

US Environmental Protection Agency Office of Pesticide Programs

BIOPESTICIDES REGISTRATION ACTION DOCUMENT
AMMONIUM NONANOATE (PC code 031802)

BIOPESTICIDE REGISTRATION ACTION DOCUMENT

AMMONIUM NONANOATE

(PC code 031802)

U.S. Environmental Protection Agency Office of Pesticide Programs Biopesticides and Pollution Prevention Division

Ammonium nonanoate (PC Code 031802)

Team Members: Raderrio Wilkins Denise Greenway Russell Jones, Ph.D. Nina Simeonova

TABLE OF CONTENTS

LI	ST OF TABLES	4
I.	EXECUTIVE SUMMARY	5
	IDENTITY	
	USE/USAGE	
	RISK ASSESSMENT	
	DATA GAPS / LABELING RESTRICTIONS	
II.	OVERVIEW	6
A.	ACTIVE INGREDIENT OVERVIEW	6
B.	USE PROFILE	6
C.	ESTIMATED USAGE	7
D.	DATA REQUIREMENTS	7
E.	REGULATORY HISTORY	7
	CLASSIFICATION	
G.	FOOD CLEARANCES/TOLERANCES	7
	SCIENCE ASSESSMENT	
A.	PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT	8
	1. Product Identity and Mode of Action:	8
	2 Physical and Chemical Properties Assessment	9
В.	HUMAN HEALTH ASSESSMENT	9
	1. Toxicology Assessment	10
	2. Dose Response Assessment	11
	3. Dietary Exposure and Risk Characterization	11
	4. Occupational and Residential Exposure	11
	5. Drinking Water Exposure and Risk Characterization	12
	6. Acute and Dietary Risks for Sensitive Subpopulations, Particularly Infants and	
	Children	
	7. Aggregate Exposure from Multiple Routes Including Dermal, Oral and Inhaon	
	8. Cumulative Effects	
	9. Effects on the Immune and Endocrine Systems	13
C.	ENVIRONMENTAL ASSESSMENT	
	1. Ecological Effects Hazard Assessment	13
	2. Environmental Fate and Ground Water Data	15
	3. Ecological Exposure and Risk Characterization	15
D.	EFFICACY DATA	15

File name: Page 3 of 19

IV. RISK MANAGEMENT DECISION	16
A. DETERMINATION OF ELIGIBILITY	16
B. REGULATORY POSITION	16
1. Unconditional Registration	
2. Tolerance Reassessment	
3. Codex Harmonization	
4. Nonfood Re/Registrations	
5. Risk Mitigation	
6. Endangered Species Statement	
C. LABELING RATIONALE	
1. Human Health Hazard	17
2. Environmental Hazards Labeling	
3. Application Rate	
D. LABELING	
V. ACTIONS REQUIRED BY REGISTRANTS	19
VI. APPENDIX A	19
APPENDIX R _ REFERENCES	20

LIST OF TABLES

Table 1.	Product chemistry data requirements	8
Table 2.	Mammalian toxicity data requirements	11
Table 3.	Non-Target Toxicity Requirements	14
Table 4.	Use Sites. Registration/Reregistration	.19

I. EXECUTIVE SUMMARY

A. IDENTITY

The new active ingredient ammonium nonanoate, is a C_9 saturated-chain fatty acid soap salt. The end use product contains 40.0% by weight ammonium nonanoate. The product chemistry data submitted by the registrant satisfies the requirements for product identity.

B. USE/USAGE

Ammonium nonanoate will be used for the suppression and control of a wide variety of weeds including: grasses, vines, and brush (non-food uses)..

C. RISK ASSESSMENT

Ammonium nonanoate is closely related to other salts of fatty acids known as soap salts. Toxicology and environmental data requirements for this biochemical herbicide product were waived, primarily via the Agency's Reregistration Eligibility Document (RED) for Soap Salts. The RED (EPA-738-F-92-013, September, 1992) concludes that no risks to human health are expected from the use of ammonium salts of higher fatty acids (C_8 - C_{18} saturated and C_{18} unsaturated) based on their low toxicity and the fact that residues from pesticide uses are not likely to exceed the levels of naturally-occurring or intentionally-added fatty acids in commonly-eaten foods. Ammonium salts of fatty acids are rapidly biodegraded in the environment, and are expected to be only minimally toxic to nontarget organisms, with the exception of aquatic invertebrates. Appropriate precautionary labeling of end use products containing ammonium salt will further minimize potential exposure and mitigate risk to humans and nontarget organisms.

The Agency has considered ammonium nonanoate in light of relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and determined there will be no unreasonable adverse effects from the use of this product. The Agency has considered available data and other factors, including the natural occurrence of soap salts, their common use as food items, and the lack of reported adverse effects, and believes that end use products containing ammonium nonanoate, can be used without causing unreasonable adverse effects to humans or the environment.

D. DATA GAPS / LABELING RESTRICTIONS

There are no data gaps. This active ingredient is toxic to fish and aquatic invertebrates and should not be applied directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark.

II. OVERVIEW

A. ACTIVE INGREDIENT OVERVIEW

Common Name: Ammonium nonanoate

Ammonium pelargonate

Pelargonic acid, ammonium salt Nonanoic acid, ammonium salt

Chemical Name: Octane-1-carboxylic acid, ammonium salt

Chemical Formula: $[C_9-H_{18}-O_2]-NH_4$

Chemical Family: Ammonium salt of fatty acids C8-C18

Trade and Other Names: RacerTM Concentrate

CAS Registry Number: 63718-65-0 OPP Chemical Code: 031082

Basic Manufacturer: Falcon Lab, LLC

1103 Norbee Drive Wilmington, DE 19803

B. USE PROFILE

The following is information on the proposed uses with an overview of use sites and application methods.

Type of Pesticide: Non-systemic, broad-spectrum contact herbicide.

Use Sites: **Ammonium nonanoate can not be used on or around food crops**. Ammonium nonanoate is to be used for the suppression and control of weeds, vines, and underbrush by home owners, master gardeners, farmers, landscape and turf professionals, and interior scapers. It may be used in nurseries, greenhouses, and lath or shade houses.

Target Pests: Weeds including: grasses, vines, underbrush, annual/perennial plants, including moss, saplings, and tree suckers.

Formulation Type: Liquid

Method and Rates of Application: Ammonium nonanoate can be applied using standard spary methods of liquid herbicide application, including hand-held, boom, pressure, and hose-end sprayers. For use, the concentrate is diluted with water to the desired concentration. Application rates are up to a maximum concentration of 6.0 % by weight (corresponding to 2.4% by weight ammonium nonanoate) in water. For the product to be effective, the leaves of undesirable vegetation must by uniformly sprayed and thoroughly wetted. Application can be repeated as often as necessary to obtain the desired control.

Use Practice Limitations: Ammonium nonanoate can not be used on or around food crops.

C. ESTIMATED USAGE

None used yet since this will be the first registration of this active ingredient.

D. DATA REQUIREMENTS

The Agency granted the registrant's request for waivers from the requirements of studies/data for acute mammalian toxicity and for certain non-target organism testing. These data were waived primarily based on information in the Agency's published RED for Soap Salts (EPA-738-F-92-013, September, 1992), including the natural occurrence of soap salts, their common use or in food items, a lack of reported adverse effects, no expected risk to human health, and no expected adverse effects to nontarget organisms when the end use product is used as directed.

Product analysis data requirements for the end use product were adequately satisfied.

The data required for granting this registration under Section 3(c)(5) of FIFRA have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD). Based on the submitted information, the Agency foresees no unreasonable adverse effects to human health and the environment from the use of ammonium nonanoate as long as it is used as labeled.

E. REGULATORY HISTORY

On **August 18, 2005**, the Agency received an application from Falcon Lab LLC, to register an ammonium nonanoate product, containing 40.0% by weight active ingredient. A notice of receipt of the application for registration of ammonium nonanoate as a new active ingredient for end use products to control unwanted vegetation was published in the Federal Register on November 23, 2005.

F. CLASSIFICATION

Ammonium nonanoate, is a C_9 saturated-chain fatty acid soap salt, and is classified as a biochemical pesticide.

G. FOOD CLEARANCES/TOLERANCES

A Proposed Rule was published on May 1, 1996 (61FR 19233-36) to exempt ammonium salts of fatty acids and related C_8 - C_{18} fatty acids ammonium salts from the requirement of a tolerance for residues in or on all raw agricultural commodities when used in accordance with good agricultural practice; however, the proposed rule was never finalized by the Agency.

III. SCIENCE ASSESSMENT

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for ammonium nonanoate are satisfied.

1. Product Identity and Mode of Action:

- **a. Product Identity:** The new active ingredient, ammonium nonanoate, is a C₉ saturated-chain fatty acid soap salt. It represents 40.0% by weight of the end use product is 40% by weight of ammonium nonanoate, which is a clear, colorless to pale yellow liquid with a slight fatty acid odor.
- **b. Mode of Action:** Ammonium nonanoate is a non-systemic, broad-spectrum contact herbicide that has no soil activity.
- **2. Physical and Chemical Properties Assessment:** The physical and chemical characteristics of ammonium nonanoate were submitted to support its registration. These are summarized in Table 1.

TABLE 1. Product chemistry data requirements				
Guideline No.		Results	MRID No.	
151-10 (OPPTS 880.1100)	Product identity	The submitted data satisfy the requirements for product identity.	46640401	
151-11 (OPPTS 880.1200)	Manufacturing process	The submitted data satisfy the requirements for the manufacturing process	46640401	
151-12 (OPPTS 880.1400)	Discussion of formation of unintentional ingredients	The submitted data satisfy the requirements for the discussion of the formation of unintentional ingredients.	46640401	
151-13 (OPPTS 830.1700)	Analysis of samples	The submitted data satisfy the requirements for the analysis of samples.	46640401	
151-15 (OPPTS 830.1750)	Certification of limits	The submitted data satisfy the requirements for the certification of limits.	46640401	
151-16 (OPPTS 830.1800)	Analytical method	An acceptable analytical method was submitted.	46640401	
	Physical/chemical Properties for the EP			
63-2 (OPPTS 830.6302)	Color	Clear, colorless to pale yellow @ 20°C	46640402	
63-3 (OPPTS 830.6303)	Physical State	Liquid @ 20°C	46640402	
63-4				

(OPPTS 830.6304)	Odor	Slightly fatty acid odor @ 20°C	46640402
63-5 (OPPTS 830.7200)	Melting point	Not required for EP	
63-6 (OPPTS 830.7220)	Boiling point	Not required for EP	
63-7 (OPPTS 830.7300)	Density	Specific gravity = 1.00 ± 0.00 @ 20°C	46640402
63-8 (OPPTS 830.7840)	Solubility	Not required for EP	
63-9 (OPPTS 830.7950)	Vapor Pressure	17.5 mm Hg at 20 °C 23.8 mm Hg at 25 °C	
63-10 (OPPTS 830.7370)	Dissociation Constant	Not required for EP	
63-11 (OPPTS 830.7550)	Octanol/water partition coefficient	Not required for EP	
63-12 (OPPTS 830.7000)	pН	7.5 ± 0.5 @ 24.0°C	46640402
63-13 (OPPTS 830.6313)	Stability	Long history of stability of fatty acid soap salts in plastic containers in the form of detergents.	
63-14 (OPPTS 830.6314)	Oxidation/reduction	Not Applicable	
63-15 (OPPTS 830.6315)	Flammability	Product is non-flammable	46640402
63-16 (OPPTS 830.6316)	Explodability	Product is non-explodable (no known explosion characteristics)	46640402
63-17 (OPPTS 830.6317)	Storage stability	Waiver requested; product consists of a soap salt of a fatty acid or a soap solution that has for several decades been routinely packaged in plastic containers and remains stable for longer than 24 months.	46640402
63-18 (OPPTS 830.7100)	Viscosity	$61.02 \pm 0.01 \text{ cP}$	46640402
63-19 (OPPTS 830.6319)	Miscibility	Completely miscible in water	46640402
63-20 (OPPTS 830.6320)	Corrosion characteristics	Not corrosive; product consists of a soap salt of a fatty acid or a soap solution that has for several decades been routinely packaged in plastic containers without exhibiting corrosive properties.	46640402
63-21 (OPPTS 830.6321)	Dielectric breakdown voltage	Not applicable, not for use in/around electrical equipment.	46640402

B. HUMAN HEALTH ASSESSMENT

1. Toxicology Assessment

The active ingredient, ammonium nonanoate, is a C_9 saturated-chain fatty acid soap salt. The Agency RED for Soap Salts (EPA-738-F-92-013, September, 1992) treats all ammonium salts of higher fatty acids (C_8 - C_{18} saturated and C_{18} unsaturated) as one active ingredient. The registrant requested waivers for the acute toxicology data requirements listed in Table 2, based on the assessment in the RED that all toxicity data requirements for active ingredients of soap salts have been fulfilled.

According to the RED, oral exposure to soaps is generally self-limiting, since the taste of soap is easily recognized and is unpleasant. In addition, ammonium soap salts have an ammonia odor that is limiting. Soap salts are of low acute toxicity when taken orally, and have been placed in Toxicity Category IV.

The RED states that soap salts are also placed in Toxicity Category IV for acute dermal toxicity. When applied to skin for longer periods of time (24 hours), soap salts can produce mild to moderate irritation. Ammonium soaps of higher fatty acids may also cause allergic skin reactions in some individuals, but the Agency believes allergic reactions are uncommon and transient. Soap salts are not classified as skin sensitizers.

Ammonium soap salts are irritating to the eyes, and can cause permanent eye damage.

A published data summary submitted by the registrant (IUCLID, 2000, cited in HERA, 2002) states that very limited data exist on the effects of acute inhalation of fatty acids or their salts. This is to be expected, since in normal use scenarios the primary route of exposure would be dermal. The only inhalation study cited in the submitted summary was one in which no deaths were seen in 10 rats exposed for eight hours to saturated vapors of mixed isomers of decanoic acid.

The RED states that DNA inhibition was reported when guinea pig cells were tested with 600 μ mol/L of the sodium salt of caprylic acid. Unscheduled DNA synthesis was found in mouse cells treated with 35 mg/kg of oleic acid. Further, cytogenetic analysis was positive for hamster fibroblasts treated with 2500 μ g/L of oleic acid and for *Saccharomyces cerevisiae* treated with 100 mg/L oleic acid. It is highly unlikely that humans would be exposed to soap salts at the doses reported above when the product is used according to label use directions.

Based on the information provided by the registrant, and the conclusion in the soap salts RED that the toxicological data base for ammonium soaps of fatty acid is adequate, the Agency granted the requested waivers for the acute toxicology data requirements (Table 2).

TABLE 2. Mammalian toxicity data requirements			
Guideline No.	Study	Results	MRID No.
152-10	Acute oral toxicity	Waiver accepted	46640403
(OPPTS 870.1100)			

152-11 (OPPTS 870.1200)	Acute dermal toxicity	Waiver accepted	46640403
152-12 (OPPTS 870.1300)	Acute inhalation toxicity	Waiver accepted	46640403
152-13 (OPPTS 870.2400)	Primary eye irritation	Waiver accepted	46640403
152-14 (OPPTS 870.2500)	Primary dermal irritation	Waiver accepted	46640403
152-18	Immune response	Waiver accepted	46640403

2. Dose Response Assessment

Based on available information, no toxicity endpoints were identified.

3. Dietary Exposure and Risk Characterization

According to the Soap Salts RED (EPA-738-F-92-013, September, 1992), exposure to low levels of soap salt residues on treated foods poses no known health risks. Soaps are mineral salts of naturally-occurring fatty acids. Fatty acids are a significant part of the normal human daily diet, since they occur in dietary lipids that usually constitute about 90 grams in a day's diet. Residues from pesticide uses of soap salts are not likely to exceed the levels of naturally-occurring fatty acids in commonly eaten foods. FDA lists salts of fatty acids as additives that may be used as binders, emulsifiers, and anti-sticking agents in food (21 CFR 172.863). Additionally, 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, as additives that may be safely used in foods (21 CFR 172.860). Stearic acid is generally recognized as safe (GRAS) for use as an ingredient in food (21 CFR 184.1090). A number of fatty acid salts are approved for uses in food packaging materials (21 CFR 181). Due to the low acute oral and acute dermal toxicity of soap salts, and because residues from pesticide uses are not likely to exceed the levels of naturally-occurring or intentionally added fatty acids in commonly-eaten foods, the Agency believes the risk to consumers from areas treated is negligible. No agricultural crop is to be treated with this active ingredient.

4. Occupational and Residential Exposure

a. Occupational Exposure and Risk Characterization: The potential for dermal, eye, and inhalation exposure to the pesticide exists for handlers and applicators. Exposure of applicators can be significant, but soaps generally have low toxicity to humans and there is no reason to expect that the use of ammonium nonanoate in accordance with label directions would constitute any significant hazard. Long-sleeved shirt, chemical-resistant gloves and boots, and protective eyewear are required to mitigate potential exposure. The Agency will require the appropriate signal word and precautionary statements to mitigate any risk from exposure.

b. Residential, School and Daycare Exposure and Risk Characterization: Because toxicological endpoints are not expected, risk from the consumption of residues of ammonium nonanoate is not expected for populations in residential, school, and daycare settings.

5. Drinking Water Exposure and Risk Characterization

No significant exposure is expected from an accumulation of ammonium nonanoate in the aquatic environment when it is used according to the precautionary label language. Ammonium nonanoate is not to be applied directly to water, and the RED states that ammonium salts of fatty acids undergo very rapid microbial degradation in soil.

6. Acute and Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure are often referred to as uncertainty or safety factors. In this instance, based on all available information, the Agency concludes that ammonium nonanoate, is practically non-toxic to mammals including infants and children. Because there are no threshold effects of concern to infants, children, and adults when ammonium nonanoate is used as labeled, the provision requiring an additional margin of safety does not apply. Further, the provisions of consumption patterns, special susceptibility, and cumulative effects do not apply. As a result, EPA has not used a margin of exposure approach to assess the safety of ammonium nonanate.

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral and Inhalation

Aggregate exposure to ammonium nonanoate, may occur via oral and dermal routes. Since the acute oral toxicity of soap salts is low (Toxicity Category IV), the risks anticipated from oral exposure are considered minimal. The acute dermal toxicity is also low (Toxicity Category IV). Longer dermal exposures can produce mild to moderate irritation, but soap salts are not skin sensitizers. As a result, the anticipated risks from dermal exposure are considered minimal. Because the inhalation route is not a likely exposure pathway, the anticipated risks from inhalation exposure are also considered minimal. Therefore, the risks from aggregate exposure via oral, dermal, and inhalation exposure are a compilation of three low-risk exposure scenarios and are negligible when appropriate protective equipment is used.

The Agency has considered the various routes of exposure and potential risks of the product and determined that the proposed use of the active ingredient does not pose significant risk to all populations, including infants and children.

8. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to pelargonic acid, ammonium salt, and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. Except for ocular exposure, ammonium nonanoate is of low toxicity, and it is not anticipated that there would be cumulative effects from common mechanisms of toxicity. The risk to eyes can be prevented by use of required protective eyewear.

9. Effects on the Immune and Endocrine Systems

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) Amay have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate. Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of the active ingredient ammonium nonanoate, at this time. The Agency has considered, among other relevant factors, available information concerning whether the active ingredient may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an "endocrine disrupter" produced by this active ingredient. Based on the low potential exposure level associated with the proposed use of this pesticide, the Agency expects no incremental adverse effects to the endocrine or immune systems.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

The registrant requested a waiver of the data requirement for background non-target plant testing (Guideline 154-10, OPPTS 850.4000). This request was based on the fact that the mode of action for ammonium nonanoate is physical contact, i.e., the product works only

when the leaves of a plant are completely drenched with the herbicide solution. Ammonium nonanoate has no systemic or residual activity. Therefore, non-target plants will not be affected by spray drift, since a plant must be thoroughly saturated to the "drip-stage" with the product for herbicidal activity to occur. Incidental exposure to plants via spray drift will have no permanent adverse effects on non-target plants. Spray drift can be mitigated by increasing spray droplet size. The Agency granted this request to waive data requirements for non-target plant testing.

No studies or waiver requests were submitted for the remainder of the Tier I non-target organism data requirements, although data contained in the Soap Salts RED (EPA, 1992) and the HERA Fatty Acid Salts (Soap) Environmental Risk Assessment (2003) may be used to support these data requirements. Based on information from the aforementioned reviews, soap salts of fatty acids are slightly toxic to birds on an acute basis and are practically non-toxic to birds on a dietary basis, slightly toxic to fish, and highly toxic to aquatic invertebrates. Ammonium salts of fatty acids are readily biodregradable and rapidly metabolized by soil microorganisms (half life < 1day). Since the product is not intended for direct application to aquatic sites, exposure to aquatic organisms (fish and invertebrates) is further mitigated. No data are available for non-target insects, the registrant must have restrictive label language in regard to non-target insects (honey bees).

Based on data contained in the Soap Salts RED (EPA, 1992) and HERA (2003), there are no concerns for non-target organisms when ammonium nonanoate is used in accordance with approved labeling.

Table3: Non-target Organism Data from the Soap Salts RED (EPA, 1992) and HERA (2003)

Data Requirement	LD50\LC50\EC50	Toxicity Category	Citation
Avian Acute Oral Toxicity OPPTS 850.2100	>2150 mg/kg (bobwhite quail)	Slightly toxic	MRID 41767112
Avian Dietary Toxicity OPPTS 850.2200	>5000 mg/kg (bobwhite quail & mallard duck)	Practically non- toxic	MRID 41767113, -14
Acute Fish Toxicity OPPTS 850.1075	96-hr: 18.06 mg/L (rainbow trout) 96 hr: 35.35 mg/L ¹ (bluegill sunfish)	Slightly toxic	EPA. (1992)
	96 hr: 54 mg/L ² (O. latipes)	Slightly toxic	HERA (2003)
Aquatic Invertebrates OPPTS 850.1010	48 hr: 0.57 mg/L (<i>D. magna</i>)	Highly toxic	MRID 400662-00
Non-Target Plants OPPTS 870.2500	No data available for any soap salt but product is intended for use as a terrestrial herbicide	-	-
Non-target Insects OPPTS 850.3020; 850.3030; 850.3040	No data available for any soap salt	-	-

potassium soap salt used; considered by the Agency to be equivalent to ammonium soap salt for ecorisk assessment purposes (EPA, 1992).

2 sodium decanoate (C_{10} fatty acid salt) was test substance.

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data [Tier II, 40 CFR 158.690(d)] was not triggered because the Tier I studies were waived. Risk is minimal due to the low toxicity, use pattern, and rapid microbial degradation of the active ingredient.

3. Ecological Exposure and Risk Characterization

According to the RED (EPA-738-F-92-013, September, 1992), end use products containing ammonium salts of fatty acids are expected to degrade rapidly, primarily via microbial action, with a half-life of perhaps less than one day. The Agency therefore believes that ammonium salts of fatty acids, when used as directed, will not persist in the environment. Data reviewed suggest that ammonium salts of fatty acids are not very toxic to upland avian species or waterfowl by either acute or dietary exposure. The RED states that ammonium salts of fatty acids are probably only slightly toxic to both warm water and cold water fish species, but are considered highly toxic to aquatic invertebrates. However, the use of ammonium nonanoate following label directions should not result in serious impact to aquatic invertebrates because it is not applied directly to water and undergoes very rapid microbial degradation in soil. In addition, mitigating label language will further reduce the risk to aquatic invertebrates. The precautionary labeling for the end use product stipulates "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."

D. EFFICACY DATA

No efficacy data were required to be submitted to the Agency, since no public health uses are involved.

IV. RISK MANAGEMENT DECISION

A. DETERMINATION OF ELIGIBILITY

Section 3(c)(7)(C) of FIFRA provides for the unconditional registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria "A" above, ammonium nonanoate, is not expected to cause unreasonable adverse effects when used according to label instructions. Criteria "B" is satisfied by the current label and by data presented in this document. It is believed that ammonium nonanoate will not cause any unreasonable adverse effect, and is an effective biochemical pesticide for unwanted vegetation, satisfying Criteria "C." Criteria "D" is satisfied in that the pesticide is not expected to cause unreasonable adverse effects when used as described on the label. Therefore, ammonium nonanoate is eligible for an unconditional registration.

B. REGULATORY POSITION

1. Unconditional Registration

The data submitted are sufficient for an unconditional registration of ammonium nonanoate an end use product.

2. Tolerance Reassessment

There is currently no tolerance or tolerance exemption for ammonium salts of fatty acids. A Proposed Rule was published on May 1, 1996 (61FR 19233-36) to exempt ammonium oleate and related C8-C18 fatty acids ammonium salts from the requirement of a tolerance for residues in or on all raw agricultural commodities when used in accordance with good agricultural practice; however, the proposed rule was never finalized by the Agency.

3. Codex Harmonization

There are no Codex harmonization considerations since there is currently no Codex tolerance for residues of ammonium nonanoate.

4. Nonfood Re/Registrations

This is a new active ingredient and, therefore, not the subject of reregistration at this time.

5. Risk Mitigation

A risk exists from ocular exposure, which is mitigated by label language requiring protective eyewear. Risk to aquatic invertebrates is mitigated by the appropriate label precautions.

6. Endangered Species Statement

Based on the non-target organism data submitted and reviewed in the Soap Salts RED (EPA, 1992) and in the HERA Fatty Acid Salts (Soap) Environmental Risk Assessment (2003), and the ready biodegradability of the active ingredient, there will be **No Adverse Affects (NAE)** to threatened and endangered species when the product is used in accordance with approved labeling.

C. LABELING RATIONALE

It is the Agency's position that the labeling for the end use product containing 40.0% by weight of the active ingredient ammounium nonanoate complies with the current pesticide labeling requirements.

1. Human Health Hazard

a. Worker Protection Standard: Any product whose labeling reasonably permits its use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7", which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170). Unless otherwise specifically directed, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those Notices.

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR 156.10 and other applicable notices, such as, and including, the WPS labeling.

- **b.** Non-Worker Protection Standard: There are no non-WPS human health hazard issues.
- c. Precautionary Labeling: The Agency has examined the toxicological data base for ammonium nonanoate, ammonium salt and concluded that the precautionary labeling required during this unconditional registration process (i.e. Signal Word, First Aid Statements, and other label statements) adequately mitigates the risks associated with the proposed uses.
- **d.** End Use Product Precautionary Labeling: For RacerTM Concentrate, "WARNING." "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." The ammonium soaps of higher fatty acids discussed in the RED are labeled "DANGER" due to potential for permanent eye damage.

e. Spray Drift Advisory No spray drift advisory statement is necessary for this use.

2. Environmental Hazards Labeling

End-Use Product Environmental Hazards Labeling: "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."

3. Application Rate

It is the Agency's position that the labeling for the end use product, which contains 40% by weight ammonium nonanoate, complies with the current pesticide labeling requirements. The product label directs the user to apply up to a maximum concentration of 6% by weight, corresponding to 2.4% by weight ammonium nonanoate, in water.

D. LABELING

Product Name: RacerTM Concentrate

ACTIVE INGREDIENT	
Ammonium nonanoate	40.0%
Other ingredients	60.0%
Total	100.0%

The end use product label shall comply with Agency labeling requirements and must contain the following information:

- Product name
- Ingredient statement
- Registration number
- "Keep out of reach of children"
- Signal word (CAUTION)
- Precautionary statements

V. ACTIONS REQUIRED BY REGISTRANTS

Registrants are required to provide reports of incidents of adverse effects to humans or domestic animals under FIFRA, Section 6(a)(2) and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16. There are no data requirements, label changes and other responses necessary for the reregistration of the product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. For the same reason, there are also no existing stocks provisions at this time.

VI. APPENDIX A

Table 4 lists the use sites for the product. The label for the product is also attached.

TABLE 4: Use Sites. Registration/Reregistration	
Racer TM Concentrate <u>Use sites</u> : Field, greenhouse, turf, and nursery use.	Official date registered:

APPENDIX B – REFERENCES

- Forster, V., and R.A. Smiley. 2005. Ammonium Nonanoate, A.P.: 40% SC (End-Use Product). Product Properties, Group A-Product Identity, Compsition, and Analysis. Falcon Lab, LLC Study ID Number Series 880.1100-880.1400 and Series 830.1700-830.1800. MRID 46640401.
- Forster, V., and R.A. Smiley. 2005. Ammonium Nonanoate, A.P.: 40% SC (End-Use Product). Product Properties, Group B-Physical/Chemical Properties. Falcon Lab, LLC Study ID Number AP-PC-01, Series 830.6302-830.7100. MRID 46640402.
- Ammonium Nonanoate, A.P.: 40% SC (End-Use Product). Waiver Request. Nontarget Plant Background. MRID 46640404.
- Ammonium Nonanoate, A.P.: 40% SC (End-Use Product). Waiver Request. Toxicology Data Requirements. MRID 46640403.
- Ammonium Nonanoate, A.P.: 40% SC (End-Use Product). Administrative Documents Data Summaries. Attachment A: Introduction and Pages 1-21 of the Registration Eligibility Document (RED) for Soap Salts, EPA, 1992.
- Ammonium Nonanoate, A.P.: 40% SC (End-Use Product). Administrative Documents Data Summaries. Attachment B: Fact Sheet for Soap Salts RED, EPA.
- Ammonium Nonanoate, A.P.: 40% SC (End-Use Product). Administrative Documents Data Summaries. Attachment C: 61FR19233:Proposed Rule to Exempt Ammonium Soap Salts from the Requirement of a Tolerance, May 1, 1996.
- Ammonium Nonanoate, A.P.: 40% SC (End-Use Product). Administrative Documents Data Summaries. Attachment D: 69FR12670: Notice of Filing to Exempt Ammonium Nonanoate from the Requirement of a Tolerance, March 17, 2004.
- Ammonium Nonanoate, A.P.: 40% SC (End-Use Product). Administrative Documents Data Summaries. Attachment E: Fatty Acid Salts. Human Health Risk Assessment. Draft (2002), and Fatty Acid Salts (Soap). Environmental Risk Assessment. Draft (2003). Published by the European Organization HERA (Human and Environmental Risk Assessment).