US ERA ARCHIVE DOCUMENT



# SEPA R.E.D. FACTS

# Soap Salts

#### **Pesticide** Reregistration

All pesticides sold or used 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 undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for soap salts.

#### **Use Profile**

Soap salts include the two pesticide active ingredients potassium salts of fatty acids (including potassium laurate, potassium myristate, potassium oleate and potassium ricinoleate), and ammonium salts of fatty acids (ammonium oleate).

Potassium salts of fatty acids are used as insecticides, acaricides, herbicides and algaecides. They are used to control a variety of insects and mosses, algae, lichens, liverworts and other weeds, in or on many food and feed crops, ornamental flower beds, house plants, trees, shrubs, walks and driveways, and on dogs, puppies and cats.

Ammonium salts of fatty acids are used as a rabbit and deer repellent on forage and grain crops, on vegetables and field crops, in orchards, and on nursery stock, ornamentals, flowers, lawns, turf, vines, shrubs and trees.

#### Regulatory History

The first pesticide product containing soap salts as an active ingredient was registered in 1947. Currently, 24 registered pesticide products contain soap salts. Some of these products also contain other active ingredients.

When EPA published reregistration List D in the <u>Federal Register</u> on May 5, 1990, Soap Salts (case 4083) contained eight active ingredients. However, four of these were combined into the single active ingredient, potassium salts of fatty acids; three others were cancelled and are no longer subject to reregistration. Thus, two active ingredients remain.

Potassium salts of fatty acids used on food and feed crops have been exempted from the requirement of a tolerance (or maximum residue limit) for all raw agricultural commodities since 1982 (please see 40 CFR 180.1068). They are generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) (please see 21 CFR 172.863). Although ammonium salts of fatty acids also were exempted from tolerance requirements in 1982, public notice was not provided. To correct this oversight, EPA will publish an appropriate Federal Register notice soon.

In 1988, EPA determined that soap salts have "no independent pesticidal activity" in antimicrobial products, and must be classified as inert ingredients in those products (please see 40 CFR 153.139.) Therefore, antimicrobial pesticides that contain soap salts as inert ingredients are not subject to this RED. Antimicrobials that still contain soap salts as active ingredients are considered misbranded and are subject to misbranding enforcement action or cancellation.

#### Human Health Assessment

#### **Toxicity**

Soap salts are of low toxicity when taken orally or exposed briefly to the skin, and have been placed in Toxicity Category IV (indicating the lowest level of toxicity) for these acute effects. However, they can cause mild or moderate irritation when exposed to the skin for longer periods of time. Ammonium salt products also can cause permanent eye damage.

Fatty acids normally are metabolized, forming simple compounds that serve as energy sources and structural components used in all living cells. However, soap salts caused reproductive and mutagenic effects when administered to laboratory animals at high doses.

#### **Dietary Exposure**

Although people could be exposed to low levels of soap salts on foods, these residues pose no known health risks. Soaps are mineral salts of naturally occurring fatty acids. These fatty acids are a significant part of the normal daily diet. Residues from the pesticide uses of soap salts are not likely to exceed levels of naturally occurring fatty acids in commonly eaten foods. Again, both potassium and ammonium salts of fatty acids are exempted from tolerance requirements, and potassium salts are generally recognized as safe by FDA.

#### **Occupational and Residential Exposure**

People applying soap salts may be exposed to these compounds. Potassium salts are of low toxicity to humans, and there is no reason to expect that reasonable use will constitute any significant hazard. However, protective eyewear is required while applying the ammonium salts of fatty acids to prevent permanent eye injury.

#### **Human Risk Assessment**

Soap salts are of low acute toxicity when taken orally or exposed to the skin. Residues from the pesticide uses of soap salts are not likely to exceed levels of naturally occurring fatty acids in commonly eaten foods. Thus, EPA believes the risks of the soap salts to applicators and consumers are negligible. The risk of eye injury to applicators of the ammonium salts can be mitigated by use of protective eyewear.

### **Environmental Assessment**

#### **Environmental Fate**

Hydrolysis of potassium salts of fatty acids (and probably also of ammonium salts) does not occur over a period of 43 days. The half-life of these fatty acids is estimated to be less than one day. As can be expected, microbial organisms rapidly degrade fatty acids in soil. Soap salts cannot dissipate totally in soil, however, because soil has a natural content of fatty acids resulting from plant metabolism and microbial action. Fatty acids are a significant part of the normal daily diet of mammals, birds and invertebrates.

#### **Ecological Effects**

Ammonium salts of fatty acids are used outdoors as a rabbit and deer repellent. They are practically non-toxic to upland game birds and waterfowl. Their other potential hazards were estimated using data from the potassium salts.

Acute and subacute toxicity studies using potassium salts of fatty acids indicate that soap salts are relatively non-toxic to birds. They are slightly toxic to both coldwater and warmwater fish species. The potassium salts are highly toxic to aquatic invertebrates.

No studies regarding the effects of the soap salts on non-target insects were available for review. Such studies still are required. In addition, product use rate information is needed to confirm that soap salts pose a minimal threat to endangered species.

#### **Environmental and Ecological Risk Assessment**

Pesticides containing potassium or ammonium salts of fatty acids are used on a wide array of outdoor sites. Once applied, however, the soap salts are degraded quickly in soil by microbes, and do not persist in the environment. The soap salts pose minimal risks to birds and are only slightly toxic to fish. They are highly toxic to aquatic invertebrates. However, since soap salts are not applied directly to water, their current uses should not seriously impact aquatic invertebrates. Additional studies are needed to assess their effects on non-target insects. The soap salts should pose minimal threats to endangered species. In summary, based on

the data reviewed, EPA finds that the soap salts will not cause unreasonable adverse effects on the environment.

#### Additional Data Required

EPA has waived all generic data requirements for the soap salts except basic product identity and chemistry studies and acute ecotoxicity studies, which were submitted and reviewed. EPA is requiring honeybee toxicity data for potassium salts and confirmatory ecotoxicity studies on fish and aquatic invertebrates for ammonium salts of fatty acids to confirm that these pesticides do not pose significant ecological hazards. Product-specific chemistry and acute toxicology studies also are required for reregistration.

# **Product Labeling Changes Required**

The labels of all registered soap salts products must comply with EPA's current pesticide labeling requirements. In addition,

- Products with outdoor uses and the manufacturing use product must bear the following label statement: "This product may be hazardous to aquatic invertebrates. Do not apply directly to water, areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of water."
- Labeling of all products must include appropriate precautionary statements.
- Labeling of ammonium salts products must require use of protective eyewear (safety glasses, goggles or faceshield).
- Labels must upgrade the ingredients statement by declaring potassium salts or ammonium salts of fatty acids, rather than "soap".
- Labels of products for crop uses must be upgraded by stating specific crops and/or crop groups.

#### Regulatory Conclusion

- All registered pesticide products containing the active ingredient soap salts are not likely to cause unreasonable adverse effects in people or the environment, and are eligible for reregistration. These products will be reregistered once the required additional generic data, product-specific data and revised labeling are received and accepted by EPA.
- Registered products containing soap salts as well as other active ingredients will be reregistered once the other active ingredients also are determined to be eligible for reregistration.

## For More Information

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for soap salts during a 60-day time period, as announced in a Notice of Availability published in the <u>Federal Register</u>. To obtain a copy of the RED or to submit written comments, please contact the Public

Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

In the future, the soap salts 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 soap salts or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000. For information about reregistration of individual soap salts products, please contact PM Team 14, Registration Division (7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-6600.

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, 24 hours a day, seven days a week, or fax your inquiry to 806-743-3094.