



R.E.D. FACTS

Flower and Vegetable Oils

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 Flower and Vegetable Oils, which contains the active ingredients essential oils (covering 24 substances), oil of lemongrass, oil of eucalyptus, soybean oil, oil of mustard, and oil of anise.

Use Profile

The reregistration case Flower and Vegetable Oils is composed of a group of compounds that are natural components of plants. These oils are active ingredients in pesticide products registered for use as animal repellants, feeding depressants, insecticides and miticides. Some of the essential oils also are included as active ingredients in antimicrobial pesticide products (disinfectants, sanitizers, bacteriostats, microbiocides and fungicides). However, since the essential oils have no independent pesticidal activity in antimicrobial products, these uses are not eligible for reregistration. Many of the flower and vegetable oils have other, more significant, non-pesticidal uses as food additives, flavorings, and components of cosmetics, soaps, perfumes, plastics, resins, and other products.

Regulatory History

The case Flower and Vegetable Oils originally included eleven active ingredients. However, five of these active ingredients were not supported by their manufacturers for reregistration (cottonseed oil, linseed oil, sesame oil, hydrogenated castor oil, and oil of geranium). The following six active ingredients are being supported for reregistration.

Essential oils, defined as any volatile oil that gives distinctive odor or flavor to a plant, flower or fruit, were first registered as pesticide active ingredients in 1947. A total of 24 distinct chemicals are covered under this active ingredient. EPA now requires that registrants identify the particular oil(s) contained in their products, rather than naming "essential oils" as the active ingredient. Approximately 25 pesticide products currently are registered which contain essential oils as active ingredients. These products are used as repellants, feeding depressants, insecticides and miticides, as well as antimicrobials. They are marketed as liquid sprays, crystals and pellets.

Oil of lemongrass was first registered in 1962 as a dog repellant. Currently, two products are registered which contain this active ingredient; both are formulated as pellets and used to repel cats and dogs from ornamentals, shade trees, patio furniture and garbage cans.

Oil of eucalyptus was first registered in 1948 as an insecticide and miticide. Currently, only one product (an herbal flea collar for pets) is registered which contains oil of eucalyptus.

Oil of mustard (allyl isothiocyanate) was first registered in 1962 as a dog repellant. Five products currently are registered; four are used outdoors either to repel cats and dogs from lawns, flowers, bushes, shade trees and refuse containers, or to kill insects. The fifth product is used indoors in a carpet freshener to repel pets. Products are formulated as liquids or pellets/tablets.

Soybean oil was first registered in 1959 for use as an insecticide and miticide. Three products currently are registered. They are emulsifiable concentrate formulations used to control insects and mites on citrus fruits and a variety of ornamentals.

Oil of anise was first registered in 1952 for use as an insecticide and miticide. Only one product currently is registered, a liquid spray used on soil near lawns, gardens and flower beds to repel cats and dogs.

Human Health and Environmental Assessment

The flower and vegetable oils are 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, except certain technical chemistry information, for most of the chemicals included in this RED. In evaluating the flower and vegetable oils' potential risks to human health and the environment, EPA relied on information commonly available in scientific literature.

Generally, these chemicals are of low acute toxicity (except for oil of mustard). Many are Generally Recognized as Safe (GRAS) by the Food and Drug Administration, are exempted from the requirement of food additive tolerances, and are used in food preparation. As pesticides, they employ a non-toxic mode of action. Since they are formulated in low concentrations into products that are used at low volumes in the United States, exposure to humans and the environment is expected to be very low. EPA has received no incident reports of adverse effects for these chemicals. In summary, the flower and vegetable oils are not likely to result in adverse effects in humans or the environment.

Outdoor use of the pelleted formulation of oil of mustard could result in exposure and adverse effects to nontarget organisms, particularly birds ingesting these pellets. However, since all presently registered products contain low concentrations of oil of mustard, exposure and risk to terrestrial species are believed to be low.

The use of essential oils for antimicrobial purposes is ineligible for reregistration. Essential oils normally have no independent pesticidal activity when included in antimicrobial products; these products contain one or more other chemicals that perform as the active ingredients. Essential oils in antimicrobial products must instead be classified as inert ingredients, or must be deleted from the product formulations.

The Agency concludes that the use of flower and vegetable oils as active ingredients 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 physical chemistry studies for all active ingredients in this case, and additional terrestrial ecological effects data for oil of mustard, as confirmatory data. EPA also is requiring product-specific data including product chemistry and acute toxicity testing, 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 flower and vegetable oils must comply with EPA's current pesticide labeling requirements. In addition,

- All registrants who have a mixture of essential oils listed as the active ingredient on their product label (and the product is not an antimicrobial) must list separately on the label each essential oil and its percentage of the product's composition.
- All registrants with antimicrobial products containing essential oils must either delete that active ingredient from their product formulations or convert that active ingredient to an inert.

Regulatory Conclusion

The use of currently registered pesticide products containing flower and vegetable oils in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all current uses of these products are eligible for reregistration except the use of essential oils in antimicrobial products, which is not eligible for reregistration. Essential oils must either be deleted from or converted to inert ingredients in antimicrobial products.

The eligible flower and vegetable oils products will be reregistered once the required physical chemistry studies, terrestrial ecological effects data for oil of mustard, product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA. Products also containing other active ingredients will be reregistered only when the other active ingredients are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for Flower and Vegetable Oils 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 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 Flower and Vegetable Oils 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 EPA's pesticide reregistration program, the Flower and Vegetable Oils RED, or reregistration of individual products containing the active ingredients covered by this RED, 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, 8:00 am until 6:00 pm Central Time, Monday through Friday.