



R.E.D. FACTS

Sulfotepp

Pesticide Reregistration

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 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 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 reregisters pesticides that meet the safety standard of FQPA 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 in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0338, sulfotepp.

Use Profile

Sulfotepp is a restricted-use organophosphate insecticide/miticide used to control ornamental plant pests. It is registered for commercial greenhouse use only. Sulfotepp is formulated into an impregnated smoke fumigant.

Regulatory History

Sulfotepp was first registered for use in the United States in 1951. EPA issued a Registration Standard for Sulfotepp in September 1988 (PB540/RS-88-086). Data Call-Ins (DCIs) issued in June 1991, August 1993, and October 1995 required additional data for sulfotepp. Currently, 2 sulfotepp products are registered. Due to the high risks estimated with available information and the registrants' inability to support the data requirements for reregistration, the registrants have signed an agreement to voluntarily cancel their registrations

effective September 30, 2002, with an existing stocks provision through September 30, 2004. By December 1999, all sulfotepp products will bear amended labels designed to improve worker protection.

Human Health Assessment

Toxicity

The toxicity database for sulfotepp is incomplete. In the absence of dermal and inhalation toxicity data, toxicity was estimated using a subchronic feeding study in dogs, published literature, and data from a similarly toxic organophosphate pesticide. The limited data indicate that exposure results in cholinesterase inhibition in erythrocytes and plasma, with accompanying clinical symptoms. Sulfotepp is in Toxicity Category I, the highest of four categories for toxicity.

Dietary Exposure

Sulfotepp is not registered for use on either food or feed crops. Therefore, dietary exposures are not expected. It is used only in greenhouses; therefore, drinking water exposure is not expected.

Occupational and Residential Exposure

Based on the use patterns of sulfotepp, occupational exposures can occur. Pesticide handlers and postapplication workers are at risk for exposure. Sulfotepp is registered for use in commercial greenhouses only, but residential and bystander exposures have occurred when sulfotepp has leaked from treated greenhouses.

Human Risk Assessment

Sulfotepp applicators are at greatest risk for inhalation exposure, while postapplication workers are at risk for both inhalation and dermal exposure. Risks to applicators can be effectively mitigated by increasing required personal protective equipment and by improving application instructions and other language on the labels. Label amendments will also reduce risks to bystanders in nearby residential areas. Risk mitigation options for postapplication exposures that are both effective and practical are limited.

Environmental Assessment

Environmental Fate/Ecological Effects

Toxicity data for sulfotepp indicate that it is toxic to wildlife, fish, and aquatic invertebrates. Based on these data, EPA presumes it is also toxic to birds. However, because sulfotepp is registered for indoor (greenhouse) use only, ecological exposure to sulfotepp is expected to be minimal.

Risk Mitigation

To lessen the risks of worker and bystander exposure posed by sulfotepp, EPA is requiring the following risk mitigation measures:

- N Production of sulfotepp products will cease effective September 30, 2002.
- N Distribution and use of sulfotepp and sulfotepp products will be unlawful after September 30, 2004.

N All sulfotepp products will bear amended labels providing greater worker and bystander protection by December 1999.

N Until September 30, 2002, formulation of sulfotepp products will be limited by a production cap.

N Registrants will notify distributors, retailers, and users of the terms and effective dates of the applicable provisions of the cancellation agreement.

Additional Data Required

Because the registrants have requested a voluntary cancellation, no additional data will be required.

Product Labeling Changes Required

All sulfotepp end-use products must comply with EPA's current pesticide product labeling requirements and with the following. For a comprehensive list of labeling requirements, please see the sulfotepp RED document.

N All applicators must wear chemical-resistant gloves in addition to baseline attire (long-sleeved shirt, long pants, socks, and shoes).

N Self-contained breathing apparatus will be required for applicators applying six or more canisters of sulfotepp OR if exposure will be greater than ten minutes. A full-face respirator will be required for applicators applying five or fewer canisters OR if exposure will be ten minutes or less.

N Use directions will be amended to state explicitly the sequence of steps required to set up and complete application so as to minimize the potential for exposure.

N Any person applying sulfotepp must maintain constant visual or voice contact with an additional person outside the greenhouse who has immediate access to personal protective equipment required for applicators.

N More protective initial ventilation criteria specific to sulfotepp will supercede that required by the Worker Protection Standard.

N Postapplication workers' time in a sulfotepp-treated greenhouse will be limited as follows: 4 hours within the first 24 hours after fumigation, and 4 hours within the second 24 hours. In addition, when a worker is present in the greenhouse during the first 48 hours after fumigation, detailed ventilation criteria must be met.

N Labels will state explicitly that use in residential greenhouses is prohibited.

N Entry into a treated greenhouse by retail customers will be prohibited for 48 hours after fumigation, or until initial ventilation criteria have been met.

N If applied to a greenhouse attached to another structure, including another greenhouse, the greenhouse to be treated must be sealed off from the other structures.

N This product may not be applied in any greenhouse that is located within 100 feet of a residential area (e.g., homes, apartments, schools, playgrounds, recreation areas).

Regulatory Conclusion

Sulfotepp was ineligible for reregistration due to the high risks estimated with available information and the lack of required data. When used in accordance with labels as amended, risks to application workers will be adequately addressed. Practical and effective options for mitigating postapplication worker risks are limited. Therefore, the registrants voluntarily cancelled the registration of sulfotepp effective September 30, 2002, with an existing stocks provision through September 30, 2004. The terms of the cancellation reflect consideration of the benefits associated with use of sulfotepp, and allow time for growers to find alternatives.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for sulfotepp 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 Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet are available on the Internet. See <http://www.epa.gov/REDS>.

Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the sulfotepp RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the sulfotepp RED, or reregistration of individual products containing sulfotepp, please contact the Special Review and Reregistration Division (7508C), 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 Pesticide Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, 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. Their internet address is ace.orst.edu/info/nptn.