation. Wash thoroughly after handling."
- Labels of products intended for use on stored grain or hay must specify clearly which such crops may be treated, as detailed in 40 CFR 180.1023.

Regulatory Conclusion

- Registered pesticide products containing propionic acid can be used without causing unreasonable adverse effects in people or the environment. Therefore, they are eligible for reregistration.
- Products containing propionic acid as the sole active ingredient will be reregistered once product-specific data and amended labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document for propionic acid 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 or to submit written comments, please contact the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-557-2805.

In the future, the RED 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 propionic acid or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000. For information about reregistration of individual propionic acid products, please contact the Registration Division (7505C), OPP, US EPA, Washington, DC 20460, telephone 703-557-5447.

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, 24 hours a day, seven days a week, or Fax your inquiry to 806-743-3094.