US ERA ARCHIVE DOCUMENT



SEPA R.E.D. FACTS

Capsaicin

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, 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 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 capsaicin.

Use Profile

Capsaicin, which is made from the Capsicum red chili pepper, is used as a bird, animal and insect repellent. Specifically, it is used to repel birds, voles, deer, rabbits, squirrels, insects and attacking dogs. Capsaicin repellents are used indoors to protect carpets and upholstered furniture, and outdoors to protect fruit and vegetable crops, flowers, ornamental plants, shrubbery, trees, and lawns.

Capsaicin is obtained by grinding dried, ripe Capsicum frutescens L. chili peppers into a fine powder. The oleoresin is derived by distilling the powder in a solvent and evaporating the solvent. The resulting highly concentrated liquid has little odor but has an extremely pungent taste.

Regulatory **History**

The U.S. Department of Agriculture first registered a pesticide product with the single active ingredient capsaicin in 1962. This product, a dog-attack repellent, still is registered. Nine additional products containing capsaicin are registered at present. These granular, dust and liquid formulations contain capsaicin alone or in combination with the active ingredients garlic or oil of mustard.

Although EPA regulated it as a conventional pesticide for many years, in November 1991 the Agency reclassified capsaicin as a biochemical pesticide because it is a naturally-occurring substance and has a non-toxic mode of action.

Human Health Assessment

Toxicity

Capsaicin is natural, processed vegetable matter that has been part of the human diet for many years. It is unlikely that pesticide products containing capsaicin will pose a significant threat to human health. Excessive exposure to capsaicin may cause some slight eye and skin irritation. However, based on the existing acute toxicity data base, the remaining toxicity studies usually required for reregistration are waived.

Dietary Exposure

Red chili peppers have long been used as food additives/ components without causing any known adverse health effects. EPA has waived the usual residue chemistry data requirements for capsaicin. However, an exemption from the tolerance (food residue limit) requirement must be established before capsaicin products will be reregistered.

Occupational and Residential Exposure

Capsaicin products formulated as powders/dusts and granulars may be applied to growing crops from the ground or by air; the liquid formulations are diluted with water and sprayed by aircraft, ground boom, hand-held garden hose and airblast spray equipment. During these applications, applicators' eyes and skin may be exposed to capsaicin. Field workers also may be exposed to capsaicin from contacting the foliage of treated growing crops.

Human Risk Assessment

Due to the nature of capsaicin and the required precautionary statements on labeling, EPA concludes that products containing capsaicin will not have adverse effects on human health.

Environmental Assessment

The basic data requirements for a biochemical pesticide consist of acute ecological effects (Tier I) studies. Environmental fate and additional ecological effects studies are required only if adverse effects are observed in the Tier I studies. As explained below, EPA has waived the Tier I studies for capsaicin.

Environmental Fate

Since capsaicin is a biochemical pesticide and all ecological effects studies have been waived, no environmental fate data are required.

Ecological Effects

EPA has waived all ecological effects data requirements for capsaicin because:

- Capsaicin is a strong, fast-acting irritant when eaten or exposed to the skin. It is used to repel birds and animals. EPA is calling in data on the effectiveness of capsaicin products in repelling birds. Pending the results, we assume that earlier studies are correct and that birds and animals avoid excessive and prolonged exposure to capsaicin, thus minimizing their risks.
- It is difficult to assess the risks posed to aquatic species by use of capsaicin. Instead of requiring studies, EPA is requiring restrictive product label statements to minimize aquatic species' exposure and reduce any risks.
- EPA also is requiring maximum application rates on all capsaicin product labels, to reduce overall environmental exposure and any attendant risks.

Ecological Effects Risk Assessment

EPA does not foresee the potential for significant environmental risks associated with the registered uses of capsaicin. With new label requirements imposed, no risk issues need to be addressed further.

Additional Data Required

No additional generic data are required at this time for reregistration of pesticide products containing the active ingredient capsaicin. Product-specific acute toxicity, product chemistry and efficacy studies are required. EPA will propose the needed tolerance exemption for capsaicin's food crop uses.

Product Labeling Changes Required

The labels of end-use products containing capsaicin must comply with EPA's current regulations and requirements. In addition, the following labeling is required:

- To protect aquatic species, other wildlife and the environment, labels must state, "This product may be toxic to aquatic organisms.
 Do not apply to or allow runoff to reach lakes, streams or ponds. Do not contaminate water by cleaning of equipment or disposal of wastes."
- Maximum application rates must be added to all capsaicin product labels. EPA will review application rates proposed by registrants.

Regulatory Conclusion

• The ten registered pesticide products that contain the active ingredient capsaicin can be used without causing unreasonable adverse effects in people or the environment. Therefore, they are eligible for reregistration.

- EPA will reregister end-use products containing capsaicin once product-specific data and revised labeling are submitted to and accepted by the Agency.
- Those capsaicin products that also contain another active ingredient (garlic or oil of mustard) will be reregistered only after their other active ingredient also is eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for capsaicin 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 703-305-5805.

In the future, the capsaicin 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 capsaicin 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 capsaicin pesticide products, please contact the Registration Division (7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-6784.

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.