US ERA ARCHIVE DOCUMENT



SEPA R.E.D. FACTS

Lauryl Sulfate Salts

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 risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for the case Lauryl Sulfate Salts, which contains the active ingredient sodium lauryl sulfate.

Use Profile

Sodium lauryl sulfate is used as a flea and tick repellant in one registered pesticide product--a flea and tick shampoo for cats and dogs. Sodium lauryl sulfate also is a widely used component of many nonpesticidal consumer products currently marketed in the United States, including shampoos and fruit juices.

Regulatory **History**

The reregistration case Lauryl Sulfate Salts originally included four active ingredients (sodium lauryl sulfate, magnesium lauryl sulfate, ammonium lauryl sulfate, and triethanolamine lauryl sulfate). In May 1988, EPA announced that these four active ingredients have no independent pesticidal activity when included in antimicrobial products, and thus are properly classified as inert ingredients in those products (please see 40 CFR 153.139). Therefore, the antimicrobial products that contain these active ingredients are not subject to this RED.

Currently, only sodium lauryl sulfate has an active (end-use) pesticide product registration, for a ready-to-use liquid pet shampoo called "Dr.

Dogkatz Critter Chaser." EPA has not issued a Data Call-In (DCI) requesting generic data on sodium lauryl sulfate prior to this RED.

The Food and Drug Administration (FDA) lists sodium lauryl sulfate as a food additive, has exempted it from the requirement of a food additive tolerance, and considers it Generally Recognized as Safe or GRAS (please see 21 CFR 172.822). Its non-pesticidal uses far outnumber its one pesticide use.

Human Health and Environmental Assessment

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

Sodium lauryl sulfate is a detergent-like substance that employs a non-toxic mode of action in controlling fleas and ticks on household pets. The potential for dermal and/or inhalation exposure exists to people applying the registered pet shampoo product. However, this exposure is not considered significant and does not create a health risk concern. Published reports suggest that sodium lauryl sulfate has low acute mammalian toxicity and no known chronic effects. EPA has no reports of adverse effects resulting from its use. Both exposure and health risks to people using the product are expected to be low.

EPA also believes that since the pesticide is used only on pets, negligible exposure to the environment and to nontarget organisms will result. The Agency concludes that the registered product and use of sodium lauryl sulfate 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 sodium lauryl sulfate used in the formulated product. 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 label of the registered end-use pesticide product containing sodium lauryl sulfate must comply with EPA's current pesticide labeling requirements. In addition, labeling must specify which pets/animals may be treated with the product.

Regulatory Conclusion

Use of the registered pesticide product containing sodium lauryl sulfate in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all current uses of the product are eligible for reregistration. This product will be reregistered once the required physical chemistry data, product-specific data, revised Confidential Statement of Formula and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for Lauryl Sulfate Salts 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 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 Lauryl Sulfate Salts RED document 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 Lauryl Sulfate Salts RED, or reregistration of the product containing sodium lauryl sulfate, please contact 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.