



R.E.D. FACTS

資料 39

THYMOL

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 or RED. This fact sheet summarizes the information in the RED for thymol.

Use Profile

Thymol is a constituent of oil of thyme, a naturally occurring mixture of compounds in the plant *Thymus vulgaris* L., or thyme. Thymol is an active ingredient in pesticide products registered for use as animal repellents, fungicides/fungistats, medical disinfectants, tuberculocides, and virucides. These products are used on a variety of indoor and outdoor sites, to control target pests including animal pathogenic bacteria and fungi, several viruses including HIV-I, and birds, squirrels, beavers, rats, mice, dogs, cats and deer. Products are liquids applied by spray, mop, brush-on, wipe-on dip, aerosol, immersion and spot treatment. Thymol also has many non-pesticidal uses, including use in perfumes, food flavorings, mouthwashes, pharmaceutical preparations and cosmetics.

Regulatory History

Thymol was initially registered as a pesticide in the United States in 1964 for use as a repellent for domestic animals. Currently, five end-use (and no manufacturing use) pesticide products containing the active ingredient

thymol are registered. Thymol, thyme essential oil and thyme (spice) are listed by the Food and Drug Administration (FDA) as foods for human consumption, as well as food additives. They are considered Generally Recognized as Safe or GRAS. (Please see 21 CFR 172.515, 182.10 and 182.20.)

Historically, certain thymol products and other liquid chemical germicides have been regulated both by EPA as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and by FDA as devices under the Federal Food, Drug, and Cosmetic Act (FFDCA). To resolve the confusion and burden of dual regulation, EPA and FDA signed a Memorandum of Understanding (MOU) on June 4, 1993, which clarifies the future regulation of these germicides. The MOU divides liquid chemical germicides used in conjunction with medical devices into two categories: sterilants, which will be regulated by FDA as devices, and general purpose disinfectants, which EPA will regulate as pesticides. Until rulemaking is completed to permanently vest jurisdiction over these categories, regulatory data need only be submitted to one Agency. For thymol, the conditions of reregistration must be fulfilled and required data must be submitted to EPA.

Human Health Assessment

Thymol 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 thymol with the exception of studies that are considered essential, including additional information about chemical purity, and product chemistry studies. In evaluating thymol's potential risks to human health and the environment, EPA relied on information commonly available in scientific literature.

Thymol is a constituent of a mixture of organic compounds known to be rapidly degraded in the environment to elemental compounds by normal biological, physical and/or chemical processes that can reasonably be expected to exist where the pesticide is applied. As a pesticide, thymol repels vertebrate pests by a non-toxic mode of action, but is toxic to microorganisms. EPA is not aware of any adverse effects of thymol to humans or the environment when it is used in a manner prescribed by product labeling. The Agency has no significant incident reports involving thymol.

Toxicity data reported in available literature indicate that acute oral toxicity for rats and guinea pigs corresponds to Toxicity Category III (Category I

signals the highest degree of acute toxicity, and Category IV the lowest). The Material Safety Data Sheet (MSDS) for technical grade thymol notes that it is irritating to humans when exposed by inhalation, dermal or eye contact. The dermal risk to humans would be Toxicity Category III.

Exposures and health risks to people using currently registered products are expected to be relatively low. However, handling and use of the end-use products could involve greater exposure by the dermal and inhalation routes. Required product specific acute toxicity testing will enable the Agency to design appropriate labeling to address these potential exposure concerns.

The uses of thymol will result in negligible exposure of the environment and nontarget organisms. EPA concludes that the use of thymol 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 for thymol, the Agency is requiring information on the manufacturing process and additional information about the characterization of the thymol used in the formulated products. EPA also is requiring product-specific data, including product chemistry, acute toxicity and efficacy studies, 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 thymol must comply with EPA's current pesticide labeling requirements.

Regulatory Conclusion

The use of currently registered pesticide products containing thymol 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 thymol products will be reregistered once the required manufacturing process information, physical and chemical properties data, product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA. Products containing other active ingredients will be reregistered only when the other active ingredients also are determined to be eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) for thymol during a 60-day time period, as announced in a