

EPA-738-F-93-008 September 1993



Wood Oils and Gums (Cedarwood Oil)

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 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 risk to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision document, or RED. This fact sheet summarizes the information in the RED document for the case Wood Oils and Gums, which contain the pesticide cedarwood oil.

Use Profile

Cedarwood oil is a natural component of wood from the tree, Juniperus virginiana L. It is an active ingredient in five pesticide products that are used as repellents and feeding depressants to control moths and fleas and retard the growth of mildew. Three of these products are solid Cedarwood blocks used to repel moths from clothing and retard mildew growth on fabrics. The other two products, which contain extracted cedarwood oil, are a pet tag or collar and ~ liquid sprayed on animal bedding. Both are intended to repel fleas from household pets. Cedar also is a major component of many non-pesticidal consumer products currently marketed in the United States.

Regulatory History

Cedarwood oil was initially registered as a pesticide in the United States in 1960, to repel moths from clothing. The re-registration case Wood Oils and Gums originally included two other active ingredients (Canadian balsam and ester gum) which were cancelled after their registrants chose not to support them through the re-registration process. The case now consists only of cedarwood oil with five end-use products and no technical product registrations.

By a notice published in the Federal Register for public comment on August 11, 1993. EPA has proposed to exempt from regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) natural cedar products which consist totally of Cedarwood, are not combined or impregnated with other substances and are intended only to repel arthropods other than ticks and/or to retard mildew. EPA believes it is unnecessary to regulate these products because they pose little or no risk to human health or the environment. Consumers are not likely to be exposed to significant amounts of cedarwood dust or oil, either dermally or by inhalation. **When using these products EPA is not aware of any evidence of injury to human health or the environment due to their use. The cost and effort involved in regulating these cedar products is not justified by the low risk concerns associated with them.**

After considering any public comments submitted if EPA decides to deregulate natural cedar products, the reregistration requirements discussed in the cedarwood oil R.E.D. will not apply to registered cedarwood block products. However, if they are not deregulated, the cedarwood block products will be subject to the requirements of the R.E.D.

Human Health and Environment Assessment

Cedarwood oil is among those pesticides for which EPA believes a broadly reduced set of generic data requirements is appropriate for reregistration. The Agency therefore has waived most generic data requirements for cedarwood oil with the exception of studies that are considered essential, including additional information about chemical purity and product chemistry studies. In evaluating cedarwood oil's potential risks to human health and the environment, EPA relied on information commonly available in scientific literature.

Cedarwood oil is a mixture of organic compounds. It is considered Generally Recognized as Safe (GRAS) as a food additive by the Food and Drug Administration. As a pesticide, it repels insects by a non-toxic mode of action. **EPA is not aware of any adverse effects caused by cedarwood oil pesticide products when used in a manner prescribed by their labeling. No incidents involving toxic effects have been reported to the Agency.**

A laboratory study using mice and a study of workers in saw mills suggest that cedarwood oil may cause liver and pulmonary toxicity. However, these effects were associated with long term exposures to relatively high levels of cedarwood oil. EPA does not expect such effects to occur among users of currently registered cedarwood oil products because their exposure is intermittent and at a low level.

EPA believes there is negligible human and environmental exposure to cedarwood oil as a result of its registered pesticidal uses. The reregistered pesticide products generally are used at a low rate, infrequently, and indoors. EPA therefore is requiring product specific acute toxicity testing to develop appropriate labeling. The Agency concludes that the use of cedarwood oil as an active ingredient in currently-registered pesticide products should not result in unreasonable adverse effects to human health or the environment

Additional Data Required

Although EPA has waived most generic studies, the Agency is requiring additional details about the chemical characterization of the cedarwood oil used in the formulated products. EPA also is requiring product-specific data including product chemistry, acute toxicity and efficacy studies for the public health pests, fleas, as well as revised Confidential Statements of Formula and revised labeling for reregistration

Product Labeling Changes Required

The labels of all registered pesticide products containing cedarwood oil must comply with EPA's current pesticide labeling requirements. In addition, products registered for use on pets or animals must specify on their labels which animals may be treated with the product.

Regulatory Conclusion

The use of currently registered pesticide products containing cedarwood oil in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

These cedarwood oil products will be reregistered once the required physical chemistry data, product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by the EPA. Products containing other active ingredients will be reregistered only when the other active ingredients also are determined to be eligible *for* reregistration.

Cedarwood oil products consisting of natural cedarwood blocks are of a character which EPA believes is unnecessary for regulation under FIFRA. If the Agency decides to deregulate the cedarwood block products, their reregistration will no longer be required.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for Wood Oils and Gums during a 60 day time period as announced in a Notice of Availability published in the Register. To obtain a copy of the RED 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.

Following the comment period, the Wood Oils and Gums 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 the EPA's pesticide reregistration program, the Wood 011s and Gums RED, or reregistration of Individual products containing cedarwood oil, please call 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.