

SEPA R.E.D. FACTS

Allium sativum (Garlic)

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 Allium sativum (garlic).

Use Profile

Allium sativum or garlic, formulated as a powder or a distilled extract from garlic cloves, is an active ingredient in four registered pesticide products; three of these products also contain the active ingredient capsaicin (red pepper). The garlic pesticides are applied aerially or by ground equipment, and are used to repel birds and/or insects and thus prevent them from damaging seeds and seedlings of vegetable plants, fruit trees, grain crops, ornamental plants and shrubbery.

Regulatory History

EPA registered the first two pesticide products containing garlic as an active ingredient in 1983 and 1985. Both products also contain red pepper, and are used to repel birds. A third garlic and red pepper product, used to repel insects, was registered in 1988. The fourth product, which contains garlic as a single active ingredient, was registered in February 1991, also to control insects.

EPA previously classified garlic as a conventional chemical pesticide. However, the Agency now is reclassifying garlic as a biochemical pesticide since it is a naturally-occurring substance and has a non-toxic mode of action.

Human Health Assessment

Although EPA has developed a set of data requirements for reregistration, the Agency believes there is a category of pesticides for which a greatly reduced set of data requirements are appropriate. Such pesticides may be exempt from the usual generic data requirements for toxicology, residue chemistry, human exposure, ecological effects and environmental fate, without compromising human health or environmental safety. However, some data requirements (such as basic product identity and product chemistry data and acute toxicology studies) usually are essential, and generally will not be waived.

Garlic is in this category of pesticides, and EPA is waiving most of the generic data requirements for its reregistration. The bulb of a plant, its primary use in the United States is non-pesticidal; it is used widely to flavor and season foods. Garlic is "generally recognized as safe," or GRAS, as a natural seasoning or flavoring (see 21 CFR 182.10, 182.20 and 184.1317).

Used as a pesticide, garlic has a non-toxic mode of action for repelling target birds and insects. Garlic is presumed to be non-persistent since it is material known to rapidly degrade in the environment. EPA has received no reports of adverse effects resulting from its use. The Agency believes that no significant adverse effects to humans or the environment are associated with the use of garlic as a pesticide.

Additional Data Required

EPA is not requiring the submission of additional generic data for the active ingredient garlic. However, EPA is requiring the submission of product specific data (chemistry, acute toxicity and efficacy). These are being required now, through the RED.

Product Labeling Changes Required

The labels of the four registered garlic pesticide products must comply with EPA's current pesticide labeling requirements. No other labeling changes are being required at this time.

Regulatory Conclusion

The registered bird and insect repellent uses of garlic are not likely to cause unreasonable adverse effects in people or the environment, and are eligible for reregistration.

The registered product that contains garlic as its only active ingredient will be reregistered once product-specific data and amended labeling are received and accepted by EPA.

The other three registered products that contain both garlic and red pepper as active ingredients will be reregistered after product specific data and labeling requested in this RED are received and accepted by EPA and after a RED is issued for red pepper.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for garlic during a 60-day time period, as announced in a Notice of Availability published in the <u>Federal Register</u>. 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 garlic 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 garlic 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 garlic products, please contact the Registration Division, PM Team 14 (7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-6600.

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.