Reregistration Eligibility Decision (RED) for Oleic Acid Sulfonates

September 30, 2004

United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7510C) | EPA 739-R-05-004 September 2005

Reregistration Eligibility Decision for Oleic Acid Sulfonates

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (EPA) has completed its review of the available data on the antimicrobial, sulfonated oleic acid, sodium salt. The Reregistration Eligibility Decision (RED) was approved in the form of a decision memorandum which summarized the regulatory decision for sulfonated oleic acid, sodium salt on September 30, 2004. The memorandum was approved and signed on September 30, 2004.

Based on the Agency's review of sulfonated oleic acid, sodium salt, the Reregistration Eligibility Decision (RED), risk management decision and associated human health and environmental risk assessments are now being published. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting documents for sulfonated oleic acid, sodium salt will be available to the public in EPA's Pesticide Docket **OPP-2005-0261** at: http://www.epa.gov/edockets.

Please note that the attached RED document pertains only to sulfonated oleic acid, sodium salt and presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to sulfonated oleic acid, sodium salt alone. This document also identifies product-specific data for which the Agency intends to issue Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. At this time, generic confirmatory data are required. For product-specific DCIs, the first set of required responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that sulfonated oleic acid, sodium salt is eligible for reregistration. Sections IV and V of the oleic acid sulfonates RED document describe product-specific and generic data requirements.

If you have questions pertaining to this document, please contact the Chemical Review

Manager, K. Avivah Jakob, at (703) 305-1328 or Jennifer Slotnick at (703) 305-0601. For questions regarding product reregistration and or the product DCI that accompanies this document, please contact Adam Heyward at (703) 308-6422.

Sincerely,

Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY DECISION

for

Oleic Acid Sulfonates

List D

Case No. 4069

Approved By:

Frank T. Sanders
Director, Antimicrobials Division
September 29, 2005

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
AD	Antimicrobials Division
ADTC	Antimicrobials Division Toxicology Endpoint Selection Committee
a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EPISUIT	Environmental Protection Agency, Estimation Program Interface Suite
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
Fl. oz.	Fluid Ounces
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FWS	United States Fish and Wildlife Services
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
HPV	High Production Volume
IDS	Incident Data System
IR	Index Reservoir
LC_{50}	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 weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	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 weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NMFS	National Marine Fishery Service
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NPTN	National Pesticide Telecommunications Network
NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	Pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PCC	National Poison Control Center
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose

RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SAR	Structure Activity Relationship Assessment
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
g/g	Micrograms Per Gram
g/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency (EPA or the Agency) has completed its human health and environmental review for sulfonated oleic acid, sodium salt and is issuing its risk management decision. The Agency has decided that sulfonated oleic acid, sodium salt is eligible for reregistration. The following Reregistration Eligibility Decision (RED) addresses the use of sulfonated oleic acid, sodium salt as a bacteriacide and sanitizer for food-contact sanitizing solutions. As an active ingredient, sulfonated oleic acid, sodium salt is used as a sanitizer for non-porous dairy, beverage, brewery and food processing equipment. Sulfonated oleic acid, sodium salt is formulated as a liquid concentrate. The following RED reassesses the exemption from the requirement for a tolerance for sulfonated oleic acid, sodium salt. The tolerance exemption for sulfonated oleic acid, sodium salt is listed in 40 CFR 180.940 (c) (69 FR 23136, Apr. 28, 2004).

Overall Risk Summary

Hazard Profile/Human Health Risk

Upon reviewing the available toxicity information, the Agency has concluded that there are no endpoints of concern for repeated oral, dermal, or inhalation exposure to sulfonated oleic acid, sodium salt based on the low toxicity observed in acute studies and the Structure Activity Relationship (SAR) assessments conducted by the Agency. Therefore a quantitative human health risk assessment was not conducted for this RED. There are no indications of special sensitivity of infants or children resulting from exposure to sulfonated oleic acid, sodium salt; therefore, the FQPA Safety Factor has been removed (i.e., reduced to 1X) for sulfonated oleic acid, sodium salt. The Agency has no risk concerns for sulfonated oleic acid, sodium salt with respect to human exposure.

The Food and Drug Administration (FDA) has approved the indirect food use of sulfonated oleic acid up to 200 ppm for food processing equipment and glass bottles for milk. This level of clearance is greater than the Agency s level of concern for indirect food uses of antimicrobial pesticides (i.e., > 200 ppb); therefore, the Agency believes that sulfonated oleic acid, sodium salt is of a low order of toxicity. Furthermore, the Agency recognizes that sulfonated oleic acid, sodium salt is a fatty acid derivative. Fatty acids are processed by known metabolic pathways within the body and are necessary for normal cellular functioning. As the exposures anticipated from the indirect food uses (as well as non-dietary dermal and or inhalation exposure) are insignificant in comparison to levels encountered for fatty acids in the normal human diet, use of this chemical in pesticide products is unlikely to pose any significant hazard to the general population or to any subgroup including infants and children.

Environmental Risk

The Agency conducted a Structure Activity Relationship (SAR) assessment to assess the environmental risks of sulfonated oleic acid, sodium salt. The result of this analysis predicts low to moderate toxicity concern for ecological effects from sulfonated oleic acid, sodium salt. Sulfonated oleic acid, sodium salt shows a tendency to be immobile, a moderate to strong

tendency to bind tightly to sediment and soils, and undergoes microbial degradation within a couple of weeks, which is expected to mitigate any potential for risk. The EPA believes that this compound will not cause unreasonable adverse effects on the environment.

The Agency has no risk concerns for sulfonated oleic acid, sodium salt with respect to non-target organisms. The Agency expects no effects to listed species or critical habitat and therefore makes a "No Effect" determination for sulfonated oleic acid, sodium salt.

Regulatory Decision

The Agency has determined that sulfonated oleic acid, sodium salt is eligible for reregistration provided that requested additional confirmatory data, which is needed to fulfill data gaps, are submitted to the Agency.

Summary of Mitigation Measures

Because no risks of concern were identified, no specific mitigation measures are needed for sulfonated oleic acid, sodium salt.

Data Requirements

Additional confirmatory and product-specific data are required to complete the reregistration of sulfonated oleic acid, sodium salt as described in Section V of this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient (a.i.), as well as a review of all submitted data by the U.S. Environmental Protection Agency. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks 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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency’s human health and ecological risk assessments and the Reregistration Eligibility Decision (RED) for sulfonated oleic acid, sodium salt.

As an active ingredient, sulfonated oleic acid, sodium salt is used as a sanitizer for non-porous dairy, beverage, brewery and food processing equipment. For these uses, sulfonated oleic acid, sodium salt is formulated as a liquid concentrate.

The Agency has concluded that the FQPA Safety Factor for sulfonated oleic acid, sodium salt should be removed (equivalent to 1X) based on: (1) the structural activity relationship analysis (SARs) conducted for sulfonated oleic acid, sodium salt and available data for other anionic surfactants (e.g., linear alkylbenzene sulfonates and alcohol sulfates) found no concerns for potential sensitivity to infants and children since all developmental effects occurred at or above those dose levels associated with maternal effects; and (2) the risk assessment does not underestimate the potential exposure for infants and children.

Risks summarized in this document are those that result only from the use of the active ingredient sulfonated oleic acid, sodium salt. The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide’s residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for sulfonated oleic acid, sodium salt and any other substances. Sulfonated

oleic acid, sodium salt does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that sulfonated oleic acid, sodium salt has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of sulfonated oleic acid, sodium salt. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for sulfonated oleic acid, sodium salt referenced in this RED. The risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.epa.gov/edocket.

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of sulfonated oleic acid, sodium salt and its regulatory history. Section III, Summary of Sulfonated Oleic Acid, Sodium Salt Risk Assessment, gives an overview of the human health and environmental assessments, based on the information available to the Agency. Section IV, Risk Management, Reregistration and Tolerance Reassessment, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. CHEMICAL OVERVIEW

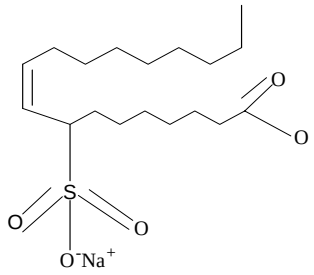
A. Regulatory History

Sulfonated oleic acid, sodium salt is registered as an active ingredient, no-rinse sanitizer for food processing facilities. The active ingredient consists of two chemical constituents, one as the primary ingredient (9-octadecenoic acid (9Z-), sulfonated, sodium salt, CAS No. 68443-05-0) and the other as a by-product of manufacturing (octadecanoic acid, sulfo, sodium salt, CAS No. 67998-94-1). There is currently one registered product containing 2.66% of sulfonated oleic acid, sodium salt (approximately 200 ppm) as an active pesticide ingredient (PER-VAD Low Foam Anionic Acid Sanitizer, Reg. No.875-90).

B. Chemical Identification

1. Technical Sulfonated Oleic Acid, Sodium Salt

a. 9-Octadecenoic acid (9Z-), sulfonated, sodium salt (Primary Ingredient)



Sulfonated Oleic acid, sodium salt

Common Name: Sulfonated oleic acid, sodium salt

Chemical Name: 9-Octadecenoic acid (9Z-), sulfonated, sodium salt

Other Name: Sodium sulfonated oleic acid

Chemical Family: Fatty Acid Salts

Case Number: 4069

CAS Registry Number: 68443-05-0

OPP Chemical Code: 079064

Molecular weight: 384.51

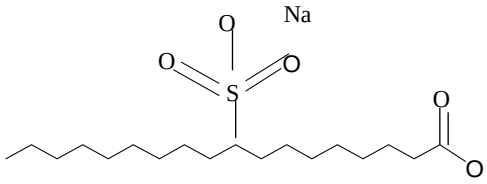
Empirical Formula: $C_{18}H_{33}NaO_5S$

Basic Manufacturers: DiversyLever

9-Octadecenoic acid (9Z-), sulfonated, sodium salt is a fatty acid derivative with a melting point of 312°C. 9-Octadecenoic acid (9Z-), sulfonated, sodium salt is dispersible in water. The vapor pressure of 9-octadecenoic acid (9Z-), sulfonated, sodium salt is less then 1×10^{-6} mmHg, and the boiling point is greater then 400°C.

2. By-Product Sulfonated Oleic Acid, Sodium Salt

a. Octadecanoic acid, sulfo, sodium salt



Common Name: Sulfonated oleic acid, sodium salt

Chemical Name: Octadecanoic acid, sulfo, sodium salt

Other Names: Sodium sulfonated oleic acid

Chemical Family: Fatty Acid Salts

Case Number: 4069

CAS Registry No.: 67998-94-1

OPP Chemical Code: To be established.

Molecular Weight: 386.52

Empirical Formula: $C_{18}H_{35}NaO_5S$

Basic Manufacturers: DiverseyLever

Octadecanoic acid, sulfo, sodium salt is a fatty acid derivative with a melting point of 311.7°C. Octadecanoic acid, sulfo, sodium salt has a water solubility of 608 mg/L. The estimated vapor pressure of octadecanoic acid, sulfo, sodium salt is 2.29×10^{-20} mmHg, and its boiling point is 712°C.

C. Use Profile

The following section provides information on the currently registered uses of the sulfonated oleic acid, sodium salt product. Included is an overview of the use sites and application methods of sulfonated oleic acid, sodium salt. Please refer to Appendix A for a comprehensive table of uses of sulfonated oleic acid, sodium salt eligible for reregistration.

Type of Pesticide: Bacteriacide/Sanitizer

Target Organism(s): Sulfonated oleic acid, sodium salt is used as a bacteriacide for animal pathogenic bacteria (g- and g+).

Use Sites: Food Uses: Sulfonated oleic acid, sodium salt is an indirect food contact sanitizer that is used on non-porous dairy, beverage, brewery and food processing equipment.

Use Classification: Sulfonated oleic acid, sodium salt is categorized as a general use pesticide.

Formulation Types: The sulfonated oleic acid, sodium salt product is formulated as a liquid soluble concentrate.

Application Rates/Methods: Sulfonated oleic acid, sodium salt can be applied manually by diluting 1 fl. oz. of the product per gallon of water (providing aproximatly 200 ppm of anionic active agent). The chemical is applied to surfaces in a variety of methods, which include brushing, flooding, immersion, or coarse droplet spraying of the sanitizing solution.

III. SUMMARY OF SULFONATED OLEIC ACID, SODIUM SALT RISK ASSESMENTS

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for sulfonated oleic acid, sodium salt. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket and may also be accessed on the Agency's website at http://epa.gov/dockets. Hard copies of these documents may be found in the OPP public docket under docket number OPP-2005-0261. The OPP public docket is located in Room 119, Crystal Mall II, 1801 Bell Street, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

A. Human Health Risk Assessment

1. Toxicity of Sulfonated Oleic Acid, Sodium Salt

A brief overview of the toxicity of sulfonated oleic acid, sodium salt is presented below. Further information on the toxicity of sulfonated oleic acid, sodium salt can be found in the document *Oleic Acid Sulfonates and Related Compounds: Antimicrobials Division Risk Assessment for the Reregistration Eligibility Decision (RED) Document and for Tolerance Reassessment* (Smegal, 2004) and in the memorandum *Similarity of Linear Alkylbenzene Sulfonates and Alcohol Sulfates to Sulfonated Oleic Acid with Respect to Toxicity* (McMahon, 2004), which are available on the Agency's website in the EPA Docket at http://www/epa.gov/edockets.

The Agency has reviewed all toxicity studies submitted for sulfonated oleic acid, sodium salt and has determined that the toxicological database is sufficient for reregistration. The toxicological database for sulfonated oleic acid, sodium salt is currently comprised of unpublished studies submitted to the Agency; however, limited data is available for sulfonated oleic acid, sodium salt. Given the limited toxicity data available for sulfonated oleic acid, sodium salt, the Agency conducted Structure Activity Relationship (SAR) assessments as well as considered toxicity data for other anionic surfactants that are believed to be toxicologically similar to sulfonated oleic acid, sodium salt (e.g., linear alkyl benzene sulfonate and alcohol sulfates). Based on data provided to the Agency, the EPA believes that alcohol sulfates have a greater similarity to oleic acid sulfonates than do the linear alkylbenzene sulfonates, which contain a benzene ring.

Table 1. Acute Toxicity of Sulfonated Oleic Acid, Sodium Salt

Test	Species	Results	MRID
Oral LD_{50}	Rat	>5000 mg/kg (Toxicity Category IV)	41861503
		>5000 mg/kg (a) (Toxicity Category IV)	43423804
Dermal LD_{50}	Rabbit	>2000 mg/kg (Toxicity Category III)	41861503
Inhalation LC_{50}	Rat	>207 mg/L (1-Hour) (Toxicity Category IV)	41861503
		>2.02 mg/L (4-Hour)(a) (Toxicity Category IV)	44008401
Dermal Irritation	Rabbit	Slight Erythema and Edema (Toxicity Category IV)	41861503
Eye Irritation	Rabbit	24-Hr: 19.3; 48-Hr: 12.3; 72-Hr: 13.3; 7-Day: 1 (Toxicity Category II)	

(a) Contains 2.6% sulfonated oleic acid, sodium salt (active)

General Toxicity Observations

Upon reviewing the available toxicity information, the Agency has concluded that there are no endpoints of concern for repeated oral, dermal, or inhalation exposure to sulfonated oleic acid, sodium salt. This conclusion is based on low toxicity observed in acute studies and Structure Activity Relationship (SAR) assessments. SAR assessments were performed in June 2004 by the Office of Pollution Prevention and Toxics (OPPT), and it was found that sulfonated oleic acid, sodium salt absorption is expected to be poor from the skin, moderate from the gastrointestinal tract and good from the lungs. There is concern for surfactant effects on the lung and irritation to the eye, skin (chronic), mucous membranes and lungs based on surfactant properties of the compound. Sulfonated oleic acid, sodium salt is judged to be of low to moderate toxicity concern. There are no concerns for mutagenicity, carcinogenicity, developmental or reproductive effects.

The FDA has approved the indirect food use of sulfonated oleic acid up to 200 ppm for food processing equipment and glass bottles for milk. This level of clearance is greater than the Agency's Level of concern for indirect food uses of antimicrobial pesticides (i.e., > 200 ppm); therefore, the Agency believes that sulfonated oleic acid, sodium salt is of a low order of toxicity. Furthermore, the Agency recognizes that sulfonated oleic acid, sodium salt is a fatty acid derivative. Fatty acids are processed by known metabolic pathways within the body and are necessary for normal cellular functioning. As the exposures anticipated from the indirect food uses (as well as non-dietary dermal and or inhalation exposure) are insignificant in comparison to levels encountered for fatty acids in the normal human diet, use of these chemicals in pesticide products is unlikely to pose any significant hazard to the general population or to any subgroup

including infants and children.

Carcinogenicity Classification

Based on the SAR assessments, there are no concerns of carcinogenicity for sulfonated oleic acid, sodium salt; therefore, no carcinogenic analysis is required.

Mutagenicity Potential

Based on the SAR assessments of sulfonated oleic acid, sodium salt, and information on structurally similar chemicals, there are no concerns for mutagenicity; therefore, no mutagenicity analysis is required.

2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X) to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, residential exposures, or to compensate for an incomplete database. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for sulfonated oleic acid, sodium salt for the following reasons: (1) The structural activity relationship (SARs) analyses conducted for sulfonated oleic acid, sodium salt and the available data for other anionic surfactants (e.g., linear alkylbenzene sulfonates and alcohol sulfates) found no concerns for potential sensitivity to infants and children because all developmental effects occurred at or above those dose levels associated with maternal effects; and, (2) The risk assessment does not underestimate the potential risk for infants and children. As confirmatory data to the SARs conducted by the Agency, a prenatal developmental toxicity study for sulfonated oleic acid, sodium salt is needed.

3. Population Adjusted Dose (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern. Since toxicological endpoints for the risk assessment were not identified based on the available data, RfDs and PADs have not been calculated for sulfonated oleic acid, sodium salt.

4. Dietary and Residential Risk Assessment

Dietary exposure could potentially occur from the use of sulfonated oleic acid, sodium salt as an active ingredient in food-contact sanitizing solutions. However, risk estimates have not been calculated for potential exposures to sulfonated oleic acid, sodium salt on food, in drinking water, or as a result of use in residential settings because there are no toxicological endpoints of concern according to a review of the available toxicity information and SARs assessments. There are no residential uses of sulfonated oleic acid, sodium salt and therefore risk estimates were not calculated for potential exposures in residential settings.

The Agency believes the possibility of surface and ground water contamination is low because sulfonated oleic acid, sodium salt shows a moderate to strong tendency to bind tightly with soils and sediments and shows a tendency to be immobile.

The FDA has approved the indirect food use of sulfonated oleic acid up to 200 ppm for food processing equipment and glass bottles for milk. This level of clearance is greater than the Agency s level of concern for indirect food uses of antimicrobial pesticides (i.e., > 200 ppb); therefore, the Agency believes that sulfonated oleic acid, sodium salt is of a low order of toxicity. Furthermore, the Agency recognizes that sulfonated oleic acid, sodium salt is a fatty acid derivative. Fatty acids are processed by known metabolic pathways within the body and are necessary for normal cellular functioning. As the exposures anticipated from the indirect food uses (as well as non-dietary dermal and or inhalation exposure) are insignificant in comparison to levels encountered for fatty acids in the normal human diet, use of this chemical in pesticide products is unlikely to pose any significant hazard to the general population or to any subgroup including infants and children.

5. Aggregate Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act require “that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information”(FFDCA, Section 408(b)(2)(A)(ii)). Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide and other non-occupational sources of exposure; however, it is important to note that there are no residential uses of sulfonated oleic acid, sodium salt.

Toxicological endpoints for the sulfonated oleic acid, sodium salt risk assessment were not identified based on the available data and therefore an aggregate risk assessment was not conducted for sulfonated oleic acid, sodium salt

6. Occupational Exposure

The occupational exposure assessment for sulfonated oleic acid, sodium salt addresses potential exposures and risks to humans who may be exposed in “occupational settings.” An occupational risk assessment is required for an active ingredient if certain toxicological criteria are triggered and there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For sulfonated oleic acid, sodium salt there is potential for exposure; however, there are no toxicological endpoints of concern according to a review of the available toxicity data and SAR analysis.

7. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), the Agency s Office of Pesticide Program s Incident Data System (IDS),

the California Pesticide Illness Surveillance Program, and the National Pesticide Telecommunications Network (NPTN). In the data sources available to the Agency, no reports of serious illness have been associated with human exposure to sulfonated oleic acid, sodium salt.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for sulfonated oleic acid, sodium salt use sites and any associated uncertainties. For further information concerning all aspects about the environmental risk assessment refer to the product chemistry, environmental fate and ecological toxicology in the sulfonated oleic acid, sodium salt risk assessment available on the Agency's website in the EPA Docket at http://www/epa.gov/edockets.

1. Environmental Fate and Transport

Sulfonated oleic acid, sodium salt shows a moderate to strong tendency to bind with soils and sediments and has a tendency to be immobile; however, various degradation models indicate that the dissipation pathway of sulfonated oleic acid, sodium salt is via biodegradation in soils and sediments and that sulfonated oleic acid, sodium salt dissipates within a maximum of a couple of weeks. Therefore, the possibility of surface and ground water contamination from sulfonated oleic acid, sodium salt is low.

Sulfonated oleic acid, sodium salt does not appear to persist in air for a long period of time and has an approximant half-life of six hours. There are no hydrolytic studies reported for sulfonated oleic acid, sodium salt. Various fate models indicate that the half-lives of oleic acid sulfonates in water will be similar to their half-lives in soils and sediments suggesting that (aerobically or anaerobically) sulfonated oleic acid, sodium salt will likely degrade in aquatic systems as readily as it does in soils and sediments.

In general, sulfonated oleic acid, sodium salt is not persistent in air, water, or soils and does not bio-accumulate in aquatic organisms. The Agency at this time has no concerns regarding the fate and transport processes of sulfonated oleic acid, sodium salt in air, soils or water.

2. Ecological Risk

a. Toxicity (Hazard) Assessment

The Agency conducted Structure Activity Relationship (SAR) assessments for sulfonated oleic acid, sodium salt as a result of there being no available eco-toxicity data (USEPA 2004). The results of the assessments are presented in Table 2. Sulfonated oleic acid, sodium salt is of moderate toxicity concern. It was found that the greater the length of the hydrophobe to the sulfonic acid, the greater the toxicity and surfactancy. Sulfonated oleic acid, sodium salt has a low potential for persistence, bioaccumulation and toxicity. Also, sulfonated oleic acid, sodium salt is immobile, binds moderately to strongly to sediment and soils and undergoes microbial

degradation within a few weeks, which is expected to mitigate any potential for risk. EPA believes that sulfonated oleic acid, sodium salt will not cause unreasonable adverse effects on the environment. Adequate review of labeling will reflect the results of the end-product acute toxicity testing and therefore should address all concerns.

Sulfonated oleic acid, sodium salt's labeled use as an active ingredient food-contact sanitizer is not expected to result in significant environmental exposure. Therefore, adverse effects on endangered/threatened terrestrial and aquatic animal species are not anticipated. However, the Agency is requesting confirmatory eco-toxicity data to support the registered uses of sulfonated oleic acid, sodium salt as an active pesticide ingredient. This information will fulfill labeling data requirements in the event that there is an accidental spill of the chemical during transport. For more information regarding the requested confirmatory data please refer to Section V of this document.

Table 2: Ecotoxicity of Oleic Acid Sulfonates

Parameter	Oleic acid, sulfonated, sodium salt (octadecanoic acid, sulfo, sodium salt) 67998-94-1	9-Octadecenoic acid (9Z-), sulfonated, sodium salt 68443-05-0
Fish 96-Hour LC_{50} (mg/L)	100, predicted	50, predicted
Daphnid 48-Hour LC_{50} (mg/L)	100, predicted	40, predicted
Green Algae 96-Hour LC_{50} (mg/L)	100, predicted	50,predicted
Chronic Fish Value (mg/L)	20, predicted	8, predicted
Chronic Daphnid Value (mg/L)	20, predicted	6, predicted
Chronic Algal Value (mg/L)	30, predicted	>10, predicted
SAR Conclusions	Moderate concern for toxicity	Moderate concern for toxicity

b. Risk to Threatened and Endangered Species

Due to the low likelihood of exposure and low toxicity of sulfonated oleic acid, sodium salt, the Agency expects no effects to listed species or critical habitat and therefore the Agency makes a "No Effect" determination for sulfonated oleic acid, sodium salt.

IV. RISK MANAGEMENT, REREGISTRATION AND TOLERANCE REASSESMENT DECSION

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of generic (i.e., active ingredient-specific) data to support reregistration of products containing sulfonated oleic acid, sodium salt as an active ingredient. The Agency has completed its review of the generic data and has determined that the data are sufficient to support reregistration of all products containing sulfonated oleic acid, sodium salt.

The Agency has completed its assessment of the dietary, occupational and ecological risks associated with the use of pesticide products containing the active ingredient sulfonated oleic acid, sodium salt. Based on a review of the data and other available information for the active ingredient, sulfonated oleic acid, sodium salt, the Agency has concluded that they have sufficient information on the human health and ecological effects of sulfonated oleic acid, sodium salt to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that sulfonated oleic acid, sodium salt containing products are eligible for reregistration provided that current data gaps and confirmatory data needs are addressed. Appendix A summarizes the uses of sulfonated oleic acid, sodium salt that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of sulfonated oleic acid, sodium salt and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

B. Public Comments and Responses

Risk assessments for sulfonated oleic acid, sodium salt were not issued for public comment per the Agency's public participation process because no toxicological endpoints were identified, and as such, these assessments were qualitative in nature. To ensure that an opportunity is presented to the public to comment on the risk assessments and risk management decisions for sulfonated oleic acid, sodium salt, the Agency will implement a public comment period on the oleic acid sulfonates RED document.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA has concluded that there are no endpoints of concern for oral, dermal, or inhalation exposure to sulfonated oleic acid, sodium salt based on a review of the available toxicity information. The Agency has concluded that the established tolerance exemption for sulfonated oleic acid, sodium salt meets the FQPA safety standards and that the risk from dietary (food sources only) exposure is within the "risk cup." An aggregate assessment was not conducted for exposures through food, drinking water and residential exposure since toxicological endpoints for the risk assessment of sulfonated oleic acid, sodium salt were not identified based on the available data. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children.

b. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with sulfonated oleic acid, sodium salt. The Agency has determined that the established tolerance exemption for sulfonated oleic acid, sodium salt meets the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of sulfonated oleic acid, sodium salt as an active ingredient in food-contact sanitizing solutions. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices, exposure scenarios and environmental behavior of sulfonated oleic acid, sodium salt.

Because no toxicological endpoints were identified for sulfonated oleic acid, sodium salt, a qualitative risk assessment was conducted. Based on this assessment, risks are not of concern for sulfonated oleic acid, sodium salt.

c. Determination of Safety to Infants and Children

The EPA has determined that the established tolerance exemption for sulfonated oleic acid, sodium salt meets the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, and that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the toxicity, use practices and environmental behavior of sulfonated oleic acid, sodium salt as noted above for the general population. The safety determination for infants and children also takes into consideration the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of sulfonated oleic acid, sodium salt residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of sulfonated oleic acid, sodium salt, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed and other information.

The FQPA Safety Factor has been removed (i.e., reduced to 1X) for sulfonated oleic acid, sodium salt because there is no pre- or post-natal evidence for increased susceptibility following exposure; however, a prenatal developmental toxicity study for sulfonated oleic acid, sodium salt is required as confirmatory data to support the Agency's SARs findings. The risk assessment does not underestimate the potential exposure for infants and children.

d. Endocrine Disruptor Effects

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

When the appropriate screening and or testing protocols being considered under the EDSP have been developed, sulfonated oleic acid, sodium salt may be subject to additional screening and or testing.

e. Cumulative Risks

Risks summarized in this document are those that result only from the use of sulfonated oleic acid, sodium salt as an active ingredient in food-contact sanitizers. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residue and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which the EPA has followed a cumulative risk approach based on a common mechanism of toxicity, the EPA has not made a common mechanism of toxicity finding for sulfonated oleic acid, sodium salt. For further information regarding the EPA s efforts to determine which chemicals have a common

mechanism of toxicity and to evaluate the cumulative effects of such chemicals, refer to the EPA s website at: http://www.epa.gov/pesticides/cumulative/.

2. Tolerance Reassessment Summary

a. Tolerance Exemptions and Tolerance Reassessment

A tolerance exemption for residues of sulfonated oleic acid, sodium salt is established under 40 CFR 180.940(c) (69 FR 23136, Apr. 28, 2004).

A tolerance exemption is currently established for sulfonated oleic acid, sodium salt when used in accordance with good manufacturing practice as an ingredient in antimicrobial pesticide formulations, provided that the substance is applied on a semi-permanent or permanent food-contact surface (other than being applied on food packaging) with adequate draining before contact with food. When used as an ingredient in antimicrobial pesticide formulations, sulfonated oleic acid, sodium salt may be applied to: food-processing equipment and utensils (40 CFR 180.940(c)).

Sulfonated oleic acid, sodium salt (CAS No. 68443-05-0) has limitations for the ready-to-use end-use concentration not to exceed 200 parts per million (ppm). The Agency is proposing to amend the current tolerance exemption for the active ingredient, sulfonated oleic acid, sodium salt, to increase the chemicals current tolerance limit of 200 ppm to 230 ppm. Increasing the existing tolerance limit from 200 ppm to 230 ppm will account for rates currently labeled on the registered product.

A new tolerance exemption 180.940(b) to account for the use of sulfonated oleic acid, sodium salt as an active ingredient in food-contact sanitizing solutions for dairy processing equipment is needed to support this use.

Table 3. Tolerance Reassessment Summary

Tolerance Exemptions Listed Under 40 CFR § 180.940 (c)				
Nomenclature or Synonyms	**Use Site/ Pattern (Pesticidal)**	**Current Limit (ppm)**	**Tolerance Reassessment (ppm)**	**Correct Definition/Comment**
Sulfonated oleic acid, sodium salt	Food-contact sanitizing solutions for food-processing equipment and utensils.	200 ppm (end-use concentration)	230 ppm (end-use concentration)	Sulfonated oleic acid, sodium salt (9-octadecenoic acid (9Z-), sulfonated, sodium salt) is exempted from the requirement of a tolerance as an antimicrobial pesticide when used in accordance with good manufacturing practice as an ingredient in an antimicrobial pesticide formulation, provided that the substance is applied on a semi-permanent or permanent food-contact surface (other than being applied on food packaging) with adequate draining before contact with food. (40 CFR 180.940(c)).
Tolerance Exemption to be Proposed Under 40 CFR § 180.940 (b)				
Nomenclature or Synonyms	**Use Site/ Pattern (Pesticidal)**	**Current Limit (ppm)**	**Tolerance Reassessment (ppm)**	**Correct Definition/Comment**
Sulfonated oleic acid, sodium salt	Sanitizing solutions for dairy processing equipment, and food-processing equipment and utensils.	200 ppm (end-use concentration)	230 ppm (end-use concentration)	Sulfonated oleic acid, sodium salt (9-octadecenoic acid (9Z-), sulfonated, sodium salt) is exempted from the requirement of a tolerance as an antimicrobial pesticide when used in accordance with good manufacturing practice as an ingredient in an antimicrobial pesticide formulation, provided that the substance is applied on a semi-permanent or permanent food-contact surface (other than being applied on food packaging) with adequate draining before contact with food. (40 CFR 180.940(b)).

b. Codex Harmonization

Currently there are no codex MRLs established for sulfonated oleic acid, sodium salt.

D. Regulatory Rationale

The Agency has determined that sulfonated oleic acid, sodium salt is eligible for reregistration provided that requested additional confirmatory data, which is needed to fulfill data gaps, are submitted to the Agency.

The following is a summary of the rationale for managing risks associated with the use of sulfonated oleic acid, sodium salt as an active ingredient. The Agency feels there is reasonable certainty of no harm resulting from exposure to sulfonated oleic acid, sodium salt as an active

ingredient (sanitizer) to the general population and to infants and children in particular. The Agency also believes there is a low to moderate toxicity concern for ecological effects based on the Structure Activity Relationship (SAR) assessment that the Agency has conducted. As a result of the expected low risk for toxicity and low human and environmental exposure rates from sulfonated oleic acid, sodium salt, the Agency determined that a qualitative approach to assessing human health risks and ecological risks from exposure to sulfonated oleic acid, sodium salt was appropriate. Therefore, no mitigation measures are necessary at this time.

However, the Agency is requesting confirmatory eco-toxicity data to further support the findings of the SAR conducted by the Agency. The confirmatory eco-toxicity data to support the registered use of sulfonated oleic acid, sodium salt as a pesticide active ingredient is a FIFRA data requirement for labeling in the event that there is an accidental spill during transport of the chemical.

1. Listed Species Considerations

a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means “to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species” (50 C.F.R. § 402.02).

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2), the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may (directly or indirectly) significantly reduce the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency’s screening-level risk assessment is performed, if any of the Agency’s Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If it is determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (*Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency -*

Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment and are considered to fall under a “no effect” determination. Due to the low likelihood of exposure and the low toxicity of sulfonated oleic acid, sodium salt, the Agency expects no effects to listed species or critical habitat and therefore makes a "No Effect" determination for this chemical.

b. General Risk Mitigation

Sulfonated oleic acid, sodium salt end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing sulfonated oleic acid, sodium salt specific to federally listed threatened and endangered species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all threatened and endangered species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting threatened and endangered species risk mitigation measures, the more stringent measure(s) should be adopted.

2. Labeling

a. Label Amendment

Currently, no label amendments are necessary in order for sulfonated oleic acid, sodium salt products to be eligible for reregistration.

V. WHAT REGISTRANTS NEED TO DO

The Agency has determined that sulfonated oleic acid, sodium salt is eligible for reregistration provided that additional data are submitted to confirm this decision. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring product-specific data and additional generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or to request time extension and or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below is a table of additional generic data that the Agency intends to require for sulfonated oleic acid, sodium salt to be eligible for reregistration. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

The registrant needs to submit the following items:

Within 90 days from receipt of the generic data call in (DCI):

1. Completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and,

2. Submit any time-extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. Cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Jennifer Slotnick at (703) 305-0601 with questions regarding generic reregistration.

By US mail:
Document Processing Desk (DCI/SRRD)
Jennifer Slotnick
US EPA (7510C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Jennifer Slotnick
Office of Pesticide Programs (7510C)
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202

The registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. Completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

2. Submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. Two copies of the confidential statement of formula (EPA Form 8570-4);

2. A completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

3. Five copies of the draft label incorporating all label amendments outlined in Table 13 of this document;

4. A completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

5. If applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

6. The product-specific data responding to the PDCI.

Please contact Adam Heyward at (703) 308-6422 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PDCI/PRB)
Adam Heyward
US EPA (7510C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/PRB)
Adam Heyward
Office of Pesticide Programs (7510C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

A. Manufacturing-Use Products

There are currently no registered manufacturing-use products for sulfonated oleic acid, sodium salt; therefore, the end-use manufacturer is responsible for the submission of any generic data requirements requested by the Agency.

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of sulfonated oleic acid, sodium salt for the above eligible uses has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory and are included in the generic DCI for this RED.

Table 4: Data Requirements for the Reregistration Eligibility Decision of Sulfonated Oleic Acid, Sodium Salt

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Dermal Sensitization	870.2600	81-6
90-Day Oral Toxicity Study in Rodents with TGAI	870.3100	82-1a
Prenatal Developmental Toxicity Study in Rodents	870.3700	83-3
Fresh Water Fish Acute Toxicity Study with TGAI	850.1075	72-1
Fresh Water Invertebrate Acute Toxicity Study with TGAI	850.1010	72-2
Avian Acute Oral Toxicity Study with TGAI	850.2100	71-1

B. End-Use Products

1. Additional Product-Specific Data and Efficacy Requirements

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 registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate Product-Specific Data Call-In (PDCI), outlining specific data requirements.

Efficacy data are required to ensure that the described labeled use of sulfonated oleic acid, sodium salt as a food-contact sanitizer in end-use products is accurate and effective. The Registrant must submit as efficacy data to the Agency, Guideline No. 810.2100 (m)(2), *AOAC Germicidal and Detergent Sanitizers Method Study* (Reg. No. 875-90) for sulfonated oleic acid, sodium salt.

VI. APENDICIES

Appendix A: Use Patterns Eligible for Reregistration

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Food handling/storage establishments premises and equipment				
Beverage Processing Equipment	Liquid Concentrate (Reg No. 875-90)	Brushing; Flooding; Immersion; Coarse Droplet Spraying ; Circulation Sanitizing	1 fl. ounce of Per-Vad per gallon of water (providing 200 ppm of anionic active agent). Thoroughly wet all surfaces by listed application methods. Allow sanitizer to contact surface for at least 1 minute. Allow surfaces to drain adequately before resuming operation.	Do not reuse circulated sanitizer for additional sanitizing.
Brewery Processing Equipment	Liquid Concentrate (Reg. No. 875-90)	Flooding; Immersion; Coarse Droplet Spraying; Circulation Sanitizing	1 fl. ounce of Per-Vad per gallon of water (providing 200 ppm of anionic active agent). Thoroughly wet all surfaces by listed application methods. Allow sanitizer to contact surface for at least 1 minute. Allow surfaces to drain adequately before resuming operation.	Do not reuse circulated sanitizer for additional sanitizing.
Food Processing Equipment	Liquid Concentrate (Reg. No. 875-90)	Flooding; Immersion; Coarse Droplet Spraying; Circulation Sanitizing	1 fl. ounce of Per-Vad per gallon of water (providing 200 ppm of anionic active agent). Thoroughly wet all surfaces by listed application methods. Allow sanitizer to contact surface for at least 1 minute. Allow surfaces to drain	Do not reuse circulated sanitizer for additional sanitizing.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			adequately before resuming operation.	
Food Contact Surfaces (Hard Non-Porous)	Liquid concentrate (Reg No.875-90)	Flooding; Immersion; Coarse Droplet Spraying; Circulation Sanitizing	1 fl. ounce of Per-Vad per gallon of water (providing 200 ppm of anionic active agent). Thoroughly wet all surfaces by listed application methods. Allow sanitizer to contact surface for at least 1 minute. Allow surfaces to drain adequately before resuming operation.	Do not reuse circulated sanitizer for additional sanitizing.
Milk Processing Equipment	Liquid concentrate (Reg. No.875-90)	Flooding; Immersion; Coarse Droplet Spraying; Circulation Sanitizing	1 fl. ounce of Per-Vad per gallon of water (providing 200 ppm of anionic active agent). Thoroughly wet all surfaces by listed application methods. Allow sanitizer to contact surface for at least 1 minute. Allow surfaces to drain adequately before resuming operation.	Do not reuse circulated sanitizer for additional sanitizing.

Appendix B: Studies Used to Support the Reregistration of Oleic Acid Sulfonates

Guide to Appendix B

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of oleic acid sulfonates. These requirements apply to sulfonated oleic acid in all products, including data requirements for which a technical grade active ingredient is the test substance. The data table is organized in the following formats:

1. **Data Requirement** (Columns 1 and 2). The data requirements are listed by Guideline Number. The first column lists the new Part 158 Guideline Numbers, and the second column lists the old Part 158 Guideline Numbers. Each Guideline Number has an associated test protocol set forth in the Pesticide Assessment Guidance, which are available on the EPA website.

2. **Guideline Description** (Column 3). Identifies the guideline type.

3. **Use Pattern** (Column 4). This column indicates the standard Antimicrobial Division use patterns categories for which the generic (not product specific) data requirements apply. The following number designations are used in Appendix B:
   (1) Agricultural premises and equipment
   (2) Food handling/storage establishment premises and equipment
   (3) Commercial, institutional and industrial premises and equipment
   (4) Residential and public access premises
   (5) Medical premises and equipment
   (6) Human water systems
   (7) Materials preservatives
   (8) Industrial processes and water systems
   (9) Antifouling coatings
   (10) Wood preservatives
   (11) Swimming pools
   (12) Aquatic areas

4. **Bibliographic Citation** (Column 5). If the Agency has data in its files to support a specific generic Guideline requirement, this column will identity each study by a "Master Record Identification" (MRID) number. The listed studies are considered "valid" and acceptable for satisfying the Guideline requirement. Refer to the Bibliography appendix for a complete citation of each study.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
		PRODUCT CHEMISTRY		
830.1550	61-1	Product Identity and Composition	2	43057701
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process	2	43057701
830.1670	61-2b	Formation of Impurities /Discussion of Impurities	2	43057701
830.1700	62-1	Preliminary Analysis	2	43057702
830.1750	62-2	Certification of Limits	2	43057702
830.1800	62-3	Analytical Method	2	43057702
830.6302	63-2	Color	2	43057703
830.6303	63-3	Physical State	2	43057703
830.6304	63-4	Odor	2	43057703
830.7050	None	UV/Visible Absorption	2	Waived[1]
830.7200	63-5	Melting Point	2	Inapplicable
830.7220	63-6	Boiling Point	2	43057703[2]
830.7300	63-7	Density	2	43057703[2]
830.7840 830.7860	63-8	Solubility	2	43057703[2]
830.7950	63-9	Vapor Pressure	2	43057703
830.7370	63-10	Dissociation Constant in Water	2	Inapplicable

[1] Study waived because the chemical structure shows that it will not absorb in the UV spectral region.
[2] Based on formula with 50% active ingredient (a.i.).

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)	2	Inapplicable
830.7000	63-12	pH	2	43057703
830.6313	63-13	Stability	2	43057703
830.6314	63-14	Oxidizing/Reducing Action	2	Inapplicable
830.6315	63-15	Flammability	2	Inapplicable
830.6316	63-16	Explodability	2	Inapplicable
830.6317	63-17	Storage Stability	2	Inapplicable
830.7100	63-18	Viscosity	2	Inapplicable
830.6319	63-19	Miscibility	2	Inapplicable
830.6320	63-20	Corrosion Characteristics	2	Inapplicable
830.6321	63-21	Dielectric breakdown voltage	2	Inapplicable
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity Test	2	Data Gap
850.2200	71-2	Avian Dietary Toxicity	2	Inapplicable
850.1075	72-1	Fish Acute Toxicity - Freshwater	2	Data Gap
850.1010	72-2	Acute Aquatic Invertebrate Toxicity	2	Data Gap
850.1075	72-3a	Acute Estuarine/Marine Toxicity - Fish	2	Inapplicable
850.1025	72-3b	Acute Estuarine/Marine Toxicity - Invertebrate (Mollusk)	2	Inapplicable
	72-3c	Estuarine/Marine Toxicity - Invertebrate (Shrimp)	2	Inapplicable
TOXICOLOGY				
870.1100	81-1	Acute Oral - Rat	2	41861503, 43423804

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.1200	81-2	Acute Dermal - Rabbit	2	41861503
870.1300	81-3	Acute Inhalation - Rat	2	41861503, 44008401
870.2400	81-4	Primary Eye Irritation - Rabbit	2	41861503
870.2500	81-5	Primary Dermal Irritation - Rabbit	2	41861503
870.2600	81-6	Dermal Sensitization	2	Data Gap
870.3100	82-1a	90-Day Feeding-Rodent	2	Data Gap
	82-1b	90-Day Feeding-Non-Rodent	2	Inapplicable
870.3200	82-2	21/28-Day Dermal Toxicity - Rat	2	Inapplicable
870.3250	82-3	90-day Dermal Toxicity - Rodent	2	Inapplicable
870.3465	82-4	90-Day Inhalation - Rat	2	Inapplicable
870.3700	83-3	Developmental Toxicity	2	Data Gap
870.3800	83-4	Reproduction and Fertility Effects - 2 Generation Repro	2	Inapplicable
870.4100	83-1a	Chronic Feeding Toxicity - Rodent	2	Inapplicable
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity	2	Inapplicable
870.4100	83-1b	Chronic Feeding Toxicity - Non-Rodent (dog)	2	Inapplicable
870.4200	83-2a	Oncogenicity - Rat	2	Inapplicable
870.4300	83-2b	Oncogenicity - Mouse	2	Inapplicable
870.5265	84-2	Bacterial Reverse Mutation Assay	2	Waived[3]
870.5385	84-2	Micronucleus Assay	2	Waived[3]
870.5375	84-2	Cytogenic assay with human lymphocytes	2	Waived[3]
870.5550	84-2	UDS Assay	2	Waived [3]

[3] Study waived because based on the SAR assessments and information on structurally similar chemicals, there are no concerns for mutagenicity; therefore, no mutagenicity analysis is required.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.7485	85-1	General Metabolism	2	Inapplicable
870.7600	85-2	Dermal Absorption	2	Inapplicable
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2400 875.2900	133-3	Dermal Passive Dosimetry	2	Inapplicable
875.2500 875.2900	133-4	Inhalation Passive Dosimetry	2	Inapplicable
875.1200 875.1600	233	Dermal Indoor Exposure	2	Inapplicable
875.1400 875.1600	234	Inhalation Indoor Exposure	2	Inapplicable
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	2	Inapplicable

Appendix C: Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 Bell Street, Arlington, VA. The OPP docket is open Monday through Friday, excluding legal holidays, from 8:30 am to 4:00 pm.

All documents in hard copy form may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following web-sites:

http://www.epa.gov/pesticides/antimicrobials
http://www.epa.gov/edockets

There are two technical supporting documents for the sulfonated oleic acid, sodium salt RED. These documents include:

U.S. Environmental Protection Agency (USEPA). Memorandum from D. Smegal & N. Shamim to K. Boyle. *Oleic Acid Sulfonates and Related Compounds: Antimicrobials Division Risk Assessment for the Reregistration Eligibility Decision (RED) Document and for Tolerance Reassessment,* (Barcode D308389). September 30, 2004.

U. S. Environmental Protection Agency (USEPA). Memorandum from T. McMahon to D. Smegal. *Similarity of Linear Alkylbenzene Sulfonates and Alcohol Sulfates to Sulfonated Oleic Acid with Respect to Toxicity*, (Barcode D308387). September 23, 2004.

U.S. Environmental Protection Agency (USEPA). Memorandum from T. McMahon. *Sulfonated Oleic Acid- Report of the Antimicrobials Division Toxicology Endpoint Selection Committee.* May 6, 2003.

Appendix D: Generic Data Requirements and Studies Used to Make the Reregistration Decision (Bibliography)

MRID STUDIES

MRID#	Citation
41861503	Slover, A. (1991) Toxicity Test Results: Sodium Salt of Sulfonated Oleic Acid: Lab Project Number: 8020529. Unpublished study prepared by Morgan Gallacher, Inc. 17 p.
43423804	Christopher, S. (1994) PER-VAD: Acute Peroral Toxicity Testing Using the Rat: Lab Project Number: 94N1449. Unpublished study prepared by Union Carbide Corp., Bushy Run Research Center. 28 p.
44008401	Douds, D. (1996) An Acute Whole-Body Inhalation Toxicity Study in Rats with PER-VAD: Final Report: Lab Project Number: 3385.6. Unpublished study.

OPEN LITERATURE

JohnsonDiversey. Memorandum from F. Heitfeld to L. Amadio. *Toxicity Review of Sulfonated Oleic Acid, Sodium Salt.* September 2, 2004.

INTERNAL LITERATURE

U.S. Environmental Protection Agency (USEPA). Memorandum from D. Smegal & N. Shamim to K. Boyle. *Oleic Acid Sulfonates and Related Compounds: Antimicrobials Division Risk Assessment for the Reregistration Eligibility Decision (RED) Document and for Tolerance Reassessment*, (Barcode D308389). September 30, 2004.

U.S. Environmental Protection Agency (USEPA). 2002. Memorandum from K. Boyle and K. Leifer to F. Forrest. *IIFG Decision Documents on Reassessment of Exemptions from the Requirement of a Tolerance for Fatty Acids*. July 21, 2002.

U.S. Environmental Protection Agency (USEPA). 2002. Memorandum from S.C. Termes & H. Craven to M. Perry. *Tolerance Review of Compounds Known as Fatty Acids, Fatty Acid Salts, and Fatty Acid Esters, and Fatty Acid Derivatives Classified as Inert Ingredients in Terrestrial and/or Aquatic Agricultural and Non-Agricultural Uses*. May 15, 2002.

U. S. Environmental Protection Agency (USEPA). Memorandum from T. McMahon to D. Smegal. *Similarity of Linear Alkylbenzene Sulfonates and Alcohol Sulfates to Sulfonated Oleic Acid with Respect to Toxicity*, (Barcode D308387). September 23, 2004.

U.S. Environmental Protection Agency (USEPA). Memorandum from T. McMahon. *Sulfonated Oleic Acid- Report of the Antimicrobials Division Toxicology Endpoint Selection Committee.* May 6, 2003.

U.S. Environmental Protection Agency (USEPA), 2004. *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations*, Appendix A, Section IIB, pg.81. U.S. Environmental Protection Agency. January 24, 2004. http://www.epa.gov/oppfead1/endanger/consultation/ecorisk-overview.pdf.

U.S. Environmental Protection Agency (USEPA). 2004. *Structure Activity Relationship (SAR) for Octadecanoic acid, sulfo, sodium salt (67998-94-1); 9-Octadecen-1-ol, hydrogen-sulfate, sodium salt, (Z)- (1847-55-8); 9-Octadecenoic acid, 12-(Sulfooxy)-,Disodium-salt, [R-(Z)] (61702-68-9); 9-Octadecenoic Acid, 12-(Sulfooxy)-, Monosodium Salt, (9Z,12R)- (29704-46-9); 9-Octadecenoic acid, 12-(sulfooxy)-, sodium salt , (9Z,12R)-(8043-44-5); Octadecanoic acid, 9(or 10)-sulfooxy)-monosodium salt (68964-56-7); Octadecanoic acid, 9(or 10)-(sulfooxy)-, sodium salt (68331-91-9); Octadecanoic acid, 9-(sulfooxy)-,sodium salt (68413-72-9); Octadecanoic acid, 9-(sulfooxy)-, disodium salt-(65151-76-0); 9-Octadecenoic acid (9Z)-sulfonated, sodium salt (68443-05-0); 9-Octadecenoic acid (9Z)-sulfonated (68988-76-1).* Structure Activity Team Report. OPPT. June 8, 2004.

WEBSITE REFRENCES

Environmental Protection Agency, 2005. "Estimation Program Interface (EPI) Suite". http://www.epa.gov/oppt/exposure/docs/episuite.htm. 2005.

Human and Environmental Risk Assessment (HERA), 2004. "Linear Alkylbenzene Sulphonate (CAS No. 68411-30-3)". May 2004. http://www.heraproject.com/RiskAssessment.cfm

Human and Environmental Risk Assessment (HERA), 2002. "Human and Environmental Risk Assessment on the Ingredients of European Household Cleaning Products, Alcohol Sulphates Human Health Risk Assessment, Draft". December 2002. http://www.heraproject.com/RiskAssessment.cfm

Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In (DCI) at a later date. See Chapter V of the oleic acid sulfonates RED for a list of studies that the Agency plans to require.

Appendix F: Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In (DCI) at a later date for the oleic acid sulfonates RED.

Appendix G: **EPA's Batching of Sulfonated Oleic Acid, Sodium Salt Products for Meeting Acute Toxicity Data Requirements for Reregistration**

Batching of sulfonated oleic acid, sodium salt products is unnecessary and will not be conducted to meet acute toxicity data requirements for reregistration as a result of there being only one registered product for sulfonated oleic acid, sodium salt.

If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards, the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. The Agency must approve any new or canceled formulations (that were presented to the Agency after the publication of the RED) before data derived from them can be used to cover other products. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material(s) by an EPA Registration Number. If more than one Confidential Statement of Formula (CSF) exists for a product, the registrant must indicate the formulation tested by identifying the corresponding CSF.

In deciding how to meet the product-specific data requirements, registrants must follow the directions given in the Data Call-In (DCI) Notice and its attachments appended to the RED. The DCI Notice contains two response forms that are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. If a registrant supplies data he/she must select one of the following options: (Option 1) Developing Data; (Option 4) Submitting an Existing Study; (Option 5) Upgrading an Existing Study; or, (Option 6) Citing an Existing Study. If a registrant depends on another's data, he/she must choose among: (Option 2) Cost Sharing; (Option 3) Offers to Cost Share; or, (Option 6) Citing an Existing Study.

Appendix H: List of Registrants Sent the Data Call-In

A list will be posted, at a later date, of the registrants who were sent a copy of the oleic acid sulfonates RED Data Call-In.

Appendix I: List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/

Online Pesticide Registration Forms are in PDF format; which, to be properly viewed, requires the use of Acrobat reader software.

Instructions:

1. Print out and complete appropriate forms (Note: Form numbers formatted in bold print may be filled out on the computer, printed and submitted to the Agency).

2. The completed form(s) must be submitted to the Agency in hard copy in accord with existing Agency policy.

3. Mail the form(s), along with any additional documents, necessary to comply with the EPA regulations pertaining to your request. Forms may be mailed to the Document Processing Desk address listed below.

DO NOT fax or e-mail any form(s) containing 'Confidential Business Information' (CBI) or 'Sensitive Information.'

If you have any problems accessing the electronic forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epa.gov.

The following is a comprehensive list of Agency pesticide registration forms, which are currently available on the internet. Form numbers, titles and internet address locations are provided:

U.S. EPA Pesticide Registration Forms

Form Number	Title	Internet Address Location
8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf

Form Number	Title	Internet Address Location
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit

The U.S. EPA's pesticide registration kit can be accessed at the following web address:

www.epa.gov/pesticides/registrationkit/

For convenience of the registrant, the US EPA has assembled an online registration kit, which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

a. 83-3 Label Improvement Program--Storage and Disposal Statements
b. 84-1 Clarification of Label Improvement Program
c. 86-5 Standard Format for Data Submitted under FIFRA
d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
b. EPA Form No. 8570-4, Confidential Statement of Formula
c. EPA Form No. 8570-27, Formulator's Exemption Statement
d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

a. Registration Division Personnel Contact List
b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
c. Antimicrobials Division Organizational Structure/Contact List
d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)

5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: http://npic.orst.edu/

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

1. Date of receipt;
2. EPA identifying number; and
3. Product Manager assignment.

Other identifying information may be included by the applicant as a means to link the acknowledgment of receipt to the specific application submitted. The EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a Chemical Abstract System (CAS) number if one has been assigned.