

**Forster & Associates Consulting, LLC**  
Providing Regulatory Expertise to the Agricultural Biotechnology and Chemical Industry

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Bob Pooler  
USDA, AMS, National Organic Program  
1400 Independence Ave. SW  
Room 4008-South  
Washington, DC  
20250

April 29, 2006

**RE: Request to Amend the NOP List §201.601(b)(1) to Add Ammonium Salts of Fatty Acids Products**

Dear Mr. Pooler,

Please find enclosed an application for the amendment of §201.601(b)(1) to include ammonium salts of higher fatty acids to the National List of Approved Organic Products.

Falcon Lab, LLC, appreciate your attention to our efforts. As acting Regulatory Affairs agent for Falcon Lab, LLC, please do not hesitate to contact me with any questions regarding this NOP application.

Best regards,



Vickie Forster,  
Agent for Falcon Lab, LLC

cc: Terry Pizzarello, Falcon Lab, LLC  
Bob Smiley, Falcon Lab, LLC

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Vickie A. Forster, Principal  
230 Steeplechase Circle, Wilmington, DE, 19808  
Tel. 302-239-6576, Fax 302-239-8466, email: vaforster@comcast.net

**Petition to amend §201.601(b)(1) to Include Soap-based Products on the National List of Substances Approved for Organic Production**

**Item A**

Purpose of Petition:

Synthetic Soap Salts of fatty acids to be ALLOWED for Organic Crop Production

**Item B**

1. Common Name:  
Ammonium soap salts of higher fatty acids [C8-C18 unsaturated and C8-C12 saturated]
2. Manufacturer's Name, Address and Telephone Number<sup>1</sup>:  
Dixie Chemical Company  
300 Jackson Hill  
Houston, TX 77007
3. Intended Use:  
As an herbicide
4. A List of Crop, Livestock and Handling Activities:  
See attached labeling for the C9 ammonium soap salt product known as RACER™ Herbicide, on the following pages.

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<sup>1</sup> Dixie Chemical Company is the manufacturer of the product RACER™ Herbicide, an ammonium salt of a C9 unsaturated fatty acid



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**Racer™  
Concentrate  
Non-selective Herbicide**

A rapid-acting, non-systemic, contact herbicide that suppresses a wide variety of undesirable vegetation such as weeds, vines and brush. A visual effect (wilting, color change) on the sprayed plants is usually observed within 2 hr. or less under normal vegetation growing conditions. **Racer** has no soil activity and is not translocated in plants. To be effective, leaves of undesirable vegetation must be uniformly sprayed and thoroughly wetted.

**Active ingredients:**

Ammonium Salts of Fatty Acids (C<sub>8</sub>-C<sub>10</sub>)\* . . . . . 40.0 wt.%

Inert ingredients . . . . . 60.0 wt.%

Total . . . . . 100.00 wt.%

\*Fatty acid equivalent, 36 wt.%

**Racer™ Concentrate** contains 3.3 lb. active ingredient per gallon.

**Racer™ Concentrate** does not contain any surfactants, stickers, spreaders, wetting agents or any other non-identified additives.

For the suppression and control of weeds, vines and underbrush by home owners, master gardeners, nurseries, farmers (including no-till), landscape and turf professionals, in greenhouses, lath or shade houses, and interior scapers.

EPA Reg. No.79766-A

EPA Establishment No.79766-DIX

This product is protected by U. S. Patent No. 6,323,156

**KEEP OUT OF REACH OF CHILDREN**

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**CAUTION**

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**FIRST AID**

**If Inhaled:** Move away from sprayed area to fresh air. Get medical attention by calling 911 if breathing does not return to normal within minutes or exposed person becomes unconscious. (Spray has a pungent, unpleasant odor so there is an odor warning as to when to move to a safe area).

**Eye Contact:** Immediately flush with water for at least 15 minutes. Get medical attention.

**Skin Contact:** Immediately remove contaminated clothing and shoes. Flush exposed area with water for at least 5 minutes. Use soap and water if available. Do not use contaminated clothing until after washing. Get medical attention if skin irritation occurs.

**If Swallowed:** Have victim drink one to two glasses of water if conscious and seek medical attention by calling 911. Inform medical personnel of type of hazard, i.e. ingested material is fatty acid.

**PRECAUTIONARY STATEMENTS**  
**HEALTH HAZARDS - CAUTION**

Inhalation may cause nose, throat and lung irritation on prolonged exposure to spray and should be minimized. Skin contact should be avoided by the use of long sleeved shirts and chemical resistant gloves and boots. **Fatty acid salts are known eye irritants**, so goggles, safety glasses with side shields or full faceshields must be used during mixing operations and application.

**ENVIRONMENTAL HAZARDS**

This product may be hazardous to aquatic invertebrates. Do not apply to water bodies such as ponds or creeks, 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 rinse water into such water bodies.

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**GENERAL USE INFORMATION**

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.**

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**Racer** is a non-selective, broad-spectrum, foliar applied, water-based herbicide that suppress the growth of actively growing undesirable vegetation by covering the leaves of such vegetation with a liquid spray consisting of **Racer Concentrate** diluted with water. It is effective on both annual and perennial plants including moss, saplings and tree suckers. **Racer** does not migrate through the soil and is not translocated in plants. **To ensure satisfactory control, plant leaves must be thoroughly and uniformly covered with Racer spray solution.** Drift or overspray are not problems since only thoroughly wetted leaves are affected.

For use, **Racer Concentrate** is diluted with water to the desired concentration for effective control of the undesirable vegetation. It can be applied using all standard methods of liquid herbicide application. Dilution should be in accordance with label instructions for best results.

**The degree of dilution for application is based on the concentration of active ingredient needed for the size of vegetation to be suppressed or the rate of herbicidal effect desired. The larger the vegetation, the higher the concentration (lower dilution) required for rapid action. See required concentration for various sized weeds and grasses in Recommended Rates Section. Hard to suppress weeds (deep-rooted perennials and some grasses) may require one or more later application for complete control.**

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**DIRECTIONS FOR USE**

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Any normal spray equipment can be used including hand-held, boom sprayers, pressure sprayers and hose-end sprayers. Spray nozzles that produce a uniform spray coverage of the leaves is recommended. **Racer** is completely soluble in water and requires only nominal mixing. Once mixed, no additional mixing or agitation is required.

**Mixing:** Fill sprayer tank with half the required amount of water, add the full amount of Racer to be used (see Dilution Factors below), then fill the sprayer tank with the rest of the water needed for the desired final concentration.

**NOTE:** In areas of hard water, the final mixture may appear milky. This condition does not change the effectiveness of the treatment. A clearly visible foam will appear on the leaves as the plants are sprayed. Overspray or drift onto desirable plants is usually not a serious problem because of the need for thorough leaf coverage for control. Repeat application as often as necessary to obtain desired control.

**Recommended Application Rates**

For general weed and grass control, rates are based on the size of the plants and/or the speed of kill. The larger the plants, the higher the recommended spray concentration. Also, the higher the concentration, the faster the plants wilt and turn brown. However, selective suppression of such weeds as crabgrass, some plantains and oxalis in established turf without killing desirable grass may be obtained at low concentrations.

<u>Size of Plants to be Controlled</u>	<u>Recommended Spray Concentration (wt.%)</u>
Weeds in established turf	0.5 - 0.75
3 inch or less	2.0 - 3.0
3 -6 inch	3.0 - 4.5
Above 6 inch	4.5 - 6.0

**NOTE:** It is recommended that the use of higher than 6% spray concentrations be avoided in a pressure sprayer since severe foaming and bubble formation may occur at the nozzle heads.

**Dilution Factors**

<u>Desired Spray Conc.</u>	<u>Amount of RACER Concentrate per U.S. Quart/Gallon of FINAL SPRAY</u>
0.50%	3/4 tbs./3 tbs. (1.6 fl.oz.)
2.0%	1.6 fl. oz./6.4 fl. oz.
2.5%	3.75 tbs./8.0 fl.oz.
3.0%	4.5 tbs./9.6 fl.oz.
3.5%	2.8 fl. oz./11.2 fl.oz.
4.0%	3.2 fl.oz./12.8 fl. oz.
4.5%	3.6 fl.oz./14.4 fl. oz
5.0%	4.0 fl. oz./16 fl.oz. (one pint)
5.5%	4.4 fl.oz./17.6 fl. oz.
6.0%	4.8 fl.oz./19.2 fl. oz.

**NOTE: RACER** is recommended to be used alone as a general burndown herbicide but it can be used with a variety of other herbicides where special circumstances call for a combination of herbicides due to the specific weeds present.

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**STORAGE AND DISPOSAL**

Store **Racer Concentrate** tightly capped in the original containers in areas inaccessible to children. Like any other water-based material, avoid storage at temperatures below 32° F. to prevent freezing. If solid forms in the product due to low temperature storage, it will redissolve on warming. Solid fatty acid salts may form around the caps or lids of previously opened containers. This should be treated in the same manner as the product, that is, avoid all contact. It can be washed off with a water hose as long as the wash water can enter a sewage system.

**Sprayer Cleanup and Container Disposal**

Since **Racer** is completely water soluble, spray equipment can be washed and rinsed with water. The rinse water must be disposed of in a sanitary sewage system. Empty containers should be rinsed out with water in the same manner as the spray equipment is cleaned. and recycled or disposed of according to local law.

For emergencies or spills, see Racer MSDS or call CHEMTREC at 800-424-9300.

**Limit of Warranty and Liability**

Falcon Lab LLC warrants to those persons lawfully purchasing this product that at the time of the first sale of this product by Seller that this product conformed to the description and was reasonably fit for the purposes stated on the label when used in accordance with this label. The supplier of **Racer** is not liable for any special, accidental, incidental or consequential damages.

**Falcon Lab LLC  
1103 Norbee Drive  
Wilmington , DE 19803-4123  
302-764-0392  
www.falconlabllc.com**

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5. Source of Substance and Manufacturing Method:

Source of Substance: C9 Nonanoic Acid

Cognis Corporation  
Cincinnati Plant  
4900 Este Avenue  
Cincinnati, OH 45232

Manufacturing Method

For production of the C9 ammonium soap salt of fatty acid, also known as, ammonium nonanoate, by batch process, charge the required amounts of active ingredients: 138 lbs., concentrated ammonium hydroxide; and 362 lbs. of nonanoic acid (C9), technical, and water (500 lbs.) into a suitably sized mixing vessel and stir with a paddle stirrer until completely mixed, while taking appropriate protection and safety procedures.

For quality control of the product, withdraw a small sample that is to be analyzed for the concentration of the active ingredient in the formulation by a GC method for analytical method for the determination of concentration of the active ingredient in RACER™ Herbicide.

Discharge and pack the finished product in the final market-size containers without any interim storage.

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6. Summary of Previous Reviews:

See Appendix A, for an EPA Fact Sheet summary and pages 1-21 of the EPA Reregistration Eligibility Document (RED) for Soap Salts, including those higher ammonium salts of fatty acids. See Appendix B for a copy of FR Notice of a Proposed Rule to Exempt Ammonium Salts from the Requirement of a Tolerance. This rule was never finalized due to an oversight by the EPA. EPA has acknowledged this oversight and pledged to correct it by acting on the petition submitted by Falcon Lab, LLC

7. EPA Registration Summary of RACER™ Herbicide:

- FIFRA Section 3 Registration (Non-food Uses) Application made to BPPD on August 18, 2005
- Registration Application Complete (PR-Notice 86-5) on September 9, 2005
- PRIA Waiver Request Received by EPA on September 6, 2005
- PRIA Waiver Accepted in Full on September 26, 2005
- Federal Register (FR) Publication of Receipt of Application (FIFRA section 3 registration) on November 23, 2005
- PRIA Registration Date set for September 21, 2006
- Secondary (Final) Data Review due out April 27, 2006
- FFDCA Section 408 (d) Tolerance Exemption for Ammonium Soap Salts submitted on March 31, 2006. The Agency is prepared to finalize this tolerance exemption as food uses for ammonium salts of fatty acids have been approved since 1982.

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8. CAS Number(s): 84776-33-0
9. Physical Properties/Mode of Action:  
Ammonium salts of higher fatty acids, including ammonium nonanoate (C9) act by physically disrupting plant cells; there is no systemic mode of action associated with the soap salts. In addition, please refer to Appendix A, pages 4-21. Also, please refer to the Product labeling for RACER™ Herbicide, included here under B.4.
  - a) *Interactions with substances used in organic production*
  - b) *Toxicity and environmental persistence*
  - c) *Environmental impacts from use or manufacture*
  - d) *Effects on human health*
  - e) *Effects on soil organisms, crops, livestock*
10. Safety Information:  
Please refer to the product labeling included herein under B.4.
11. Research Information regarding the Substance:  
Please refer to Appendix A.
12. “Petition Justification Statement”  
Ammonium soap salts of fatty acids have been used on foods since 1982 with Agency approval. Today, food uses are labeled on Weed-Aside, EPA Reg. No. 67702-8-56872, a product which has as a labeled active ingredient ammonium soap salts of fatty acids. In a proposed rule to exempt ammonium salts of fatty acids from the exemption of a tolerance, the Environmental Protection Agency stated that, “The residues of these [ammonium] salts of fatty acids from pesticide use are not likely to exceed levels of naturally occurring fatty acids in commonly eaten foods. Both potassium and ammonium salts of fatty acids are generally recognized as safe by the Food and Drug Administration.” (61FR19233-19236).

Falcon Lab, LLC, believe that including ammonium soap salts of higher fatty acids in the National Organic Program National List of Substances Approved for Organic Production will protect the public health, by offering to organic growers a herbicide option for which they is a demonstrated need. As is documented by the EPA in the RED for Soap Salts, these pesticides are of extremely low toxicity and residue levels are unlikely to exceed those of fatty acids naturally occurring in common foods.

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# Reregistration Eligibility Document (RED)

*Appendix  
A*

## Soap Salts

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# R.E.D. FACTS

## Soap Salts

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### 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 algacides. 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.

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When EPA published reregistration List D in the Federal Register 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 Toxicity Assessment**

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

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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

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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 Federal Register. To obtain a copy of the RED or to submit written comments, please contact the Public



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**Response and Program Resources Branch, Field Operations Division (H-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 (H-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 (H-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.**

United States  
Environmental Protection  
Agency

Office of Prevention, Pesticides  
And Toxic Substances  
(H-7508W)

September 1992

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# **Reregistration Eligibility Document (RED)**

## **Soap Salts**

**REREGISTRATION ELIGIBILITY DOCUMENT**

**Soap Salts**

**LIST D**

**CASE 4083**

**ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDE PROGRAMS  
SPECIAL REVIEW AND REREGISTRATION DIVISION  
WASHINGTON, D.C.**

## **EPA SOAP SALTS REREGISTRATION ELIGIBILITY TEAM**

### **Office of Pesticide Programs:**

#### **Biological and Economic Analysis Branch**

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Margette Cogdell      Biological Analysis Branch  
William Gross Jr.      Biological Analysis Branch

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Betsy Grim      Science Analysis and Coordination Staff  
Carol Belew      Ecological Effects Branch

#### **Health Effects Division**

Judy Smith      Occupational and Residential Exposure Branch  
Pat McLaughlin      Toxicology Branch II  
Chris Swartz      Chemistry Branch II: Registration Support  
Linda Kutney      Chemical Coordination Branch

#### **Program Management and Support Division**

BeWanda Alexander      Information Services Branch

#### **Registration Division**

Barbara Madden      Insecticide Rodenticide Branch  
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Ian Blackwell      Registration Support Branch  
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Sami Malak      Antimicrobial Program Branch

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Veronica Dutch      Accelerated Reregistration Branch

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Beverly Updike

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**APPENDIX A - Soap Salt Use Patterns Subject to Reregistration**

**APPENDIX B - Generic Data Requirements for Reregistration of Soap Salts and Data Citations Supporting Reregistration**

**APPENDIX C - Citations Considered to be Part of the Data Base Supporting the Reregistration of Soap Salts**

**APPENDIX D - PR Notice 91-2**

**APPENDIX E - Pesticide Reregistration Handbook**

**APPENDIX F - Generic DCI Data Call-In**

**Attachment A - Chemical Status Sheet**

**Attachment B - Generic DCI Response Forms (Form A) plus Instructions**

**Attachment C - Generic Requirements Status and Registrant's Response Forms (Form B) Plus Instructions**

**Attachment D - List of all Registrant(s) Sent this DCI**

**Attachment E - EPA Acceptance Criteria and PR-Notice 86-5**

**Attachment F - Cost Share/Data Compensation Forms**

**APPENDIX G -Product Specific DCI Response Forms**

**Attachment A - Chemical Status Sheet**

**Attachment B - Product Specific DCI Response Forms (Form A) plus Instructions**

**Attachment C - Requirements Status and Registrants' Response Forms (Form B) plus Instructions**

**Attachment D - EPA Groupings of End-Use Products for Meeting Data Requirements for Reregistration**

**Attachment E - EPA Acceptance Criteria**

**Attachment F - List of all Registrant(s) sent this DCI**

**Attachment G - Cost Share/Data Compensation Forms Application for Registration**

## GLOSSARY OF TERMS AND ABBREVIATIONS

<b>A.I.</b>	<b>Active Ingredient</b>
<b>CAS</b>	<b>Chemical Abstracts Service</b>
<b>CFR</b>	<b>Code of Federal Regulations</b>
<b>CSF</b>	<b>Confidential Statement of Formula</b>
<b>EPA</b>	<b>U.S. Environmental Protection Agency</b>
<b>EP</b>	<b>End-Use Product</b>
<b>FDA</b>	<b>Food and Drug Administration</b>
<b>FIFRA</b>	<b>Federal Insecticide, Fungicide, and Rodenticide Act</b>
<b>GRAS</b>	<b>Generally Recognized As Safe</b>
<b>LC<sub>50</sub></b>	<b>Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the mass of substance per body mass of animal or volume of water or feed, e.g., mg/l or ppm.</b>
<b>LD<sub>50</sub></b>	<b>Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a mass of substance per unit mass of animal, e.g. mg/kg.</b>
<b>MRID</b>	<b>Master Record Identification (number). EPA's system of recording and tracking studies submitted to the EPA.</b>
<b>ppm</b>	<b>Parts per Million</b>
<b>RED</b>	<b>Reregistration Eligibility Document</b>
<b>TGAI</b>	<b>Technical Grade of the Active Ingredient</b>



## **EXECUTIVE SUMMARY**

This Reregistration Eligibility Document (RED) addresses the pesticide active ingredients potassium and ammonium salts of fatty acids and their uses in the chemical case soap salts. Soap salts-containing products are currently registered as acaricides, algacides, herbicides, insecticides and animal repellents. They are intended for either residential or commercial use. All applicable products containing potassium or ammonium salts of fatty acids as active ingredients and that registered for these uses are eligible for reregistration.

The U.S. Environmental Protection Agency (EPA) has conducted a review of the scientific data base and other relevant information supporting the reregistration of soap salts and has determined that the data base is sufficient to allow EPA to make a reregistration eligibility decision. All data requirements have been submitted or waived for these active ingredients.

Accordingly, EPA has determined that all products containing potassium or ammonium salts of fatty acids as the active ingredient are eligible for reregistration and will be reregistered when acceptable labeling and product specific data are submitted and/or cited. Before reregistering each product, the EPA is requiring that product specific data and revised labeling be submitted by the registrants within eight months of the issuance of this document. After reviewing these data and the revised labels, EPA will determine whether or not the conditions of FIFRA 3(c)(5) have been met, that is, whether product composition and labeling are acceptable and the product's uses will not cause unreasonable adverse effects to humans or the environment. If these conditions are met, EPA will reregister the product. Any end-use product containing soap salts in combination with other active ingredients will not be reregistered until the Agency issues reregistration eligibility decisions for all active ingredients contained in that product.

## **I. INTRODUCTION**

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the eligibility for reregistration of soap salts. The document consists of six sections. Section I is the introduction. Section II describes soap salts, their uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV discusses the eligibility for reregistration decision for soap salts. Section V discusses the reregistration requirements for soap salts. Section VI is the Appendices which support this Reregistration Eligibility Document. Additional details concerning the Agency's review of applicable data are available on request.<sup>1</sup>

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<sup>1</sup> EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

## **II. CASE OVERVIEW**

### **A. Chemical Overview**

The active ingredients potassium and ammonium salts of fatty acids are covered by this Reregistration Eligibility Document.

**1. Chemical Name: Potassium salts of fatty acids [C<sub>12</sub>-C<sub>18</sub> saturated and C<sub>18</sub> unsaturated], including potassium laureate, potassium myristate, potassium oleate and potassium ricinoleate.**

**CAS Registry Number: 10124-65-9**

**Office of Pesticide Programs Chemical Code: 0079201**

**Empirical Formula: [C<sub>12</sub>-C<sub>18</sub> H<sub>x</sub>-H<sub>y</sub> O<sub>x</sub>-O<sub>y</sub>]K**

**2. Chemical Name: Ammonium salts of higher fatty acids [C<sub>8</sub>-C<sub>18</sub> saturated and C<sub>18</sub> unsaturated], including ammonium oleate.**

**CAS Registry Number: 84776-33-0**

**Office of Pesticide Programs Chemical Code: 031801**

**Empirical Formula: [C<sub>8</sub>-C<sub>18</sub> H<sub>x</sub>-H<sub>y</sub> O<sub>x</sub>-O<sub>y</sub>]NH<sub>4</sub>**

### **B. Use Profile For Potassium Salts of Fatty Acids**

**Mechanism of Action: Insects-- Disrupts the integrity of the exoskeleton by dissolving portions, causing body fluids to exude from the body and ultimately, death. Plants--Disrupts the photosynthetic process, thereby killing the plant.**

#### **Use Sites:**

**Terrestrial Food+Feed Crops: Beans, peas, tomatoes, white potatoes, seed and pod vegetables and other unspecified vegetables; nut crop/nut trees, citrus, pome fruits, subtropical fruits, grapes, trees and other unspecified fruit; and cotton.**

**Terrestrial Food Crops: Broccoli, brussels sprouts, cabbage, cauliflower, cucumber, eggplant, lettuce, melons, okra, pepper, pumpkins, radish, squash (summer), squash**

(winter), squash (zucchini), asparagus, and stone fruits.

**Greenhouse Food Crops:** fruit trees and other unspecified fruits.

**Terrestrial Greenhouse Food Crops:** asparagus, cucurbits, flavoring and spice crops, fruiting vegetables, leafy vegetables, root crop vegetables and other unspecified vegetables.

**Indoor Residential:** Adult dogs, puppies and cats.

**Outdoor Residential:** Walks, driveways, ornamental flower beds, trees and shrubs.

**Pests:**

Spider mites, whiteflies, aphids, squash bugs, flea beetles, green stink bugs, cabbageworms, leafhoppers, lace bugs, mealybugs, earwigs, grasshoppers, plant bugs, psyllids, sawfly larvae, scales, tent caterpillars, thrips, fleas, sarcoptic mange mites, wasp, hornets and ants. The potassium salts are also labeled to control mosses, algae, lichens, liverworts, and unspecified weeds.

**Formulation Types Registered:** Liquid and Solid

**Single Active Ingredient Products:**

Liquid concentrates: 18 to 50.5% potassium salts of fatty acids.

Solid Soap Cake: 25.0% potassium salts of fatty acids.

Ready to Use Sprays: 1.0 to 3.0% potassium salts of fatty acids.

**Multiple Active Ingredient Products:**

Solid soap cake: 89.0% potassium salts of fatty acids, 0.120% petroleum distillate, 0.084 N-Octyl bicycloheptene dicarboximide, 0.05% piperonal butoxide technical and 0.025% pyrethrins.

Liquid concentrates: 20.0% potassium salts of fatty acids, and 0.20% pyrethrins.

Ointment: 7.5% soap (anhydrous) and 30% benzyl benzoate.

Ready to Use Spray: 1.0% potassium salts of fatty acids and 0.01% pyrethrins.

**Methods and Rates of Application:**

Products containing potassium salts of fatty acids are applied as sprays, in a solid form ("soap cake"), and as an ointment. For specifics in application methods and rates on

application methods and rates, please refer to Appendix A.

**Limitations:** None

**C. Use Profile for Ammonium Salts of Fatty Acids**

**Mechanism of Action:** Negatively affects the olfactory nerves of deer and rabbits.

**Use Sites:**

**Terrestrial Food+Feed Crops:** Grapes, cereal grains, unspecified vegetables, unspecified orchards, unspecified field crops, grass forage/fodder/hay and non-grass forage/fodder/hay.

**Terrestrial Non-Food Crops:** Ornamental herbaceous plants, ornamental lawns and turf, ornamental woody shrubs and vines and ornamental shade trees.

**Pests:**

Deer and rabbits

**Formulation Type Registered:** Liquid

**Single Active Ingredient Products:**

Liquid concentrates: 15.0% ammonium soaps of higher fatty acids.

**Methods and Rates of Application:**

Because of the variation in rates and methods of application of this chemical, please refer to Appendix A for methods and rates of application.

**Limitations:** Do not apply product through any type of irrigation system. Product is not compatible with soluble metallic salts such as zinc, manganese, and iron sulfates.

**D. Regulatory History**

The first soap salts product with pesticidal uses was registered in 1947. Currently there are twenty four "soap" products registered. The May 5, 1990 Federal Register publication of List D chemicals subject to reregistration, Soap Salts, case 4083, included

soap, oleic acid, sodium oleate, ammonium oleate, potassium laureate, potassium myristate, potassium oleate and potassium ricinoleate. However previously in March of 1989 the Agency determined, "all potassium salts of fatty acids, and all combinations of these chemicals, to be a 'single active ingredient' for purposes of pesticide registration." An Agency review of May 4, 1992 determined that this position would only include potassium salts of C<sub>12</sub>-C<sub>18</sub>, saturated and unsaturated. "Any other chain length (either shorter or longer) should be considered a different active ingredient for registration purposes." Presently, of those chemicals included in Case 4083, only two active ingredients described above are currently associated with active product registrations. Products containing the remaining chemicals contained in this case (soap, as discussed below, oleic acid, and sodium oleate), are cancelled and these active ingredients have been removed from the list of chemicals subject to reregistration.

EPA published in the Federal Register of January 13, 1982 " an exemption from the requirement of a tolerance for residues of the insecticide potassium oleate and related C<sub>12</sub>-C<sub>18</sub> fatty acid potassium salts in or on all raw agricultural commodities when applied in accordance with good agricultural practices."

The Thompson-Hayward Chemical Company submitted an amendment to add food uses to the label of their registered product (EPA Reg. No. 1148-13) in July of 1979. This product, which was transferred December 29, 1982 to the Uniroyal Chemical Company (EPA Reg. No. 400-383) contains ammonium salts of fatty acids as the active ingredient. The Thompson-Hayward Company made a formal request for an exemption from the requirement of a tolerance for ammonium salts of fatty acids in a letter to the Agency dated September 10, 1980. The request was reviewed by the Agency which had no objections to the addition of food uses but required results of an inhalation test which was submitted and found acceptable. The addition of food uses was accepted in 1982.

Though the company made a formal request for an exemption of ammonium salts of fatty acids from the requirement of a tolerance and the Agency reviewed the data, a formal notice was not drafted and published in the Federal Register. To correct that oversight the Agency will draft a proposed exemption from tolerance and publish it in the Federal Register.

In the Federal Register Notice of May 4, 1988 and as set forth in 40 CFR §153.139, the Agency determined that "soap", "has no independent pesticidal activity when included in antimicrobial products for the designated uses, and thus is properly classified as an inert ingredient." Because EPA has determined that "soap" compounds is not an active ingredient but rather an inert in antimicrobial products, such products are not subject to the Soap Salts Reregistration Eligibility Document.

In accordance with the Pine Oil Label Improvement Program (Federal Register dated June 5, 1980 and PR Notice 80-1) the majority of labels for these antimicrobial products were revised to include "soap" as an inert ingredient. The Agency has issued a letter on May 5, 1992 notifying registrants of antimicrobial products that still have "soap" listed under

the active ingredient statement that the label and Confidential Statement of Formula must be amended to delete "soap" from the active ingredient statement.

Although most registrants of antimicrobial products listing "soap" as an active ingredient have voluntarily amended their registrations to redesignate soap as inert, there remain a small number of registered antimicrobial products for which an amendment to effect this change has not been submitted to the EPA. While these products are not subject to the data requirements of the Soap Salts Reregistration Eligibility Document, the registrants of the products are being notified that the Agency considers antimicrobial products with "soap" listed on the label as an active ingredient to be misbranded under section 2(q)(1)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Accordingly, unless these product labels are amended to delete soap as an active ingredient, the Agency may bring misbranding action under section 12(a)(1)(E) of FIFRA or may cancel such products under 6(b) of FIFRA.

The Food and Drug Administration lists salts of fatty acids, except ammonium, as additives that may be safely used in foods. This denotation appears in 21 CFR §172.863.

### **III. SCIENCE ASSESSMENT OF SOAP SALTS**

The Agency has reviewed the scientific data base for soap salts, primarily relying on information from published literature submitted by the registrant. These sources of information are cited in Appendix C.

#### **A. Product Chemistry Assessment**

In the May 5, 1990 Federal Register publication of List D chemicals, Soap Salts, case 4083, included soap, oleic acid, ammonium oleate, sodium oleate, potassium laureate, potassium myristate, potassium oleate and potassium ricinoleate. By definition "ordinary soap is a mixture of the sodium salts of various fatty acids of natural oils and fats. It is made by heating oils with caustic soda, salting out the soluble soap formed, and drawing off the dilute glycerol produced. Thus, common soap is largely a mixture of the sodium salts of palmitic, stearic and oleic acids. The term soap is also applied to individual components such as sodium palmitate, sodium stearate, etc. If another metal or basic radical is present instead of sodium, a modified term such as potash soap, calcium soap or amine soap is used (1). This latter category also includes ammonium soaps (ammonium salts of fatty acids).

Case 4083, soap salts, are comprised of only two active ingredients which are currently associated with active product registrations. These two chemicals are: (1) ammonium salts of [C8-C18 saturated and C18 unsaturated] fatty acids, including

ammonium oleate; and, (2) potassium salts of [C12-C18 saturated and C<sub>18</sub> unsaturated] fatty acids, including potassium laureate, potassium myristate, potassium oleate, and potassium ricinoleate.

The technical grade of the active ingredient (TGAI) per se is not isolated during the manufacturing process. Given that these active ingredients are exempt from the requirement of a tolerance (40 CFR §180.1068), the Agency has not required generic data requirements to be satisfied using the TGAI as the test substance.

**B. Human Health Assessment**

**1. Toxicology Data Base**

The toxicological data base on soap salts is adequate and will support reregistration eligibility of the active ingredients.

**a. Acute Toxicity**

TEST	ACUTE TOXICITY DATA
Oral LD50	IV
Dermal LD50	IV
Eye effects	Irritation
Skin effects	Mild - moderate irritation; Non-sensitizing

Oral exposure to soaps is generally self-limiting because the taste of soap is easily recognized and unpleasant. The ammonium soap salts also have a notable ammonia odor that is limiting. Fatty acids such as oleic acid and related C<sub>12</sub>--C<sub>18</sub> fatty acids are generally considered to be of low toxicity by the oral route of exposure, and potassium salts of these fatty acids are not expected to be very toxic. The oral LD50 for oleic acid in rats was 74 g/kg (14).

On human skin, 2.5 mg of soap for 24 hours caused moderate irritation; and 10 mg of soap on rabbit skin caused mild irritation (14). On human skin, 11,800 mg of the potassium salt of palmitic acid was irritating (15). For the potassium salt of caprylic acid, 7320 mg was irritating on human skin (15). Stearic acid was mildly irritating to human skin when 75 mg was applied intermittently for 3 days (15). On rabbit skin, 500 mg of stearic



acid applied for 24 hours was moderately irritating (15) . Oleic acid was moderately irritating to human skin when 15 mg was applied intermittently for 3 days; and mildly irritating to rabbit skin when 500 mg was applied (14).

The potassium salt of oleic acid was irritating when 12 mg were placed in rabbit eyes (48 hours) (14,15).

b. Metabolism

Fatty acids are normally metabolized by the cells, where they are oxidized to simple compounds for use as energy sources and as structural components utilized in all living cells. Potassium, sodium and ammonium are normally part of the body's metabolism and electrolyte balance.

c. Reproduction and Developmental Toxicity

When given to mice on days 2-13 of pregnancy, the potassium salts of coco fatty acids were reported to have an effect on post-implantation mortality at 6 gm/kg, and to cause musculo-skeletal system abnormalities at 600 mg/kg (15).

d. Mutagenicity

DNA inhibition was reported with 600 umol/l of the sodium salt of caprylic acid, tested with guinea pig kidney cells (15). Unscheduled DNA synthesis was found in mouse cells with 35 mg/kg of oleic acid (14). Cytogenetic analysis was positive for 2500 ug/L of oleic acid with hamster fibroblasts and for 100 mg/L with Saccharomyces cerevisiae (14).

2. Dietary Exposure

There is a tolerance exemption for potassium oleate and related C<sub>12</sub>-C<sub>18</sub> fatty acid potassium salts [40 CFR §180.1068]. Salts of fatty acids (not including ammonium salts) are food additives [21 CFR §172.863]. Residue chemistry data requirements are not applicable due to the tolerance exemption. While there are registered food uses for ammonium salts of fatty acids, there is neither a tolerance nor a tolerance exemption for these salts under 40 CFR Section 180. The Agency will correct this discrepancy by proposing a tolerance exemption.

3. Occupational and Residential Exposure

Products containing potassium salts of selected fatty acids are used on various crops, shrubs and trees, as well as household plants. Other uses include moss control in lawns as well as control of algae, lichens, and liverworts on roofs, walks, and fences, and in

greenhouses. Ammonium salts of fatty acids are used as a rabbit and deer repellent on forage and grain crops, vegetables and field crops (unspecified), non-crop areas, nursery stock and ornamentals, flowers, roses, shrubs, fruit trees and vines.

The end-use product labels for the potassium salts of fatty acids bear the signal word "CAUTION" and do not recommend any measures to reduce exposure. The labels for the two end-use product labels for the ammonium soaps of higher fatty acids bear the signal word "DANGER" due to potential eye irritation and require that users wear protective eyewear, i.e., glasses, goggles, or faceshield, to protect against ocular exposure. The products may also cause allergic skin reactions in some individuals, however, no measures are recommended to reduce skin exposure because the Agency believes allergic reactions are uncommon and transient.

The toxicological data base on these soap salts is adequate and will support reregistration. Because the toxicity of these chemicals is generally low, the Agency is not requiring any exposure data. Exposure to users during application can be significant, but soaps generally have low toxicity to humans and, there is no reason to expect that pesticide use in accordance with use directions would constitute any significant hazard. Protective eyewear is required for ammonium soap salt products to mitigate potential ocular exposure and irritation for the ammonium salts of fatty acids.

#### 4. Risk Assessment

Soaps are mineral salts of naturally occurring fatty acids. The fatty acids are a significant part of the normal daily diet, for they occur in dietary lipids which usually constitute about 90 grams in a day's diet. Residues from the pesticide uses are not likely to exceed levels of naturally occurring fatty acids in commonly eaten foods. The Food and Drug Administration lists salts of fatty acids, including the potassium salts, as additives that may be used as binders, emulsifiers, and anticaking agents in food (21 CFR 172.863). Also, FDA lists oleic acid derived from tall oil fatty acids (21 CFR 172.862), and lists fatty acids, including capric, caprylic, lauric, myristic, oleic, palmitic, and stearic acids, (21 CFR 172.860) as additives that may be safely used in foods. Stearic acid is generally recognized as safe for use as an ingredient in food (21 CFR 184.1090). A number of fatty acid salts are prior sanctioned for uses in food packaging materials (21 CFR 181).

Because of the low acute toxicity (toxicity category IV) of soap salts via oral and dermal routes, and because residues from the pesticide uses are not likely to exceed levels of naturally occurring or intentionally added fatty acids in commonly eaten foods, the Agency believes the risks to applicators and consumers of treated foods are negligible. There is a risk of permanent eye injury to applicators but this risk can be mitigated by the use of eye wear protection, i.e., safety glasses, goggles or a faceshield. Protective eyewear is required for ammonium soap salt products to mitigate potential ocular exposure and irritation.

### **C. Environmental Assessment**

The Agency has reviewed the data base for environmental effects for potassium and ammonium salts of fatty acids and has determined that the data base is adequate and will support reregistration.

#### **1. Environmental Fate Assessment**

Hydrolysis of potassium salts of fatty acids was shown not to occur over a period of 43 days (MRID 00164005). This is consistent with the literature on fatty acids, which indicates that the primary environmental degradation route of fatty acids is by microfloral action (the cleavage of the carbon chain of fatty acids by oxidative chemistry) as opposed to hydrolysis. Due to the similarity of chemical structure, it is expected that hydrolysis of the ammonium salts of fatty acid would be similar to that of the potassium salts of fatty acids.

Studies submitted to the Agency indicate that the half-life of these fatty acids is approximately less than one day (MRID 00157476). As can be expected, there is very rapid microbial degradation of fatty acids in soil. Fatty acids and their salts are excellent substrate for microbial growth, serving both as carbon sources, and as energy sources. The active ingredient cannot totally dissipate from soil, because there is a natural content of fatty acids in soil resulting from plant metabolism and by formation by microbial organisms. Fatty acids constitute a significant portion of the normal daily diet of mammals (including humans), birds, and invertebrates since they are found in large amounts in the form of lipids in all living tissues (including seeds). Potassium salts of fatty acids are naturally occurring. Microbial metabolism of fatty acids has the effect of either converting the degradates to CO<sub>2</sub> and ester (if used as an energy source) or converting the carbon content of the fatty acid to any of the thousands of naturally occurring organic substances produced by the soil microflora (if used as a carbon source).

#### **2. Ecological Hazard Assessment for Ammonium Salts of Fatty Acids**

Topical summaries addressing each data requirement:

##### **(i.) Effects on Birds**

Three studies were submitted by Uniroyal Chemical Company Inc. to determine the effect of ammonium salts of fatty acid on birds. The three studies were determined to be supplemental because test material used in the study was reported to be only 14.65 percent pure.

<u>Author</u>	<u>Date</u>	<u>MRID No.</u>
Pederson	1991	41767112
Pederson	1991	41767113
Pederson	1991	41767114

To establish the toxicity of ammonium of fatty acids to birds, the following tests are required using the technical grade material (TGAI).

- A. One avian single-dose oral study on either a waterfowl species (mallard duck) or an upland species (bobwhite quail).
- B. Two subacute dietary studies: one study on a species of upland game bird(bobwhite quail) and one study on a waterfowl species (mallard duck).

Studies submitted included:

Study and Species	% A.I.	LD/LC50	Date	MRID	Fulfills Requirement
71-1 Avian Oral- Bobwhite Quail	14.65	2,150 ppm	1/91	41767112	Y
71-2 Bobwhite Quail-	14.65	5,000 ppm	1/91	41767113	Y
Mallard Duck	14.65	5,000 ppm	1/91	41767114	Y

Although these avian studies are classified as supplemental (the active ingredient was determined to be only 14.65 % pure) data could be used to satisfy the data requirement. The oral LD50 was determined to be 2,150 ppm for mature bobwhite quail given a single oral dose of ammonium salts of fatty acids (Pederson, 1991, MRID 41767112). The results of 8-day dietary studies (Pederson, 1991, MRID's 41767113 and 41767114) indicate that the LC50 for ammonium soap salts is greater than 5,000 ppm for both mallard ducks and bobwhite quail. The available data indicate that ammonium salts of fatty acids is practically non-toxic to upland game birds and waterfowl.

### Precautionary Labeling

The available toxicity data do not indicate a requirement of precautionary labeling for birds on products containing Ammonium salts of fatty acids.

**(ii.) Effects on Freshwater Invertebrates**

No studies were received on ammonium salts of fatty acids for freshwater invertebrates. Minimum data requirement to establish the acute toxicity of ammonium salts of fatty acids to freshwater invertebrates includes:

- A. A 48-hour acute study using the technical grade material. Test organisms should be first installed Daphnia magna.

Data for aquatic invertebrates used in the hazard assessment were derived from tests conducted on Potassium Salts of Fatty Acids. Science staff determined that the chemical properties for all soap salts were very similar. Although this does not necessarily mean the biological effects are similar, the Ecological Effects Branch has tentatively concluded that the worst case scenario for Ammonium Salts of Fatty Acids is not likely to be significantly different than Potassium Salts of Fatty Acids. The core study for Potassium soap salts indicates that potassium soap salts are highly toxic ( $LC_{50} = 0.57$  ppm) to freshwater invertebrates (MRID 400662-00).

**Precautionary Labeling**

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.

**(iii.) Effects on Freshwater Fish**

The minimum data required for establishing the acute toxicity of ammonium salts of fatty acids to freshwater fish are two 96-hour freshwater fish studies with the technical grade active ingredient. The following studies are required:

- A. One 96-hour study with a coldwater fish species (preferable rainbow trout)
- B. One 96-hour study performed with a warmwater fish species (preferably bluegill sunfish).

No studies using ammonium salts of fatty acids were submitted under this topic; however, a tentative position can be taken that because of the similarities of soap salts, the potassium salts of fatty acid data can probably be substituted for ammonium salts of fatty acids.

Two tests were performed on freshwater fish using the potassium salt technical grade material. The LC50's were determined to be 18.06 ppm and 35.35 ppm for trout and bluegill respectively. One study with the typical end-use product performed on fathead minnows produced a LC50 of 21 ppm. These data indicate that potassium soap salts, and by presumption, ammonium soap salts are slightly toxic to both coldwater and warmwater fish species.

#### Precautionary Labeling

The available acute toxicity data indicate that precautionary labeling for fish toxicity is not required.

#### (iv.) Effects on Non-Target Insects

No studies were received on the effects of ammonium salts of fatty acids on non-target insects.

#### Precautionary Labeling

Precautionary labeling will be required if data to be submitted indicates a significant risk.

### **3. Ecological Hazards Assessment for Potassium Salts of Fatty Acids**

Topical summaries addressing each data requirement:

#### (i.) Effects on Birds

Seventeen studies were submitted from 2 different companies to determine the effect of potassium salts of fatty acid (soap salts) on birds. Seven of the 17 studies submitted were acceptable for use in the risk assessment. Ten of the studies can be used to supplement the core data used in the risk assessment.

Author	Date	MRID No.
Grimes	1987	94240004 (TGAI)
Grimes	1987	94240004 (TEP)
Grimes	1987	94240005 (TGAI)
Grimes	1987	94240005 (TEP)
Grimes	1987	94240005
Wildlife Int. Ltd.	1981	00096639A
Wildlife Int. Ltd.	1981	00096639B
Wildlife Int. Ltd.	1981	00157472
Wildlife Int. Ltd.	1981	00010504 (2 studies)

To establish the toxicity of potassium salts of fatty acids to birds, the following tests are required using the technical grade material (TGAI).

A. One avian single-dose oral study on either a waterfowl species (preferably mallard duck) or an upland species (preferably bobwhite quail).

B. Two subacute dietary studies: one study on a species of upland game bird (preferably bobwhite quail and one study on a species of waterfowl (preferably mallard duck).

The acceptable acute oral toxicity studies are listed below:

Data Requirements	Test Substance	Bibliographic Citation	Validation	Company	Results
<b><u>AVIAN TESTING</u></b>					
71-1 Avian Oral Bobwhite	TEP	94240004	Supplemental	Reuter	LD50 = > 2,250 mg/kg
	TGAI	94240004	Core	Reuter	LD50 = > 2,000 mg/kg
Mallard Duck	TGAI	00096639B	Supplemental	Safer	LD50 = > 2,510 mg/kg
	TGAI	00096639A	Supplemental	Safer	LD50 = > 2,510 mg/kg

The acceptable subacute dietary toxicity studies are listed below:

Data Requirements	Test Substance	Bibliographic Citation	Validation	Company	Results
71-2 Avian Dietary Bobwhite	TGAI	00096640	Core	Safer	LC50 = > 5,620 ppm
	TGAI	00010504	Core	Safer	LC50 = > 5,620 ppm
	TGAI	00010504	Supplemental	Safer	LC50 = > 10,000 ppm
	TEP	942400-05	Supplemental	Reuter	LC50 = > 5,620 ppm
	TGAI	942400-05	Core	Reuter	LC50 = > 5,620 ppm
Mallard Duck	TGAI	942400-05	Core	Reuter	LC50 = > 5,620 ppm
	TEP	942400-05	Supplemental	Reuter	LC50 = > 5,620 ppm

An LD50 greater than 2,000 mg/kg was determined for bobwhite quail given a single oral dose of soap salts (Reuter Company, 1987 MRID 94240004). Also a LD50 greater 2,510 mg/kg was determined for mallard ducks (Safer, 81992, MRID 00096639). Therefore, soap salts can be considered relatively non-toxic to bobwhite quail and mallard duck on an acute oral basis.

Results from the 8-day Subacute Dietary LC50 for mallard ducks and bobwhite quail were determined to be greater than 5,620 ppm (Safer Company, 1992, MRID 00096640 and Reuter Company, 1987, MRID 94240005). These data indicate that soap salts are practically non-toxic to bobwhite quail and mallard ducks on a dietary basis.

### Precautionary Labeling

The available toxicity data indicates that precautionary labeling for birds on products containing potassium salts of fatty acids is not required.

### (ii) Effects on Freshwater Invertebrates

Three studies were received and evaluated under this topic. All studies were found acceptable for use in a hazard assessment. However, two of the studies were considered supplemental in nature because the typical end use product was used in the studies (50% A.I.). The studies are listed below:



<u>Author</u>	<u>Date</u>	<u>MRID No.</u>
Condrashoff	1979	00030865
Condrashoff	1979	00096638
Harrison	1986	40066200

To establish the acute toxicity of potassium salts of fatty acids to aquatic invertebrates, the following test is required using technical grade material (TGAI).

A. A 48-hour acute study using the technical grade material. Test organisms should be first instal Daphnia magna.

The studies acceptable for use in the hazard assessment are listed below:

<u>Date Requirements</u>	<u>Test Substance</u>	<u>Bibliographic Citation</u>	<u>Validation</u>	<u>Company</u>	<u>Results</u>
<u>AQUATIC TESTING</u>					
72-2					
Daphnia	TGAI	00030865	Supplemental	Safer	LC50 = 102 ppm
Daphnia	TGAI	00096638	Supplemental	Safer	LC50 = 102 ppm
Daphnia	TGAI	400662-00	Core	Reuter	LC50 = .57 ppm

A 48-hour LC50 of 0.57 ppm was found for Daphnia magna exposed to technical potassium salts of fatty acids (Reuter Company, 1987 MRID 40066200). The results of this study indicate that potassium salts of fatty acids are highly toxic to aquatic invertebrates. The results of this study triggers a Daphnia life-cycle study. However, this study will not be needed to assess the effect of potassium salts of fatty acids on aquatic invertebrates, since due to the expected fate of the material, significant concentrations of the pesticide are not expected to occur in aquatic environments.

#### Precautionary Labeling

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.

**(iii.) Effects of Freshwater Fish**

Five studies were evaluated under this topic. All five studies were considered acceptable for use in a hazard assessment.

<u>Author</u>	<u>Date</u>	<u>MRID No.</u>
Analytical BioChem.Lab.	1985	00157473
Applied Bio. Science Lab.	1981	00096637
Applied Bio. Science Lab.	1981	00096636
Obenchain	1986	40066200 (2 studies)

The minimum data required for establishing the acute toxicity of soap salts to freshwater fish are two 96-hour studies with the technical grade product both coldwater and warmwater species of fish. The preferred coldwater species is rainbow trout and the preferred warmwater species is bluegill sunfish).

The acceptable acute toxicity data are listed below:

<u>Data Requirements</u>	<u>Test Substance</u>	<u>Bibliographic Citation</u>	<u>Validation</u>	<u>Company</u>	<u>Results</u>
<b><u>AQUATIC TESTING</u></b>					
<b>72-1 Freshwater Fish</b>					
Trout	TGAI	00096636	Supplemental	Safer	LC50= 18.06 ppm
Fathead Minnow	TEP	00096637	Supplemental	Safer	LC50= 21 ppm
Bluegill Sunfish	TGAI	157473	Core	Safer	LC50= 35.35 ppm
Bluegill Sunfish	TGAI	400662	Supplemental	Reuter	LC50= 23 ppm
Trout	TGAI	4006200	Supplemental	Reuter	LC50= 9.19 ppm

Two tests were performed on freshwater fish using the technical grade material. The LC50's were determined to be 18.06 pm and 35.35 ppm for trout and bluegill respectively. One study with the typical end-use product performed on fathead minnows produced a LC50 of 21 ppm. These data indicate that soap salts are slightly toxic to both coldwater and warmwater fish species.

### Precautionary Labeling

The available acute toxicity data indicate that precautionary labeling for fish toxicity is not required.

#### **(iv.) Effects on Non-Target Insects**

No studies were received on the effects of soap salts on non-target insects. To establish the toxicity of soap salts to honey bees, a Honey Bee Acute Contact LD50 test. This test is required because the use patterns and target crops of soap salt correspond with the locations and use patterns that may effect pollinators.

#### **4. Environmental Risk Assessment of Potassium and Ammonium Salts of Fatty Acids**

As presented above and in Appendix A, pesticide products containing potassium or ammonium salts of fatty acids are registered for use on a wide array of field, fruit and vegetable crops and ornamental turf and plants, as well as a few other uses. The active ingredients applied to these sites are expected to be degrade rapidly, perhaps a half-life of less then one day. Microbial degradation is the primary path of this rapid degradation. Therefore, the Agency believes that these chemicals, when used as directed, will not persist in the environment.

Data reviewed suggest that neither potassium or ammonium salts of fatty acid are very toxic to upland avian species or waterfowl by either acute or dietary exposure. Therefore, the Agency believes the potential risks to avian species is minimal.

For aquatic species, the Agency believes the available data on potassium salts of fatty acid suggest this active ingredient, and probably ammonium salts of fatty acids, are only slightly toxic to both warmwater and coldwater fish species. However, for aquatic invertebrates, these chemicals are considered highly toxic. The Agency believes, though, that the current uses should not result in serious impact to aquatic invertebrates because these pesticides are not applied directly to water and undergo very rapid microbial degradation in soil.

No studies were received on the effects of soap salts on non-target insects. To establish the toxicity of soap salts to honey bees, the Agency is requiring a Honey Bee Acute Contact LD50 test. This test is required because the use pattern and target crops of soap salts correspond with the locations and use patterns that may effect pollinators. Based upon the

available data, ammonium and potassium salts of fatty acids should pose minimal threats to endangered species. This conclusion is tentative pending submission of maximum application use rates for certain uses.

#### **IV. RISK MANAGEMENT AND REREGISTRATION DECISION FOR SOAP SALTS**

##### **A. Determination of Eligibility**

Section 4(g)(2)(A) of FIFRA requires the Agency to determine, after consideration of relevant data of an active ingredient whether products containing the active ingredient are eligible for reregistration. The Agency has considered available data and other factors including soap salts's natural occurrence, its common use as food items, and the lack of reported adverse effects information. The Agency has completed its consideration of these data and other factors and has determined this information is sufficient to support reregistration of products containing soap salts as an active ingredient. The reregistration of particular products is addressed in Section V of this document.

Although the Agency has concluded that products containing soap salts are eligible for reregistration, the Agency may take regulatory actions in the future that would affect the continued registration of soap salts-containing products if significant new information about these active ingredients and/or their products comes to the Agency's attention. Such regulatory action could include requiring the submission of additional data if the data requirements for registration (or the guidelines for generating such data) change.

##### **B. Additional Generic Data Requirements**

The generic data base supporting the reregistration of products containing soap salts has been reviewed and determined to be substantially complete for reregistration. However, the Agency is requiring acute ecotoxicity studies on fish and aquatic invertebrates for ammonium salts of fatty acids and an acute toxicity study on honey bees for the potassium salt to confirm its opinion that the potential ecological hazards from these pesticides are not greater than suggested by the currently available data. See Appendix F for details.

##### **C. Labeling Requirements For Manufacturing-Use Products Of Soap Salts**

No manufacturing-use products are registered.

## **V. ACTIONS REQUIRED BY REGISTRANTS OF END-USE PRODUCTS**

### **A. Determination Of Eligibility**

Based on the reviews of the generic data for the active ingredients, the products containing potassium or ammonium salts of fatty acids are eligible for reregistration. As mentioned above, the Agency is requiring certain ecotoxicology studies to confirm its risk assessment. These must be conducted and submitted in conformance with specifications in Appendix F. Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Agency will review these data when they have been submitted and/or cited and determine whether to reregister individual products.

#### **1. Product Specific Data Requirements**

The Agency is requiring certain product chemistry and acute toxicology studies for end-use products. The specific data requirements are stated in Attachment C.

#### **2. Labeling Requirements For End-Use Products**

a. The labels and labeling of all products must comply with the Agency's current regulations and requirements. Follow the instructions in the Product Reregistration Handbook with respect to labels and labeling.

b. The following statement must appear under the title Environmental Hazards on the product labels marketed for outdoor use.

"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."

c. The active ingredient statement must identify the type of soap salts and not just list "soap." Therefore, the active ingredient statement must read "ammonium salts of fatty acid" or "potassium salts of fatty acids."

**d. For products containing ammoniated soaps, safety glasses, or a face shield must be required under the Precautionary Statements.**

**e. Under the Directions for use, the statement "including but not limited to" for food/feed uses must be removed and all crops or crop groupings must be listed.**

carbonate, which participates in atmospheric photochemical reactions.

(1) This includes any such organic compound other than the following, which have been determined to have negligible photochemical reactivity: methane; ethane; methylene chloride (dichloromethane); 1,1,1-trichloroethane (methyl chloroform); 1,1,2-trichloro-1,2,2-trifluoroethane (CFC-113); trichlorofluoromethane (CFC-11); dichlorodifluoromethane (CFC-12); chlorodifluoromethane (HCFC-22); trifluoromethane (HFC-23); 1,2-dichloro-1,1,2,2-tetrafluoroethane (CFC-114); chloropentafluoroethane (CFC-115); 1,1,1-trifluoro-2,2-dichloroethane (HCFC-123); 1,1,1,2-tetrafluoroethane (HFC-134a); 1,1-dichloro-1-fluoroethane (HCFC-141b); 1-chloro-1,1-difluoroethane (HCFC-142b); 2-chloro-1,1,1,2-tetrafluoroethane (HCFC-124); pentafluoroethane (HFC-125); 1,1,2,2-tetrafluoroethane (HFC-134); 1,1,1-trifluoroethane (HFC-143a); 1,1-difluoroethane (HFC-152a); parachlorobenzotrifluoride (PCBTF); cyclic, branched, or linear completely methylated siloxanes; acetone; perchloroethylene (tetrachloroethylene); 3,3-dichloro-1,1,1,2,2-pentafluoropropane (HCFC-225ca); 1,3-dichloro-1,1,2,2,3-pentafluoropropane (HCFC-225cb); 1,1,1,2,3,4,4,5,5,5-decafluoropentane (HFC 43-10mee); and perfluorocarbon compounds which fall into these classes:

\* \* \* \* \*

[FR Doc. 96-10809 Filed 4-30-96; 8:45 am]  
BILLING CODE 6560-50-P

#### 40 CFR Parts 52 and 81

[MI43-02-7256; AMS-FRL-5466-8]

#### Approval And Promulgation Of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; Michigan; Extension of Comment Period

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of proposed rulemaking; extension of the comment period.

**SUMMARY:** The EPA is extending the comment period for a proposed action published on April 2, 1996 (61 FR 14522) pertaining to the Grand Rapids moderate ozone nonattainment area. On April 2, 1996, the EPA proposed approval of Michigan's request to redesignate the Grand Rapids moderate ozone nonattainment area to attainment for ozone and associated section 175A maintenance plan revision to the Michigan State Implementation Plan (SIP) contingent on the State's submittal

*Appendix B*

the public comment period based on the fact that the revision to the section 175A maintenance plan SIP was not available in the EPA's docket until April 15, 1996. Since the revision to the section 175A maintenance plan SIP revision was not available for approximately the first two weeks of the public comment period, the EPA is extending the comment period only on the aspects of the redesignation and corresponding section 175A maintenance plan SIP revision components pertaining to the State's revision to the maintenance plan submitted on April 15, 1996 for 14 days. The public comment period pertaining to the other components of the redesignation request and maintenance plan SIP revision are not extended and comments on these components are due to EPA by May 2, 1996.

**DATES:** Comments on the aspects of the April 2, 1996, (61 FR 14522) proposed action on the redesignation and corresponding section 175A maintenance plan pertaining to the State's April 15, 1996 SIP revision must be received in writing by May 16, 1996.

**FOR FURTHER INFORMATION CONTACT:** Jacqueline Nwia, Environmental Engineer, Regulation Development Section, Air Programs Branch (AR-18J), United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-6081.

#### SUPPLEMENTARY INFORMATION:

##### List of Subjects

##### 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Motor vehicle pollution, Nitrogen oxides, Ozone, Volatile organic compounds.

##### 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401-7671q.

Dated: April 24, 1996.

Valdas V. Adamkus,

Regional Administrator  
[FR Doc. 96-10782 Filed 4-30-96; 8:45 am]

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#### 40 CFR Part 180

[OPP-300422; FRL-5362-9]

RIN 2070-AB18

#### Capsaicin, and Ammonium Salts of Fatty Acids; Proposed Tolerance Actions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** For the pesticides subject to the actions listed in this proposed rule, EPA has completed the reregistration process and issued a Reregistration Eligibility Decision (RED). In the reregistration process, all information to support a pesticide's continued registration is reviewed for adequacy and, when needed, supplemented with new scientific studies. Based on the RED tolerance assessments for the pesticide chemicals subject to this proposed rule, EPA is proposing to exempt from the requirement of a tolerance, all registered food uses for the pesticides, capsaicin and ammonium salts of fatty acids.

**DATES:** Written comments, identified with the docket number [OPP-300422] should be submitted to EPA by July 1, 1996.

**ADDRESSES:** By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA. Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment(s) that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. Any written comments will be available for public inspection in Rm. 1132 at the Virginia address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

RECEIVED  
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U.S. ENVIRONMENTAL PROTECTION AGENCY  
REGIONAL OFFICE  
CHICAGO, ILLINOIS

Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-300422]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

**FOR FURTHER INFORMATION CONTACT:** By mail: David H. Chen, Special Review and Reregistration Division (7508W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location: Special Review Branch, Crystal Station #1, 3rd floor, 2800 Crystal Drive, Arlington, VA 22202. Telephone: (703)-308-8017, e-mail: chen.david@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:**

**I. Legal Authorization**

The Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. 301 et seq.) authorizes the establishment of tolerances (maximum legal residue levels) and exemptions from the requirement of a tolerance for residues of pesticide chemicals in or on raw agricultural commodities pursuant to section 408 [21 U.S.C. 346(a)]. Without such tolerances or exemptions, a food containing pesticide residues is considered "adulterated" under section 402 of the FFDCA, and hence may not legally be moved in interstate commerce [21 U.S.C. 342]. To establish a tolerance or an exemption under section 408 of the FFDCA, EPA must make a finding that the promulgation of the rule would "protect the public health" [21 U.S.C. 346a(b)]. For a pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 136 et seq.).

In 1988, Congress amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 136 et seq.) and required EPA to review and reassess the potential hazards arising from currently registered uses of pesticides registered prior to November 1, 1984. As part of this process, the Agency must determine whether a pesticide is eligible for reregistration or whether any subsequent actions are required to fully attain reregistration status. EPA has chosen to include in the reregistration process a reassessment of existing tolerances or exemptions from the need for a tolerance. Through this

reassessment process, based on more recent data, EPA can determine whether a tolerance must be amended, revoked, or established, or whether an exemption from the requirement of one or more tolerances must be amended or is necessary.

The procedure for establishing, amending, or revoking tolerances or exemptions from the requirement of tolerances is set forth in 40 CFR parts 177 through 180. The Administrator of EPA, or any person by petition, may initiate an action proposing to establish, amend, revoke, or exempt a tolerance for a pesticide registered for food uses. Each petition or request for a new tolerance, an amendment to an existing tolerance, or a new exemption from the requirement of a tolerance must be accompanied by a fee. Current Agency policy on tolerance actions arising from the reregistration process is to administratively process some actions without requiring payment of a fee; this waiver of fees applies to revisions or revocations of established tolerances, and to proposed exemptions from the requirement of a tolerance if the proposed exemption requires the concurrent revocation of an established tolerance. Comments submitted in response to the Agency's published proposals are reviewed; the Agency then publishes its final determination regarding the specific tolerance actions.

**II. Chemical-Specific Information and Proposed Actions**

**A. Capsaicin: Exemption from the Requirement of a Tolerance**

**1. Regulatory history.** Capsaicin (8-methyl-*n*-vanillyl-6-non) and related capsaicinoids are the ingredients that produce the "hotness" in certain species of peppers in the Genus *Capsicum*. When used as a toxicant or repellent, products may consist simply of ground hot peppers or as an oleoresin extracted from the ground hot peppers. In either case, the amount of the actives must be verified by High Performance Liquid Chromatography. Products containing capsaicin and related capsaicinoids typically are formulated alone or in combinations with other active ingredients, such as garlic, allyl isothiocyanate (the active ingredient in oil of mustard), and egg solids. Formulations include dusts, granulars, gels, aerosols, and liquids. The U.S. Department of Agriculture first registered a product containing these actives in 1962, as a dog-attack repellent (Reregistration Eligibility Document for Capsaicin, Case 4018, U.S. Environmental Protection Agency, June 1992, Page 3).

Currently, capsaicin is registered for use as an animal repellent against attacking dogs, birds, voles, deer, rabbits, and tree squirrels, and for use as an insect toxicant and repellent. Capsaicin products are used indoors in crack and crevice, on carpets and upholstered furniture, and outdoors on fruit and vegetable crops, grains, ornamental plants and shrubs, flowers, lawns, gardens and garbage bags. Because capsaicin is a naturally-occurring substance which exhibits a non-toxic mode of action in humans, in 1991, EPA reclassified capsaicin as a biochemical pesticide.

**2. Current proposal.** Red peppers have long been used as a food without any known adverse health effects to man. In the absence of known toxicological concerns from the ingestion of capsaicin and related capsaicinoids, the Agency does not believe a tolerance for capsaicin is needed to protect the public health. Therefore, EPA proposes to exempt capsaicin from the requirement of a tolerance for residues in or on fruits, vegetables, and grains.

**B. Ammonium Salts of Fatty Acids: Exemptions from the Requirement of a Tolerance**

**1. Regulatory history.** Pesticidal products containing mineral salts of fatty acids were first registered in 1947 (Reregistration Eligibility Document for Soap Salts, Case 4083, U.S. Environmental Protection Agency, September 1992). Currently, the two active ingredients are potassium salts of fatty acids, which are registered as insecticides, acaricides, herbicides, and algacides, and ammonium salts of fatty acids which are registered for use as rabbit and deer repellent on forage and grain crops, vegetables, and field crops. Similar to potassium salts of fatty acids, structurally, ammonium salts are linked with naturally occurring fatty acids comprising of C<sub>8</sub>-C<sub>18</sub> saturated and C<sub>18</sub> unsaturated chain lengths. Naturally occurring fatty acids constitute a significant part of the normal daily diet, are of low toxicity when taken orally, and pose no known health risks. The residues of these salts of fatty acids from pesticide use are not likely to exceed levels of naturally occurring fatty acids in commonly eaten foods. Both potassium and ammonium salts of fatty acids are generally recognized as safe by the Food and Drug Administration of the Department of Health and Human Services. An exemption from the requirement of a tolerance for all food uses already exists for potassium salts of fatty acids (40 CFR 180.1068).

**2. Current proposal.** On September 10, 1980, the Thompson-Hayward Co.



made a formal request to the EPA for an exemption from the requirement of a tolerance for ammonium salts of fatty acids. The request was reviewed by the Agency, which had no objections to the addition of food uses. The addition of food uses was accepted in 1982. However, a formal notice of the proposed exemption was not published in the Federal Register. The Agency is now proposing to establish an exemption from the requirement of a tolerance for all food uses under FFDCA section 408 for ammonium salts of fatty acids, because a tolerance is not needed to protect the public health.

### III. Public Comment Procedures

EPA invites interested parties to submit written comments, information, or data in response to this proposed rule. Comments must be submitted by July 1, 1996. Comments must bear a notation indicating the docket number. Three copies of the comments should be submitted to either location listed under ADDRESSES.

Information submitted as a comment concerning this document may be claimed confidential by marking any or all of that information as "Confidential Business Information" (CBI). EPA will not disclose information so marked, except in accordance with procedures set forth in 40 CFR part 2. A second copy of such comments, with the CBI deleted, must also be submitted for inclusion in the public record. EPA may publicly disclose without prior notice information not marked confidential.

Any person who has registered or submitted an application for registration of a pesticide, under FIFRA, as amended, that contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

EPA has established a record for this proposed rule under docket number [OPP-300422], (including comments submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, except legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov  
The official record for this proposed rule, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official proposed rule record which will also include all comments submitted directly in writing. The official proposed rule record is the paper record maintained at the "ADDRESSES" at the beginning of this document.

### IV. Regulatory Assessment Requirements

To satisfy requirements for analysis specified by Executive Order 12866, the Regulatory Flexibility Act, the Paperwork Reduction Act, and the Unfunded Mandates Reform Act, EPA has considered the impacts of this proposal.

#### A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not a "significant regulatory action," because it does not meet any of the regulatory-significance criteria listed above.

#### B. Regulatory Flexibility Act

EPA has reviewed this proposed rule under the Regulatory Flexibility Act of 1980 [Pub. L. 96-354; 94 Stat. 1164, 5

U.S.C. 601 *et seq.*], and has determined that it will not have a significant economic impact on any small businesses, governments, or organizations. The proposed actions are not expected to significantly impact entities of any size.

Accordingly, I certify that this proposed rule does not require a separate regulatory flexibility analysis under the Regulatory Flexibility Act.

#### C. Paperwork Reduction Act

This proposed regulatory action does not contain any information collection requirements subject to review by OMB under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

#### D. Unfunded Mandates

This proposed rule contains no Federal mandates under Title II of the Unfunded Mandates Reform Act of 1995, Pub. L. 104-4, for State, local, or tribal governments or the private sector, because it would not impose enforceable duties on them.

#### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 12, 1996.

Lois Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

#### PART 180—[AMENDED]

1. The authority citation for part 180 would continue to read as follows:

Authority: 15 U.S.C. 346a and 371.

2. Section 180.1165 is added to subpart D to read as follows:

##### § 180.1165 Capsaicin; exemption from the requirement of a tolerance.

Capsaicin is exempted from the requirement of a tolerance for residues in or on fruits, vegetables, and grains, when used in accordance with labelled rates and with good agricultural practice.

3. Section 180.1166 is added to subpart D to read as follows:

##### § 180.1166 Ammonium salts of fatty acids; exemption from the requirement of a tolerance.

Ammonium oleate and related C<sub>8</sub>-C<sub>18</sub> fatty acids ammonium salts, are exempted from the requirement of a tolerance for residues in or on all raw agricultural commodities when used in

accordance with good agricultural practice.

[FR Doc. 96-10804 Filed 4-30-96; 8:45 am]

BILLING CODE 6560-50-F

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 1, 2, 21 and 94

[ET Docket No. 95-183; PP Docket No. 93-253; DA 96-455]

#### 37.0-38.6 GHz and 38.6-40.0 GHz Bands and Implementation of Section 309(j) of the Communications Act—Competitive Bidding

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule; denial of request for extension of time.

**SUMMARY:** The Commission denies an extension of time for filing reply comments in this proceeding on licensing and technical rules for fixed point-to-point microwave operations in the 37.0-38.6 GHz and 38.6-40.0 GHz bands. This action is taken because the filing dates were previously extended and it is the Commission's policy that extensions of time not be routinely granted. The intended effect of this action is to expedite the resolution of the issues raised in this proceeding.

**DATES:** Reply comments were due on April 1, 1996.

**ADDRESSES:** Federal Communications Commission, 1919 M Street N.W., Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Freda Lippert Thyden, Wireless Telecommunications Bureau, (202) 418-0627.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Order, DA 96-455, adopted March 28, 1996 and released March 28, 1996. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, N.W., Washington, D.C. 20554, and may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street, N.W., Washington, D.C. 20037.

By this action, we deny a third extension of time in which to file reply comments in this proceeding. (61 FR 2465, January 26, 1996). Bachow and Associates, Inc. ("Bachow"), requested that the time for filing reply comments in this proceeding be extended from April 1, 1996 to April 22, 1996.

By way of background, on January 16, 1996, the Commission's Office of Engineering Technology, on its own motion, extended the initial comment and reply comment period in the above-captioned proceeding from January 16, 1996, and January 31, 1996, respectively, to February 12, 1996, and February 27, 1996, respectively. On February 9, 1996, the Private Wireless Division further extended the deadline for filing comments and replies to March 4, 1996, and April 1, 1996, respectively, at the request of Winstar Wireless Fiber Corporation, GHz Equipment Company, Inc., and the Fixed Point-to-Point Communications Section, Network Equipment Division of the Telecommunications Industry Association (61 FR 6809, February 22, 1996).

Bachow contends that the volume of comments, the number and complexity of the issues involved and the initial delay in availability of filed comments necessitate an extension of three weeks for the filing of replies. We disagree. The facts of this case do not warrant what, in essence, would be a third extension of the filing period. It is the policy of the Commission that extensions of time not be routinely granted. Upon granting the last extension, the public was fully apprised of our increasing concern over the delay in this proceeding. In requesting additional time, Bachow has failed to cite any convincing reason for again postponing the deadline for filing reply comments.

#### Ordering Clauses

Accordingly, it is hereby ordered that the Motion for Extension of Time to File Reply Comments filed by Bachow and Associates, Inc., on March 25, 1996 is denied.

This action is taken pursuant to the authority provided in Section 1.46 of the Commission's Rules.

Federal Communications Commission.

Robert H. McNamara,

Chief, Private Wireless Division, Wireless Telecommunications Bureau.

[FR Doc. 96-10165 Filed 4-30-96; 8:45 am]

BILLING CODE 6712-01-P

## DEPARTMENT OF TRANSPORTATION

### Surface Transportation Board

#### 49 CFR Parts 1100 Through 1149

[STB Ex Parte No. 527]

#### Expedited Procedures for Processing Rail Rate Reasonableness, Exemption and Revocation Proceedings

**AGENCY:** Surface Transportation Board.

**ACTION:** Advance notice of proposed rulemaking; extension of comment due date.

**SUMMARY:** The original comment due date in this proceeding of May 6, 1996, is extended to May 20, 1996, at the request of the Association of American Railroads (AAR), Edison Electric Institute (EEI), National Grain & Feed Association (NG&FA), National Industrial Transportation League (NITL), The Society of the Plastics Industry, Inc. (SPI), and Western Coal Traffic League (WCTL).

**DATES:** Comments are due on May 20, 1996.

**ADDRESSES:** Send comments (an original and 10 copies) referring to STB Ex Parte No. 527 to: Surface Transportation Board, Office of the Secretary, Case Control Branch, 1201 Constitution Ave., N.W., Washington, DC 20423-0001. Parties are encouraged to submit all pleadings and attachments on a 3.5-inch diskette in WordPerfect 5.1 format.

**FOR FURTHER INFORMATION CONTACT:** Thomas J. Stilling, (202) 927-7312. (TDD for the hearing impaired: (202) 927-5721.)

**SUPPLEMENTARY INFORMATION:** On March 22, 1996, an Advance Notice of Proposed Rulemaking (ANPR) was served and published in the Federal Register, at 61 FR 11799, soliciting comments on how existing regulations could be modified to expedite the handling of rail rate reasonableness and exemption/revocation proceedings. On April 19, 1996, AAR, EEI, NG&FA, NITL, SPI, and WCTL jointly requested an extension of the comment due date until May 20, 1996, so that they can better respond to the ANPR. Because the parties requesting the extension represent a significant segment of railroad and shipper interests that are seeking "to identify and develop consensus positions on the major issues," the due date for comments is extended to May 20, 1996. Given our tight statutory deadline, we do not anticipate further extensions.

Decided: April 26, 1996.