United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA 739-R-06-006
July 2006

Reregistration Eligibility Decision for Alkylbenzene 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 (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessments for the antimicrobial alkylbenzene sulfonates (ABS). The enclosed Reregistration Eligibility Decision (RED) document was approved on July 27, 2006.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for alkylbenzene sulfonates and its associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting risk assessments for alkylbenzene sulfonates are available to the public on the U.S. Federal Government website www.regulations.gov. The docket is EPA-HQ-OPP-2006-0156.

The alkylbenzene sulfonates RED was developed through EPA's public participation process, published in the Federal Register on September 10, 2004, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the alkylbenzene sulfonates risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, occupational, residential and ecological risks posed by exposure to alkylbenzene sulfonates alone. This document also identifies both generic and product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. Additionally, 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 alkylbenzene sulfonates will be eligible for reregistration provided that all the conditions identified in this document are satisfied. Sections IV and V of this RED document describe the necessary labeling amendments for end-use products and data requirements. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that will accompany this DCI.

If you have questions on this document or the label changes relevant to this reregistration decision, please contact the Chemical Review Manager, Heather Garvie, at (703) 308-0034. For questions about product reregistration and/or the Product DCI that will follow this document, please contact Adam Heyward at (703) 308-6422.

Sincerely,

Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY
DECISION
for
Alkylbenzene Sulfonates
List D
CASE 4006

Approved By:

Frank T. Sanders
Director, Antimicrobials Division
July 27, 2006

Attachment

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
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
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24C of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed preliminary risk assessments and its review of error correction and public comments on the human health and environmental risk assessments for alkylbenzene sulfonates and is issuing its risk management decision. The Agency will accept public comments on this decision and supporting documents for 60 days following publication. The Agency has decided alkylbenzene sulfonates are eligible for reregistration provided all measures outlined in this document are implemented. If during the comment period the Agency receives new or additional information that substantially changes the risk assessment findings or the risk management decision, the Agency will issue an amendment to this document.

Alkylbenzene sulfonates are used largely as food-contact sanitizers in food processing plants and eating establishments. They are also used as disinfectants and sanitizers for agricultural, commercial, institutional, industrial, and public access uses. Approximately 300,000 pounds of alkylbenzene sulfonates are used in EPA registered antimicrobial products. However, the largest overall use of alkylbenzene sulfonates is in household laundry and dish detergents. The alkylbenzene sulfonates are listed on the EPA High Production Volume (HPV) Challenge Program. HPV chemicals are those that are manufactured or imported into the U.S. in production volumes greater than one million pounds per year.

Overall Risk Summary

An acute dietary assessment was not conducted because there are no adverse effects attributable to a single dose seen in animal studies. Chronic dietary risk estimates were provided for the general U.S. population and all population subgroups. All chronic dietary risk estimates are below the Agency's level of concern.

Because there are no adverse effects attributable to acute exposure, an acute aggregate assessment was not conducted. An intermediate-term aggregate assessment was not conducted because there are no residential exposures of this duration. Therefore, only short-term and chronic aggregate assessments were conducted. In addition, because there are no long-term residential exposures, the chronic aggregate assessment only considered food and drinking water exposures. The short-term aggregate assessment considers both the active and inert uses of the alkylbenzene sulfonates. The chronic aggregate assessment considers average dietary exposure (food and drinking water) from both the active food contact sanitizer uses and the inert uses on agricultural commodities. The dietary exposures from the fruit and vegetable wash were not considered because it would be overly conservative to assume simultaneous exposure to alkylbenzene sulfonates from three different use patterns. The short-term aggregate oral and inhalation risks are not of concern for adults or children. In addition, the chronic aggregate assessment found no risk of concern for children or adults.

The Agency's human heath risk assessment indicates that there are four occupational handler inhalation scenarios with MOEs less than the target of 100. These four scenarios have MOEs between 90 and 93. Although these MOEs are below the Agency target of 100, the

Agency is not requiring mitigation since the risk assessment is based on conservative assumptions and the MOEs are very close to the target so that the Agency does not have risk concerns.

Dermal exposures were not considered in the risk assessment because a toxicological endpoint was not established for this route of exposure.

An environmental risk assessment was also conducted for alkylbenzene sulfonates. Due to limited potential for environmental exposure, environmental risks are below the Agency's level of concern.

Dietary Risk

The Agency conducted three chronic dietary exposure and risk assessments for alkylbenzene sulfonates: (1) as an active ingredient in food contact sanitizing solutions; (2) as an active ingredient in a fruit and vegetable wash; and (3) as an inert ingredient in pesticide formulations that may be applied to growing agricultural crops, raw agricultural commodities after harvest, and to animals. An acute dietary assessment was not conducted because there are no adverse effects attributable to a single dose in animal studies.

The dietary risk estimates for the active ingredient, total food contact sanitizing uses are below the Agency's level of concern for the general U.S. population for all age groups (less than 11% of the cPAD). The dietary risk estimates for the fruit and vegetable wash are also below the Agency's level of concern for all age groups (less than 71.2% of the cPAD).

The dietary risk estimates for the inert ingredient uses are below the Agency's level of concern for the general U.S. population (24% of the cPAD) and all population subgroups (84% of the cPAD for children 1-2 years of age). There is no concern for aggregate food and drinking water exposures to the alkylbenzene sulfonates resulting from their use as inert ingredients in pesticide products.

The chronic dietary risk assessment concludes that risk estimates are below the Agency's level of concern for the general U.S. population and all subpopulations. Therefore, no mitigation measures are necessary.

Drinking Water Risk

There are no currently registered outdoor uses of alkylbenzene sulfonates as active ingredients. However, the potential exists for transport into drinking water resulting from the pesticidal inert ingredient uses of alkylbenzene sulfonates. Therefore, the Agency estimated drinking water concentrations resulting from the inert ingredient uses of these substances. The Agency did not estimate acute drinking water risks for the inert ingredient use because an acute dietary endpoint (i.e., aPAD) was not selected as there were no effects attributable to a single dose exposure in animal studies. The Agency concluded that there are no risk concerns for the

general U.S. population and all population subgroups for drinking water exposures to the alkylbenzene sulfonates as pesticide inert ingredients.

Residential Risk

Residential handler and post-application exposure scenarios were assessed using high end exposure scenarios, end-use product application methods and use rates for inert uses. For each of the use scenarios, the Agency assessed residential handler (applicator) inhalation exposure and post application incidental ingestion by toddlers. All margins of exposure (MOEs) for short-term inhalation exposure for residential handlers are above the target MOE of 100 and, therefore, not of concern, with the exception of the flea and tick product where the MOE was 87. However, this screening level assessment was conducted using conservative assumptions because it assumes a person treats his/her pet with 0.5 cans of flea product that contains 24% alkylbenzene sulfonates every day for a month. All MOEs for residential post-application exposure are above the target of MOE of 100 and, therefore, are not of concern. Therefore the Agency does not have risk concerns.

Aggregate Risk

The chronic aggregate assessment considers average dietary exposure (food and drinking water) from both the active food contact sanitizer uses and the inert uses on agricultural commodities. The dietary exposures from the fruit and vegetable wash were not considered because it would be overly conservative to assume simultaneous exposure to alkylbenzene sulfonates from three different use patterns. Oral and inhalation exposure and risk estimates were conservatively combined for the aggregate risk assessment. Both short-term and chronic aggregate assessments were conducted. The short-term aggregate oral and inhalation risks are not of concern for adults, as the total aggregate MOE is 340 which is greater than the target of 100. For children, the aggregate risk estimate is very close to the target MOE of 100 (MOE=99). Because of the conservative nature of the assessment, the Agency does not have any risks of concern for children. The chronic aggregate assessment found no risk of concern for children or adults.

Occupational Risk

The Agency's human heath risk assessment indicates that there are four occupational handler inhalation scenarios with MOEs less than the target of 100. These four scenarios have MOEs between 90 and 93. The Agency is not requiring mitigation because the conservative assumptions used in the risk assessment, combined with the nearness of the MOE to the target, do not suggest concerns.

For most of the occupational scenarios, postapplication dermal exposure is not expected to occur or is expected to be negligible based on the application rates and chemical properties of alkylbenzene sulfonates.

Alkylbenzene sulfonates are dermal irritants at concentrations greater than 20%. Almost all of the labels require the use of gloves by workers.

Ecological Risk

Minimal or no environmental exposure to terrestrial or aquatic organisms is expected to occur from the majority of alkylbenzene sulfonate antimicrobial indoor pesticide uses given that only a very small number of total alkylbenzene sulfonates pounds are used for these purposes. Available data suggest that the alkylbenzene sulfonates may be more toxic to aquatic organisms as the number of carbons in the chain increase. Available data also indicate that the alkylbenzene sulfonates are slightly toxic to green algae.

The inert agricultural uses of alkylbenzene sulfonates are not expected to adversely affect avian or mammalian species on an acute or chronic basis. Aquatic organisms are also not expected to be adversely affected by inert alkylbenzene sulfonates use acutely or chronically due to the low estimated level of alkylbenzene sulfonates in water.

Use of alkylbenzene sulfonates in agricultural pesticide formulations is not expected to result in significant environmental exposure, therefore, no adverse effects (NE) to listed species are anticipated.

Regulatory Decision

The Agency has completed its review and has determined that the data are sufficient to support reregistration of all supported products containing alkylbenzene sulfonates. The Agency is issuing this RED for alkylbenzene sulfonates, as announced in a Notice of Availability published in the *Federal Register*. The RED and supporting risk assessment documents for alkylbenzene sulfonates are available to the public on the U.S. Federal Government website www.regulations.gov. The docket is EPA-HQ-OPP-2006-0156.

This RED document includes guidance and time frames for making any necessary label changes for products containing alkylbenzene sulfonates.

Summary of Mitigation Measures

Since no risks of concern were identified, no specific mitigation measures are needed for alkylbenzene sulfonates.

Data Requirements

Additional confirmatory data is required to complete the reregistration of alkylbenzene sulfonates. A complete list of data gaps is presented Section V and Appendix B (Table of Generic Data Requirements). In addition, product-specific data is required for all products containing alkylbenzene sulfonates 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 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (EPA or the 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 hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether 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 revised human health and ecological risk assessments and the Reregistration Eligibility Decision (RED) for alkylbenzene sulfonates (ABS).

The alkylbenzene sulfonates case is comprised of three active ingredients: sodium dodecylbenzene sulfonate, dodecylbenzene sulfonic acid and alklybenzene sulfonic acid. Sodium dodecylbenzene sulfonate and dodecylbenzene sulfonic acid (DDBSA) were first registered with the EPA on September 25, 1968 and February 24, 1969. C10-16 alkylbenzene sulfonic acid was registered on September 20, 1988.

As the case currently stands, sodium dodecylbenzene sulfonate (PC Code 079010) has three active products. Dodecylbenzene sulfonic acid (PC Code 098002) has 18 active products. C10-16-alkylbenzene sulfonic acid (PC Code 190116) has one active product. For a list of all the current products, please see Appendix A. In addition, these chemicals are also used as inert ingredients in other pesticide products.

Alkylbenzene sulfonates are antimicrobial pesticides that are used largely as food-contact sanitizers in food processing plants and eating establishments. They are also used as disinfectants and sanitizers for agricultural, commercial, institutional, industrial, and public access uses.

Tolerance exemptions for the active food-contact sanitizer uses of these ingredients have been established and can be found at 40 CFR 180.940(b) and (c).

The Agency has concluded that the FQPA Safety Factor for alkylbenzene sulfonates should be removed (equivalent to 1X), based on the available data and the risk assessment that does not underestimate risks for infants and children. A number of developmental studies via the oral route have been performed with alkylbenzene sulfonates in rats, mice and rabbits. The available information in these studies does not suggest any qualitative or quantitative evidence for susceptibility between the fetuses and maternal animals. The alkylbenzene sulfonates were tested in several multigeneration studies in rats, and there were no effects on offspring in any of these tests at doses up to 250 mg/kg/day.

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 alkylbenzene sulfonates and any other substances. Alkylbenzene sulfonates do not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that alkylbenzene sulfonates have 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 alkylbenzene sulfonates. 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 alkylbenzene sulfonates referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at www.regulations.gov.

This document consists of six sections. Section I is the Introduction. Section II, Chemical Overview, provides regulatory history, a profile of the use and usage of alkylbenzene sulfonates and a basic overview of the chemical. Section III, Summary of Alkylbenzene Sulfonates Risk Assessments, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, 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, if any, 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

The alkylbenzene sulfonates case is comprised of three active ingredients. Sodium dodecylbenzene sulfonate (PC Code 079010) and dodecylbenzene sulfonic acid or DDBSA (PC Code 098002) were first registered with the EPA on September 25, 1968 and February 24, 1969, respectively. C10-16-alkylbenzene sulfonic acid (PC Code 190116) was not registered until 1988. According to the unregistered technical manufacturers, at least some of the technical material contains a carbon mixture (C10-16) in the alkyl string and not pure C12 (as the name dodecyl- implies). As the case currently stands, sodium dodecylbenzene sulfonate has three active products. Dodecylbenzene sulfonic acid has 18 active products. C10-16-alkylbenzene sulfonic acid has one active product.

These chemicals are antimicrobials used largely as food-contact sanitizers in food processing plants and eating establishments. They are also used as disinfectants and sanitizers for agricultural, commercial, institutional, industrial, and public access uses. In addition to the pesticidal uses, the linear alkylbenzene sulfonate (LAS) surfactants are used in laundry and dish detergents as well as many other common uses. As inert ingredients in pesticide products, the chemicals are used in residential and outdoor agricultural settings.

The DDBSA Steering Committee/Joint Venture ("Joint Venture") formed on January 23, 1992 in response to EPA's October 23, 1989 notice initiating reregistration under FIFRA § 4 for List D of active pesticide ingredients. Current Joint Venture Members include: Acuity Specialty Products/Zep; Alex C. Fergusson, Inc.; Anderson Chemical Co.; DeVere Chemical Co., Inc.; Ecolab, Inc.; Hydrite Chemical Co.; JohnsonDiversey, Inc.; Morgan-Gallacher, Inc.; Oakite Products, Inc.; Quadra Chemical, Inc.; Thatcher Company; and West Agro, Inc.

Exemptions from the requirement of a tolerance for the active food-contact sanitizer uses of these ingredients have been established in the 40 CFR 180.940(b) and (c).

B. Chemical Identification

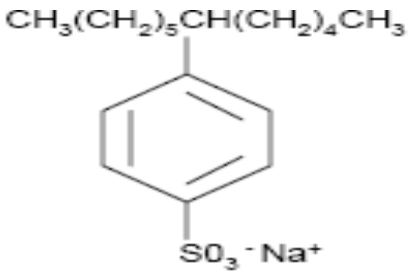

Figure 1: Sodium Dodecylbenzene Sulfonate (also named as dodecylbenzene sulfonic acid, sodium salt)

1. Sodium Dodecylbenzene Sulfonate (079010)

a. Chemical Overview

Common Name:	Sodium dodecylbenzene sulfonate
Chemical Name:	Alkyl(C12) benzenesulfonic acid, sodium salt Benzenesulfonic acid, dodecyl-, sodium salt Dodecylbenzene sodium sulfonate Dodecylbenzenesulfonic acid, sodium salt Sodium laurylbenzenesulfonate
OPP Chemical Codes:	079010
CAS Registry No.:	25155-30-0
Case Number:	4006
Empirical Formula:	$C_{18}H_{29}NaO_3S$ / $C_{12}H_{25}C_6H_4SO_3Na$
Molecular Weight:	348.5
Highest Percentage of Active:	3.6%
End-Use Product Distributors:	Oakite Products Inc. Microcide Inc.

b. Use Profile

Type of pesticide:	Disinfectant	Sanitizer
	Microbiocide	Microbiostat
	Bacteriocide	Bacteriostat

Use Sites:
FOOD HANDLING/STORAGE ESTABLISHMENT PREMISES AND EQUIPMENT
Fruit and Vegetable Wash Water
Food Processing, Handling, and Storage Plant Surfaces, Equipment, and Premises
Milk and Dairy Processing Plant Surfaces, Equipment, and Premises
Meat and Poultry Processing Plant Surfaces, Equipment, and Premises
Eating Establishment Food Contact Surfaces, Equipment and Utensils
Food Dispensing Equipment
Vending Machines
Soft Custard Equipment

COMMERCIAL, INSTITUTIONAL, INDUSTRIAL PREMISES AND EQUIPMENT
Mine Acid Control

2. Dodecylbenzene Sulfonic Acid (098002)

a. Chemical Overview

Common Name:	Dodecylbenzene sulfonic acid
Chemical Name:	Dodecylbenzene sulfonic acid
OPP Chemical Codes:	098002
CAS Registry No.:	27176-87-0
Case Number:	4006
Empirical Formula:	$C_{18}H_{30}O_3S$ / $C_{12}H_{25}C_6H_4{\cdot}SO_3H$
Molecular Weight:	326.5
Highest Percentage of Active:	15.67%
End-Use Product Distributors:	Anderson Chemical Co. ZEP Manufacturing Co. Hydrite Chemical Co. Devere Company Inc. Morgan-Gallacher Inc. FiveStar Affiliates Inc Alex C. Fergusson, Inc. International Chemical Corp. Chemical Systems of Florida Inc. Diverseylever Ecolab, Inc. West Argo Inc. US Chemical Corp. Drexel Chemical Co.

b. Use Profile:

Type of Pesticide:	Sanitizer	Disinfectant
	Virucide	Bacteriocide
	Bacteriostat	

Use Sites:

AGRICULTURAL PREMISES AND EQUIPMENT
Dairy Farms (enclosed premise treatment)
Milking Equipment
Teat Liner

FOOD HANDLING/STORAGE ESTABLISHMENTS PREMISES AND EQUIPMENT
Dairy Equipment, Premises, and Utensils
Milk Storage (bulk)
Fruit and Vegetable Wash Water
Food/Milk Transportation Vehicles
Food Processing Plant Equipment, Premises, and Surfaces
Bakery Processing Equipment
Brewery Process Plant Equipment and Surfaces
Cannery Processing Equipment
Milk and Dairy Processing Plant Equipment, Premises, and Surfaces
Potato Washing Machines
Fruit and Vegetable Processing Equipment
Meat and Poultry Processing Plant Equipment, Premises, and Surfaces
Winery Processing Equipment
Egg Processing Equipment
Beverage Processing Equipment and Surfaces
Fish Processing Equipment
Eating Establishment Equipment, Glassware, Utensils, Surfaces
Food Vending Machines
Food Dispensing Equipment
Food Store/Market/Supermarket Premises
Seed Houses/Stores/Storage Areas/Warehouses

COMMERCIAL, INSTITUTIONAL, INDUSTRIAL PREMISES AND EQUIPMENT
Research Animal Facilities (enclosed premise treatment)
Zoo Premises (enclosed premise treatment)
Airports
Campgrounds
Commercial Transportation Facilities
Aircraft (non feed/food)
Buses (non feed/food)

Ships
Railroad Trains
Commercial Premises and Equipment
Shower Stalls
Urinals
Toilet Bowls

RESIDENTIAL AND PUBLIC ACCESS PREMISES
Boat Premises
Automobiles

MEDICAL PREMISES AND EQUIPMENT
Sickroom Premises

3. Benzenesulfonic acid, C10-16-alkyl derivatives (190116)

a. Chemical Overview

Common Name:	Benzenesulfonic acid, C10-16-alkyl derivs.
Chemical Name:	C10-16-Alkylbenzene sulfonic acid
OPP Chemical Codes:	190116
CAS Registry No.:	68584-22-5
Case Number:	4006
Empirical Formula:	$C_{16\text{-}22}H_{30}O_3S$ / $C_{10\text{-}16}H_{25}C_6H_4{\cdot}SO_3H$
Molecular Weight:	324
Highest Percentage of Active:	25.6%
End-Use Product Distributors:	Kay Chemical Co. Quadra Chemicals, Inc.

b. Use Profile:

Type of Pesticide:	Sanitizer	Bacteriocide
	Bacteriostat	

Use Sites:
AGRICULTURAL PREMISES AND EQUIPMENT
Dairy/Milking Equipment and Utensils

FOOD HANDLING/STORAGE ESTABLISHMENTS PREMISES AND EQUIPMENT

Milk Storage (bulk)
Food Processing Plant Equipment and Surfaces
Meat and Poultry Processing Plant Equipment and Premises
Milk and Dairy Processing Plant Equipment and Premises
Beverage Processing Plant Equipment, Premises, and Surfaces
Eating Establishment Equipment, Utensils, and Surfaces

III. Summary of Alkylbenzene Sulfonates Risk Assessments

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 alkylbenzene sulfonates. While the risk assessments and related addenda are not included in this document, they are available from the U.S. Federal Government Public Docket at www.regulations.gov. The docket identification number is EPA-HQ-OPP-2006-0156. Hard copies of these documents may be found in the OPP public docket which is located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, 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

The Agency's use of human studies in the alkylbenzene sulfonates risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

1. Toxicity of Alkylbenzene Sulfonates

A brief overview of the toxicity studies used for determining endpoints in the risk assessments are outlined below in Table 1. Further details on the toxicity of alkylbenzene sulfonates can be found in the "Alkylbenzene Sulfonates (ABS) Toxicology Chapter for the Reregistration Eligibility Decision (RED) Document," dated July 06 , 2006; and "Sulfonates (ABS) Revised Risk Assessment for the Reregistration Eligibility Decision (RED) Document," dated July 19, 2006. These documents are available on the U.S. Federal Government Public Docket website at www.regulations.gov.

The Agency has reviewed all toxicity studies submitted for alkylbenzene sulfonates and has determined that the toxicological database is sufficient for reregistration. The studies have been submitted to support guideline requirements. Major features of the toxicology profile are presented in Table 1.

Table 1. Acute Toxicity Studies for Alkylbenzene Sulfonates			
Guideline No./ Study Type	**MRID No.**	**Results**	**Toxicity Category**
870.1100 Acute oral toxicity	43498402 43498408 43498430	LD_{50} = range from 404 to over 5000 mg/kg	III-IV
870.1200 Acute dermal toxicity	94032006	LD_{50} = 1200 mg/kg	II
870.1300 Acute inhalation toxicity	Open Literature	LC_{50} = 0.31 mg/L	II
870.2400 Acute eye irritation	43498405	Corneal opacity not reversed at 72 hours.	I
870.2500 Acute dermal irritation	40359306	Severe irritation at 72 hours	II
870.2600 Skin sensitization	Open Literature	Non-Sensitizer	

The doses and toxicological endpoints selected by the Agency for the various exposure scenarios are summarized below in Table 2.

Table 2. Summary of Toxicological Dose and Endpoints for Alkylbenzene Sulfonates			
Exposure Scenario	**Dose Used in Risk Assessment, UF**	**Special FQPA SF*, endpoint and Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary (All populations)	No endpoint was selected. No effects are attributable to a single dose in animal studies.		

Table 2. Summary of Toxicological Dose and Endpoints for Alkylbenzene Sulfonates			
Exposure Scenario	**Dose Used in Risk Assessment, UF**	**Special FQPA SF*, endpoint and Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Chronic Dietary (All populations)	Systemic/ Reproductive NOAEL= 50 mg/kg/day UF = 100 **Chronic RfD** = 0.5 mg/kg/day	FQPA SF = 1X **cPAD** = chronic RfD / FQPA SF = 0.5 mg/kg/day	NOAEL = 40 mg/kg/day (0.07%) and LOAEL= 114 mg/kg/day (0.2%) based on increased caecum weight and slight kidney damage in a 6 month rat dietary study (Yoneyama et al 1972 Ann. Rep. Tokyo Metrop. Res. Lab. Public Health 24:409-440) **plus** Systemic/Reproductive NOAEL = 50 mg/kg/day and LOAEL = 250 mg/kg/day based on decreased Day 21 female pup body weight (Buehler, E. et al. 1971. Tox. Appl. Pharmacol. 18:83-91) **plus** NOAEL = 85 mg/kg/day and LOAEL= 145 mg/kg/day from 9 month drinking water rat study based on decreased body weight gain, and serum/ biochemical and enzymatic changes in the liver and kidney (Yoneyama et al. 1976 Ann. Rep. Tokyo Metrop. Res. Lab. Public Health 27(2):105-112)

General Toxicity Observations

Acute Toxicity. Alkylbenzene sulfonates exhibit a wide range of acute toxicity via the oral route in rats (LD_{50}s of 404 – 1980 mg/kg), with a narrower range in mice (LD_{50}s of 1259-2300 mg/kg). This spans the acute oral toxicity categories of III-IV. Alkylbenzene sulfonates are classified as acute toxicity category II for the dermal and inhalation routes of exposure. They are irritants to the eye (category I) and skin (category II), and are not skin sensitizers.

Absorption, Distribution, Metabolism, Excretion. In animal tests (oral – monkeys, pigs, rats), alkylbenzene sulfonates are readily absorbed from the gastrointestinal tract, are distributed throughout the body, and are extensively metabolized. Excretion is via both the urine and feces. Available dermal absorption data (rats and guinea pigs) indicate that alkylbenzene sulfonates are poorly absorbed from the skin, although prolonged contact may lead to irritation and thus compromise the skin to permit more absorption (WHO, 1996 and HERA, 2004).

Repeated Dose Toxicity (Subchronic and Chronic). There have been many oral repeated dose studies performed with alkylbenzene sulfonates ranging from a 28-day study in monkeys to nine month studies conducted with rats and mice. There have also been repeated dose dermal (guinea pigs, rabbits, and rats) and inhalation studies (dogs and monkeys). Collectively, animal data suggests that the liver, kidney and caecum (for oral studies) are the major target organs for toxicity. The liver and kidney effects were dose and duration related in that mild effects (organ weight changes and serum enzyme/clinical chemistry changes indicative of mild organ effects) were seen at lower doses, but increased in severity with both dose and time.

For the purposes of this hazard assessment, several studies were considered collectively to determine a no-observable adverse effect level (NOAEL) of 50 mg/kg/day for the chronic dietary endpoint. This is based on: increased caecum weight and slight kidney damage (at a NOAEL of 40 mg/kg/day and at a LOAEL of 114 mg/kg/day in the six month rat study); reduced body weight in 21-day old pups (at a NOAEL of 50 mg/kg/day and a LOAEL of 250 mg/kg/day in a reproductive toxicity rat study); and significant decreases in renal biochemical parameters (at a NOAEL of 85 mg/kg/day and a LOAEL of 145 mg/kg/day in a nine month drinking water study in rats).

Developmental Toxicity. A number of developmental studies via the oral and dermal routes have been performed with alkylbenzene sulfonates in rats, mice and rabbits; there were also several subcutaneous injection developmental studies reported in mice (WHO, 1996). In these developmental studies, there is varying quality in the more than 20 studies submitted. However, it is concluded that some developmental effects (including some terata) were observed at high doses at which maternal toxicity was observed and the available information does not suggest any qualitative or quantitative susceptibility differences between fetuses and maternal animals.

Reproductive Toxicity. Alkylbenzene sulfonates were tested in several multigeneration studies in rats. There were no effects on reproductive parameters in any of these tests at doses up to 250 mg/kg/day.

Carcinogenicity. The available long-term studies that assessed carcinogenicity were older studies (pre-1970) that would not be acceptable under current standards due to low number of animals used, insufficient number of doses and duration of dosing, and limited histopathological examinations. However, the limited studies provide no evidence of carcinogenicity in animals given alkylbenzene sulfonates orally.

Genotoxicity. The toxicological data show that alkylbenzene sulfonates were not genotoxic in vitro or in vivo.

Neurotoxicity. There is no evidence in the available toxicity studies or scientific literature to indicate neurotoxic effects of the alkylbenzene sulfonates in humans or laboratory animals.

Endocrine Disruption Potential. EPA is required under the Federal Food Drug and Cosmetic Act (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 such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was 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 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). When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupting Screening Program (EDSP) have been developed, alkylbenzene sulfonates may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

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, or residential exposures, or to compensate for an incomplete database. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for alkylbenzene sulfonates based on: (1) a lack of evidence that alkylbenzene sulfonates will induce neurotoxic effects, (2) no quantitative or qualitative evidence of increased susceptibility to the fetus following *in utero* exposure in the prenatal developmental toxicity studies, and (3) no quantitative or qualitative evidence of increased susceptibility to the offspring when adults are exposed in the two-generation reproductive study. The FQPA Safety Factor assumes that the exposure databases (food, drinking water, and residential) are complete and that the risk assessment does not underestimate the potential risk for infants and children. These criteria have been met for alkylbenzene sulfonates. Based on the analysis of submitted developmental toxicity studies, the Agency determined that no special FQPA Safety Factor was needed since there were no residual uncertainties for pre- and/or postnatal toxicity.

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.

a. Acute PAD

Acute dietary risk is assessed by comparing acute dietary exposure estimates (in mg/kg/day) to the acute Population Adjusted Dose (aPAD). Acute dietary risk is expressed as a percent of the aPAD. An acute dietary assessment for alkylbenzene sulfonates was not conducted because there are no adverse effects attributable to a single dose exposure in animal studies.

b. Chronic PAD

Chronic dietary risk for alkylbenzene sulfonates is assessed by comparing chronic dietary exposure estimates (in mg/kg/day) to the chronic Population Adjusted Dose (cPAD). Chronic dietary risk is expressed as a percent of the cPAD. The cPAD is the chronic reference dose (0.5 mg/kg/day) modified by the FQPA safety factor. The chronic RfD is 0.5 mg/kg/day for all populations, using a NOAEL of 50 mg/kg/day based on a weight of evidence from three toxicological studies that observed decreased pup body weight at 250 mg/kg/day and increased caecum weight, slight kidney damage at 114 mg/kg/day and significant decreases in renal biochemical parameters at 145 mg/kg/day. The NOAELs in the three studies used to develop the chronic endpoint are 40, 50 and 85 mg/kg/day as shown in Table 2. An uncertainty factor of 100 (10X for interspecies extrapolation, 10X for intraspecies variability) was applied to the NOAEL to obtain the chronic RfD. The alkylbenzene sulfonates cPAD is 0.5 mg/kg/day based on a reference dose of 0.5 mg/kg/day, which includes the incorporation the FQPA safety factor (1X) for the overall U.S. population or any population subgroups.

4. Dietary Exposure Assumptions

Chronic dietary exposure assessments for alkylbenzene sulfonates were conducted for the following uses: (1) as active ingredients in food contact sanitizing solutions; (2) as active ingredients in a fruit and vegetable wash; and (3) as inert ingredients in pesticide formulations that may be applied to growing agricultural crops, raw agricultural commodities after harvest, and to animals (pet product).

In the absence of residue data for residues of alkylbenzene sulfonates on treated food contact surfaces, the Agency estimated residue levels that may occur in food from the application rates on food contact surfaces. As mentioned previously, to determine the Estimated Daily Intake (EDI), the Agency has used an FDA model. The maximum percentage of active ingredient for dodecylbenzene sulfonates in food handling establishments from the various labels is 400 ppm. The Agency estimates that use of this product results in food residues of 530 ppb (µg/kg). The Agency assumed that food can contact 4000 cm^2 of treated surfaces, utensils, glassware, or pots and pans and that 100% of the pesticide migrates to food based on the standard assumptions used in the FDA Sanitizing Solution Guidelines. It was assumed that an adult and child consume 3000 and 1500 grams of food per day, respectively that will contact the treated surfaces.

The Agency used the FDA milk truck model to estimate residues in milk that could result from the use of alkylbenzene sulfonates in the food processing equipment, as representative of the potential uses in the food processing industry. As a conservative measure, the Agency assessed the maximum application rate of 400 ppm for dodecylbenzene sulfonates, as listed on the labels, although the current tolerance exemption has a limitation of 5.5 ppm for dairy processing equipment. The Agency estimates that use of this product results in maximum milk residues of 10 ppb (µg/kg). The Agency will be proposing a change to the 40 CFR 180.940(b) to have the end-use concentration not to exceed 400 ppm, rather than the current limitation of 5.5 ppm.

The Agency also estimated dietary exposure from the fruit and vegetable wash of the alkylbenzene sulfonates. This use is regulated by the FDA in 21 CFR 173.315, which permits the wash solution to contain dodecylbenzene sulfonic acid up to a maximum application rate of 0.2% (2000 ppm), without a potable rinse. The Agency assumed this maximum application rate of 2000 ppm in wash solution, along with assumptions for Thompson Seedless grapes as a surrogate to represent residues on all treated fruits and vegetables. The model estimates dodecylbenzene sulfonic acid residues of 9.25 ppm. Most of the pesticide labels are in compliance with this limitation. One label however, allows a vegetable wash solution containing 0.31% (3100 ppm) dodecylbenzene sulfonic acid, but requires a potable rinse following washing. The Agency plans to establish 0.2% as the maximum application rate that can be used without a potable rinse.

As inert ingredients in pesticide formulations, a conservative screening level dietary exposure model, Exposure Evaluation Model (DEEM™), was used that assumed 100% of all commodities, and 100% of all crops were treated with the alkylbenzene sulfonates, with no limitation on the fraction of inert ingredient. A complete explanation of the assumptions used in the generic screening model for estimating inert ingredient dietary exposure is given in Appendix A of the Inert Ingredient Dietary Risk Assessment for Linear Alkyl Benzenesulfonate.

5. Dietary (Food) Risk Assessment

a. Acute and Chronic Dietary Risk

Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concerns. A summary of chronic risk estimates for active uses is shown in Table 3. A summary of chronic risk estimates for inert uses is shown in Table 4. Based on the pesticide labels, the Agency assessed dietary exposure that could result from the use of alkylbenzene sulfonates in the food service industry (treated surfaces, dishes, utensils, glassware, pots and pans), in the food processing industry (food processing equipment such as breweries and beverage plants, meat and poultry processing plants, milk and dairy products/packing plants etc), and as a fruit and vegetable wash. For additional information, please see the Dietary Exposure Assessments for the Reregistration Eligibility Decision and the Inert Ingredient Dietary Risk Assessment for Linear Alkyl Benzenesulfonate documents.

The daily estimates for food handling establishments, food processing equipment and the fruit and vegetable wash were conservatively used to assess chronic dietary risks, which are shown below in Table 3. As noted previously, an acute dietary assessment was not conducted because there were no adverse effects attributable to a single dose exposure in animal studies.

The dietary risk estimates for the total food contact sanitizing uses are below the Agency's level of concern for all age groups (less than 11% of the cPAD). In addition, the dietary risk estimates for the fruit and vegetable wash for adults and young children are below the Agency's level of concern for all age groups (less than 71.2% of the cPAD). These risk estimates are based on a number of conservative assumptions, and thus may overestimate the actual risks.

Table 3. Summary of Dietary Exposure and Risk for Alkylbenzene Sulfonates Pesticidal Active Uses

Use	Population Subgroup	Chronic Dietary	
		Dietary Exposure (mg/kg/day) a	% cPAD b
Food Service Industry (treated surfaces, utensils, glassware, etc)	adult male	0.023	4.6
	females (13-50 years)	0.027	5.4
	infants/children	0.053	10.6
Food Processing Industry (Food Processing Equipment)	adult male	0.00043	0.086
	females (13-50 years)	0.0005	0.1
	infants/children	0.001	0.2
Total Food Contact Surface Sanitizing Uses	adult male	0.023	4.6
	females (13-50 years)	0.027	5.4
	infants/children	0.054	10.8
Fruit and Vegetable Wash	U.S population	0.0979	19.6
	children 1-2 yrs	0.3558	71.2
	children 3-5 yrs	0.2573	51.5

NA=not applicable

a-- chronic exposure analysis based on body weights of 70 kg, 60 kg, and 15 kg for adult males, females and children, respectively.

b-- %PAD = dietary exposure (mg/kg/day) / cPAD, where cPAD=0.5 mg/kg/day for all populations.

b. Dietary Exposure for Inert Ingredient Uses

Included in this RED is the reassessment of alkylbenzene sulfonates when used as an inert ingredient in pesticide products. Alkylbenzene sulfonates are used as solvents, surfactants, dispersants, detergents, or wetting agents. Some of these products are designed for use in agricultural settings (pre- and post-harvest and when applied to animals), where there is a potential for dietary exposure.

Inert Dietary Exposure Assumptions

A dietary exposure analysis for the inert ingredient use of the alkylbenzene sulfonates was conducted using a screening model for estimating inert ingredient dietary exposure. The dietary assessment is unrefined and extremely conservative in nature because the screening model assumes that the inert ingredient is used on all commodities, and that 100 percent of crops are treated with the inert ingredient. Further, the model assumes residues will be present for every consumed commodity (including meat, milk, poultry and eggs) that is included in the Dietary Exposure Evaluation Model (DEEM™). The conservative nature of this assessment is believed to capture all potential dietary exposures, including those from direct application to animals.

The alkylbenzene sulfonates assessed in this document are constituents of a larger group of compounds that have a tolerance exemption as an inert ingredient in 40 CFR 180.910 and 180.930. The tolerance exemption is listed as Alkyl (C8-C24) benzenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc salts.

Inert Dietary Risk from Food

Table 4 provides a summary of the results of the chronic dietary risk estimates for alkylbenzene sulfonates as an inert ingredient.

Based on the use of the screening level inert ingredient dietary exposure model, there are no risk concerns associated with dietary exposures as the estimated dietary exposures for the U.S. population and all population subgroups are below 100% of the cPAD. As noted, a number of conservative assumptions were used in this screening level dietary risk assessment of inert uses.

Table 4. Summary of Dietary Exposure and Risk for Alkylbenzene Sulfonates as Inert Ingredients		
Population Subgroup	**Chronic Dietary**	
	Dietary Exposure (mg/kg/day)	**% cPAD a**
U.S. population	0.12	24
females (13-50 years)	0.087	17
children 1-2 yrs	0.422	84
children 3-5 yrs	0.31	62

a-- %PAD = dietary exposure (mg/kg/day) / cPAD, where cPAD=0.5 mg/kg/day for all population

c. Dietary Risk from Drinking Water

The drinking water exposure analysis is based on a derivation of estimated upper bound drinking water concentrations from these substances' use as pesticidal inert ingredient from the FQPA Index Reservoir Screening Tool (FIRST). The results of the FIRST modeling analysis and the conservative assumptions utilized as inputs into the inert ingredient drinking water exposure assessment model are provided in Appendix B of the Inert Ingredient Dietary Risk Assessment for Linear Alkyl Benzenesulfonate.

For chronic drinking water exposures to linear alkylbenzene sulfonates as inert ingredients, the Drinking Water Level of Comparison (DWLOC) range for chronic exposure is 38-1500 µg/L for the general U.S. population and 8-500 µg/L for children 1-2 years old. The Estimated Drinking Water Concentration (EDWC) used to assess chronic (non-cancer) dietary risk from drinking water is 6.6 µg/L. The chronic estimated concentration is below the DWLOCs for the general U.S. population and all population subgroups. Drinking water risks, therefore, are not of concern.

The Agency did not estimate acute drinking water risks for the inert ingredient use because an acute dietary endpoint (i.e., aPAD) was not selected as there were no effects attributable to a single dose exposure.

The estimated chronic drinking water concentration and drinking water level of concern for chronic exposure to linear alkyl benzenesulfonates is given in Table 5.

Table 5. Chronic Drinking Water Exposure Estimates for Inert Ingredient Uses of Alkylbenzene Sulfonates			
Population Subgroup	**EDWC[1] (µg/L)**	**%cPAD[2]**	**DWLOC[3] (µg/L)**
U.S. Population (total)	6.6	<0.1%	38 -1,500
Children (1-2 years)	6.6	<0.1%	8 - 500

1 Estimated Drinking Water Concentration (EDWC) for chronic drinking water exposure as determined by the use of FIRST modeling analysis described above for inert ingredient use. [The EDWC for linear alkyl benzenesulfonates is the value reported as the "Adjusted Annual Average (Chronic) Untreated Water Concentration"]

2 %cPAD = drinking water exposure (mg/kg/day) / cPAD, where cPAD=0.5 mg/kg/day for all populations. It was assumed that a 15 kg child ingests 1 L water per day and that a 70 kg adult ingests 2L water per day.

3 Drinking Water Level of Comparison (DWLOC) is the maximum contribution from water allowed in the diet based on food and drinking water from inert use only. In this case, since the allowable risk contribution from food is based on a screening level model, the use of a single, deterministic value for the DWLOC is not appropriate. Rather a DWLOC range is given, with the values in the range corresponding to an upper value of range of drinking water concentrations ranging from 100% of the cPAD (i.e., assuming no food exposure) to a lower value that considers food exposures to be at the dietary screening level value.

6. Residential Risk Assessment

Residential exposure assessment considers all potential pesticide exposure, other than exposure due to residues in food or in drinking water. Exposure may occur during treatment of outdoor residential turf, while cleaning indoor hard surfaces, or while using pet flea and tick products. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate NOAEL. Based on its use patterns, alkylbenzene sulfonates has been assessed for the residential mixing/loading/applicator (or "handler") exposure for applications by homeowners using an aerosol spray or by using a ready-to-use liquid with a low pressure hand wand, a hose or a sprinkling can. An inhalation post-application assessment was not conducted because the vapor pressure of the alkylbenzene sulfonates is extremely low ($5.1x10^{-10}$ to $6x10^{-15}$ mmHg). In addition, a dermal assessment was not conducted because of the lack of a dermal toxicological endpoint. Post application incidental ingestion by toddlers that may contact turf, hard surfaces or a pet treated with pesticide products containing alkylbenzene sulfonates is expected to be minimal, and all the scenarios evaluated have MOEs above 100.

a. Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary risks for alkylbenzene sulfonates are listed in Table 6.

A MOE greater than or equal to 100 is considered adequately protective for the residential exposure assessment for the incidental oral and inhalation routes of exposure. The MOE of 100 includes 10X for interspecies extrapolation and 10X for intraspecies variation.

Table 6. Summary of Toxicological Dose and Endpoints for Assessing Occupational and Residential Risk for Alkylbenzene Sulfonates			
Exposure Scenario	**Dose Used in Risk Assessment, UF**	**Special FQPA SF*, endpoint and Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Short-Term Incidental Oral (1-30 days)	Oral NOAEL= 50 mg/kg/day UF = 100	**Residential** LOC for MOE < 100	NOAEL = 40 mg/kg/day (0.07%) and LOAEL= 114 mg/kg/day (0.2%) based on increased caecum weight and slight kidney damage in a 6 month rat dietary study (Yoneyama et al 1972 Ann. Rep. Tokyo Metrop. Res. Lab. Public Health 24:409-440) **plus** Systemic/Reproductive NOAEL = 50 mg/kg/day and LOAEL = 250 mg/kg/day based on decreased Day 21 female pup body weight (Buehler, E. et al. 1971. Tox. Appl. Pharmacol. 18:83-91) **plus** NOAEL = 85 mg/kg/day and LOAEL= 145 mg/kg/day from 9 month drinking water rat study based on decreased body weight gain, and serum/ biochemical and enzymatic changes in the liver and kidney (Yoneyama et al. 1976 Ann. Rep. Tokyo Metrop. Res. Lab. Public Health 27(2):105-112)
Short-, Intermediate- and Long-Term Inhalation (1 to 30 days, 1-6 months, >6 months)	Inhalation study NOAEL= 1mg/m^3 detergent dust combined with up to 0.1 mg/m^3 enzyme dust Equivalent to approximately 0.14 mg/kg/day (a) (inhalation absorption rate = 100%) purity= 13% active ingredient UF = 100	**Residential** LOC for MOE < 100 **Occupational** LOC for MOE < 100	Subchronic Inhalation Monkey Study LOAEL = 10 mg/m^3 detergent combined with 0.1 mg/m^3 enzyme dust. Toxicological effect is weight loss and decreased weight gain (W. Coates, et al 1978. Tox. Appl. Pharmacol. 45: 477-496) This air concentration is equivalent to approximately 1.4 mg/kg/day (a)

Table 6. Summary of Toxicological Dose and Endpoints for Assessing Occupational and Residential Risk for Alkylbenzene Sulfonates			
Exposure Scenario	**Dose Used in Risk Assessment, UF**	**Special FQPA SF*, endpoint and Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Dermal Endpoint	Quantification of dermal risk is not required since: 1) the alkylbenzene sulfonates are surfactants that are dermal irritants at concentrations generally greater than 20% solution. The requirement of the dermal toxicity studies with the end-use products will determine the personal protective clothing necessary to protect against irritation during product use; 2) no systemic toxicity was seen following repeated dermal applications to rabbits at 200 mg/kg/day (with an end use product), and 3) no developmental toxicity concerns were seen following repeated dermal applications to pregnant mice, rats or rabbits (developmental effects were seen either in the presence of maternal toxicity or at doses higher than those that caused maternal toxicity).		
Cancer (oral, dermal, inhalation)	No evidence of carcinogenicity in reported studies in rats		

(a) Equation used to convert inhalation air concentration to a dose= mg/L* absorption*respiratory volume (L/hr)*duration (hrs) * activity factor / body weight. Thus, 0.001 mg/L * 1*67.94 L/hr (based on default respiratory volumes for a New Zealand Rabbit which is used as a surrogate for a cynomolgus monkey) * 6 hrs * 1 / 2.98 kg (body weight for New Zealand Rabbit used as a surrogate for cynomolgus monkey, study reports monkey body weight ranges from 1.6 to 3.7 kg).

b. Residential Handler

i. Exposure Scenarios, Data and Assumptions

Residential exposure may occur for alkylbenzene sulfonates during applications of turf treatment, hard surface cleaners and pet flea and tick products. A number of assumptions, or estimates, such as adult body weight and area treated per application, are made by the Agency for residential risk assessment. Also, note that residential handlers are sometimes addressed somewhat differently than occupational handlers in that homeowners are assumed to complete all elements of an application (mix/load/apply) without the use of personal protective equipment.

The quantitative exposure/risk assessment developed for residential handlers is based on these scenarios:

1) outdoor residential turf treatment (ready to use liquid),
2) indoor hard surface cleaner (ready to use liquid), and
3) pet flea and tick products (aerosol can spray).

For the purposes of this screening level assessment, the Agency selected representative scenarios for the vast majority of products, based on end-use product application methods and use amounts. The above scenarios reflect high-end exposure and risk estimates for all products represented in a residential setting.

For most residential scenarios, the Agency used EPA's Pesticide Inert Risk Assessment Tool (PiRat) to estimate residential applicator and post-application exposures and risks from the use of alkylbenzene sulfonates as an inert ingredient in representative residential products. For the assessment of the pet products and hard surface cleaners, the Agency used assumptions in the Residential Standard Operating Procedures (SOPs). Typically, most products used in a residential setting result in exposures occurring over a short-term duration. Thus, the residential handler and postapplication scenarios are assumed to be of short- term duration (1-30 days).

An inhalation post-application assessment was not conducted because the vapor pressure of the alkylbenzene sulfonates is extremely low ($5.1x10^{-10}$ to $6x10^{-15}$ mmHg) and not expected to result in inhalation exposure. In addition, a dermal assessment was not conducted because of the lack of a dermal toxicological endpoint was not identified in animal studies.

ii. Residential Handler Risk Estimates

Based on toxicological criteria and potential for exposure, the Agency has conducted incidental oral and inhalation exposure assessments. As noted previously, MOEs greater than or equal to 100 for the inhalation route of exposure and 100 for incidental oral exposure are considered adequately protective for the residential exposure assessment.

A summary of the residential handler exposures and risk are presented in Table 7. For residential handlers that handle products containing alkylbenzene sulfonates as inert ingredients, the short-term inhalation MOEs were above the target MOE of 100, and thus, do not exceed the Agency's level of concern, with the exception of the flea and tick product where the MOE was 87 for the high-end formulation containing 24% alkylbenzene sulfonates. This scenario is conservative because it assumes a person treats their pet with 0.5 cans of flea product that contains 24% alkylbenzene sulfonates every day for a month. It is unlikely that a person would treat his/her pet every day for one month. Therefore, the Agency is not requiring risk mitigation. In addition, there are no risk concerns for the majority of pet products containing 2% alkylbenzene sulfonates.

Table 7. Estimates of Inhalation Exposures and Risks to Residential Handlers of Alkylbenzene Sulfonates as Inert Ingredients (Short-Term Duration)				
Product Use	**Application Method**	**Area Treated/Quantity Handled[a]**	**Inhalation Exposure (mg/kg/day)**	**Inhalation MOEs[c] (Target MOE ≥ 100)**
Outdoor Products				
Ready to Use Liquid Turf spot/gardens[b]	Low pressure handwand; MLAP	1000 ft^2/day (spot)	$7.07x10^{-6}$	20,000
	Hose end sprayer; MLAP	$2x10^4$ ft^2/day (full broadcast)	$4.48x10^{-5}$	3,100
	Backpack; MLAP	1000 ft^2/day (spot)	$7.07x10^{-6}$	20,000
	Sprinkling can; MLAP		$2.24x10^{-6}$	63,000
Indoor Products				
Ready to Use Liquid (hard surface cleaner)[d,e]	Low pressure handwand; MLAP	0.5 gallons/day	$1.37x10^{-4}$	1.000
Pet Flea and Tick Product[f]	Aerosol Can Spray	0.5 6 oz can	$1.61x10^{-3}$	87

a: Standard PiRat model input parameters, except for pet products and hard surface cleaner, which are based on an AD assumption.
b: percent formulation used = 11%; an application rate of 0.00015 lb product/ft^2 was assumed for all scenarios and the body weight = 70kg.
c: MOEs = NOAEL / exposure where inhalation NOAEL = 0.14 mg/kg/day and the target MOE ≥ 100
d: % formulation used = 8%
e: An application rate of 8 lb/gallon, which is the density of water, was assumed for all scenarios and the body weight =70kg.
f= % formulation = 24%.

c. Residential Post-Application

Residential post application exposures occur when bystanders contact areas in which the antimicrobial end use product has recently been applied. For alkylbenzene sulfonates there are no residential postapplication risk concerns for the household products that contain alkylbenzene sulfonates as an inert ingredient as shown on Table 8. All of the scenarios evaluated have short-term MOEs above 100, and thus are not of concern including postapplication incidental oral risks to children that may contact turf, hard surfaces or a pet treated with pesticide products containing alkylbenzene sulfonates as an inert ingredient. The postapplication MOEs range from 106 to 7,400.–

Table 8. Summary of Short-Term Residential Postapplication Exposure and Risk Estimates from Alkylbenzene Sulfonates as Inert Ingredients[a]

Product Use	Route of Exposure	Exposure mg/kg/day[b]	MOEs[c] (Target MOE ≥ 100
Ready to Use Liquid Turf spot/gardens[d]	Incidental ingestion: hand to mouth	1.08×10^{-2}	4,600
Ready to Use Liquid (hard surface cleaner)[a, e]		0.0068	7,400
Pet Flea and Tick Product[f]	Incidental ingestion: hand to mouth	0.4739	106

a: The representative use sites assessed through using PiRAT for incidental oral post application exposures to toddlers are turf products. Exposure from hard surface cleaner and pet products was based on AD assumptions.
b: The body weight used in this calculation was 15kg, which is assumed to be the body weight of a toddler.
c: MOEs = NOAEL / exposure where incidental oral NOAEL = 50 mg/kg/day. Target MOE ≥ 100.
d: % formulation used = 11%
e: % formulation used = 8%
f: % formulation used = 24%

7. Aggregate Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) 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." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure. Aggregate exposure is the total exposure to a single chemical (or its residues) that may occur from dietary (i.e., food and drinking water), residential, and other non-occupational sources, and from plausible exposure routes (oral, dermal, and inhalation).

In performing aggregate exposure and risk assessments, the Office of Pesticide Programs has published guidance outlining the necessary steps to perform such

assessments (General Principles for Performing Aggregate Exposure and Risk Assessments, November 28, 2001; available at: http://www.epa.gov/pesticides/trac/science/aggregate.pdf . Steps for deciding whether to perform aggregate exposure and risk assessments are listed and include: identification of toxicological endpoints for each exposure route and duration; identification of potential exposures for each pathway (food, water, and/or residential); reconciliation of durations and pathways of exposure with durations and pathways of health effects; determination of which possible residential exposure scenarios are likely to occur together within a given time frame; determination of magnitude and duration of exposure for all exposure combinations; determination of the appropriate technique (deterministic or probabilistic) for exposure assessment; and determination of the appropriate risk metric to estimate aggregate risk.

Typically, aggregate risk assessments are conducted for acute (1 day), short-term (1-30 days), intermediate-term (1-6 months) and chronic (6 months to lifetime) exposures. However, an acute aggregate assessment was not conducted because there are no adverse effects attributable to acute exposure. An intermediate-term aggregate assessment was not conducted because there are no residential exposures of this duration. In addition, because there are no long-term residential exposures, the chronic aggregate assessment only considered food and drinking water. Thus, only short-term and chronic aggregate assessments were conducted. Oral and inhalation exposure and risk estimates were conservatively combined for the aggregate risk assessment because these endpoints both identify adverse effects on body weight. Dermal exposures were not considered in the risk assessment because a toxicological endpoint was not established.

a. Short- Term Aggregate Risk

This assessment considers both the active and inert uses of the alkylbenzene sulfonates. For children, the short-term aggregate assessment includes average dietary exposure (food and drinking water) from both the active food contact sanitizer uses and the inert uses on agricultural commodities, in addition to estimated incidental oral exposures to children from residential uses such as hard surface cleaning products as an inert ingredient. For adults, the aggregate assessment includes dietary (food and drinking water) from both active and inert uses and residential inhalation exposures from wiping a hard surface cleaning products since this scenario represents the highest exposure from the inert use. The residential handler scenario for pet flea and tick products (inhalation MOE of 87) was not included in the aggregate assessment. The pet flea and tick product assumes a person treats his/her pet with 0.5 cans of flea product that contains 24% alkylbenzene sulfonates every day for a month. The Agency does not have any risks of concern for this scenario because it is very conservative in nature.

The aggregate oral and inhalation risks are not of concern for adults, as the total aggregate MOE is 340 which is greater than the target of 100. For children, the aggregate risk estimate is very close to the target MOE of 100 (MOE = 99). As noted previously, several conservative assumptions were used in this assessment, and thus the Agency does

not have any risk concerns. The assumptions and equations are presented in the footnotes on Table 9.

Table 9 presents a summary of the short-term aggregate risk MOEs.

Table 9. Summary of Short-Term Aggregate Risk Estimates

Exposure Scenario	Dose [a] (mg/kg/day)		Total MOE[b] (Target MOE≥100)	
	Child	Adult	Child	Adult
Oral Exposure				
Dietary Exposure				
Food Contact Sanitizer	0.054	0.027	926 (10.8% of cPAD)	1,850 (5.4% of cPAD)
Inert Ingredient Uses (Food)	0.422	0.12	118 (84% of cPAD)	417 (24% of the cPAD)
Drinking Water Exposure (Inert) c	0.00044	0.000189	114,000 (<1% of cPAD	227,000 (<1% of cPAD)
Hard Surface Cleaner (2% Inert)	0.0068	NA	7,400	NA
Inhalation Exposure				
Handler of hard surface cleaning products (2% Inert)	NA	0.000137	NA	1,000
Total Aggregate Dose and MOE	0.5	0.147	99	340

NA= Not applicable

(a) Chronic dietary exposure for females 13-50 years for sanitizer use. The total general population dietary exposure was used to assess inerts, since this population has higher exposure than females 13-50 years.

(b) MOE = NOAEL (mg/kg/ day) / potential dose rate (mg/kg/day) [Where short-term oral NOAEL = 50 mg/kg/day]. Target MOE ≥ 100.

(c) Exposure estimates assume a 15 kg child ingests 1L water/day and that a 60 kg adult female ingests 2L water per day of 6.6 ppb (the chronic estimated drinking water concentration (EDWC) based on the inert ingredient use.

b. Chronic Aggregate Risk

The chronic aggregate assessment considers average dietary exposure (food and drinking water) from both the active food contact sanitizer uses and the inert uses on agricultural commodities. The dietary exposures from the fruit and vegetable wash were not considered because it would be overly conservative to assume simultaneous exposure to alkylbenzene sulfonates from three different use patterns. As shown on Table 10, the dietary aggregate risk is 95% of the cPAD for children, while for adults it is 29% of the cPAD.

It should also be recognized that the majority of the uses of alkylbenzene sulfonates are not in pesticide products, but rather are used in household laundry and dish detergents. Over 800 million pounds of these compounds are produced each year, while only 300,000 pounds are used in EPA registered antimicrobial products. The Agency did

not consider potential exposure and risks from the numerous other residential exposures to alkylbenzene sulfonates because the Agency lacks reliable information at this time.

Table 10 presents a summary of the chronic aggregate risk estimates.

Table 10.
Summary of Chronic Aggregate Risk Estimates

Exposure Scenario	Dose [a] (mg/kg/day)		%cPAD[b]	
	Child (15 kg)	Adult	Child (15 kg)	Adult
Oral Exposure				
Dietary Exposure				
Food Contact Sanitizer	0.054	0.027	10.8%	5.4%
Inert Ingredient Uses (Food)	0.422	0.12	84%	24%
Drinking Water Exposure (Inert) c	0.00044	0.000189	<1%	<1%
Total Aggregate Dose and Risk	0.476	0.147	95%	29%

NA= Not applicable

(a) Chronic dietary exposure for females 13-50 years for sanitizer use. The total general population dietary exposure was used to assess inerts, since this population has higher exposure than females 13-50 years.

(b) %cPAD = dietary exposure (mg/kg/day) / cPAD, where cPAD -= 0.5 mg/kg/day for all populations.

(c) Exposure estimates assume a 15 kg child ingests 1L water/day and that a 60 kg adult female ingests 2L water per day containing 6.6 ppb alkylbenzene sulfonates. The 6.6 ppb estimate is based on the chronic estimated drinking water concentration (EDWC)) resulting from agricultural use of products that contain the alkylbenzene sulfonates as an inert ingredient.

8. Occupational Exposure and Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of alkylbenzene sulfonates include workers in a variety of occupational settings. Additionally, postapplication exposures are likely to occur in these settings. The representative scenarios selected for assessment were evaluated using maximum application rates as recommended on the product labels for alkylbenzene sulfonates.

Occupational risk is assessed for exposure at the time of application (termed "handler" exposure) and is assessed for exposure following application, or post-application exposure. Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site, and by the application rate.

Occupational risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from toxicological studies. In the case for alkylbenzene sulfonates, MOEs greater than 100 for inhalation exposures

are not of concern to the Agency for short- and intermediate-term exposures. For workers entering a treated site, MOEs are calculated for each day after application to determine the minimum length of time required before workers can safely re-enter.

a. Occupational Toxicity

Table 6 provides a listing of the toxicological endpoints used in the occupational risk assessment for alkylbenzene sulfonates.

b. Occupational Handler Exposure

The Agency has determined that there is potential for dermal and inhalation worker exposure to alkylbenzene sulfonates at various use sites when used at various use sites including agricultural premises, food handling, and commercial/institutional/industrial premises. Representative scenarios were selected for evaluation based on the use sites and maximum application rates for all three of the active ingredients in this assessment. As noted previously, the Agency did not select a dermal endpoint, and thus only inhalation exposure and risk estimates are presented.

To assess the handler risks, the Agency used surrogate unit exposure data from both the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study and the Pesticide Handlers Exposure Database (PHED). Short-, and intermediate-term inhalation risks to occupational handlers for sanitizing scenarios, and estimated risks are presented in Table 11.

The Agency also calculated a total MOE for one of the active ingredients, sodium dodecylbenzene sulfonate based on the label use directions, which recommend the same product be used for both cleaning and sanitizing. Short-, and intermediate-term inhalation risks to occupational handlers cleaning and sanitizing with products that contain sodium dodecylbenzene sulfonate are shown in Table 12.

c. Occupational Handler Risk Summary

The occupational handler risk assessment included only inhalation exposures because the Agency did not select a dermal endpoint. For the occupational handler inhalation risk assessment, the short- and intermediate- term risks calculated at baseline exposure (no respirators) were above target MOEs for all scenarios (i.e., inhalation MOEs were >100), except:

- Short-Term and Intermediate-Term inhalation exposure from cleaning hard surfaces via wiping in the food handling category, inhalation MOE = 93.

Due to the conservative nature of the assessment, the Agency does not have a risk concern for this scenario.

The Agency also calculated a total MOE for one of the active ingredients, sodium

dodecylbenzene sulfonate based on the label use directions, which recommend the same product be used for both cleaning and sanitizing. As shown on Table 12, all total inhalation MOEs for cleaning and sanitizing (baseline) were above the target MOE of 100 for all scenarios, except the following:

- Short-Term and Intermediate-Term inhalation exposure from cleaning indoor hard surfaces via wiping and then following with sanitizing via immersion/flooding in the food handling premises category, inhalation MOE = 93.
- Short-Term and Intermediate-Term inhalation exposure from cleaning indoor hard surfaces via wiping and then following with sanitizing via low pressure spray in the food handling premises category, inhalation MOE = 90.
- Short-Term and Intermediate-Term inhalation exposure from cleaning indoor hard surfaces via sponge/mesh/wiping and then sanitizing via immersion/flooding in the food handling premises category, inhalation MOE = 90.

Again, due to the conservative nature of the assessment, risk estimates making a lot of assumptions, and the MOEs being so close to the target, the Agency does not have a risk concern for these scenarios.

Table 11. Short-, and Intermediate-Term Inhalation Risks for Occupational Handlers for Sanitizing (Representative Scenarios)

Exposure Scenario	Method of Application	Application Rate (lb ai/ gallon)	Quantity Handled/ Treated per day (gallons)	Baseline Inhalation MOE (a) (Target MOE≥100)
Agricultural Premises and Equipment				
Application to hard surfaces	Brush	0.0667	0.26	2,000
	Mechanical Foam	0.0667	0.26	430
	Flooding	0.00183	10	280
	Cleaning in place (CIP)	0.00195	10,000	1,200
	High Pressure spray	0.00326	40	630
	Immersion	0.00334	10	160
	Low pressure spray	0.00334	10	430
	Trigger Pump Spray	0.00334	0.26	8,700
Food Handling				
Application to indoor hard surfaces	Brush	0.0667	0.26	2,000
	Mechanical Foam	0.0667	0.26	430
	Immersion	0.00334	10	160
	Trigger Pump Spray	0.00334	0.26	8,700
	Low pressure handwand (clean)	0.00603	2	1,200

Table 11. Short-, and Intermediate-Term Inhalation Risks for Occupational Handlers for Sanitizing (Representative Scenarios)				
Exposure Scenario	**Method of Application**	**Application Rate (lb ai/ gallon)**	**Quantity Handled/ Treated per day (gallons)**	**Baseline Inhalation MOE (a) (Target MOE≥100)**
	High pressure spray (sanitize)	0.0115	40	180
	Immersion, flooding for RTU (sanitize)	0.003	10	170
	Mopping	0.00244	2	840
	Wiping (clean)	0.00603	0.26	93
	Sponge/mesh wipe (clean)	0.003	0.26	190
	Cleaning in Place (CIP) (clean and sanitize)	0.00358	10,000	680
Food dispensing equipment	Cleaning in Place (CIP) (clean)	0.00603	10,000	400
	Cleaning in Place (CIP) (sanitize)	0.00302	10,000	810
Fruits and vegetables	Immersion	0.00455	10	110
	Trigger pump spray	0.003	0.26	9,700
Commercial/Institutional Premises				
Application to indoor hard surfaces (includes utensils and silverware)	Brush	0.0667	0.26	2,000
	Mechanical Foam	0.0667	0.26	430
	Immersion	0.00334	10	160
	Low Pressure Handwand	0.00334	2	2,200
	Trigger Pump Spray	0.00334	0.26	8,700
Shower stalls and toilets	Mopping	0.0177	2	120
	Swabbing after a liquid pour	0.0177	0.26	1,100

(a) MOE = NOAEL (mg/kg/day) / Daily Dose [Where short-and intermediate-term NOAEL = 0.14 mg/kg/day for inhalation exposure] Target MOE is ≥ 100.

Table 12. Short, and Intermediate Term Inhalation Risks to Occupational Handlers Cleaning and Sanitizing with Products That Contain Sodium Dodecylbenzene Sulfonate			
Representative Use	**Method of CLEANING Application (Baseline MOE)**	**Method of SANITIZING Application (Baseline MOE)**	**Total Inhalation MOE (Baseline) (Target MOE≥100)**
Food Handling/Storage Establishments Premises and Equipment			
Indoor Hard Surfaces (includes dishes and silverware)	High pressure spray (1,100)	High pressure spray (180)	150
		Brush (12,000)	1,000
	Brush (75,000)	High pressure spray (180)	180
		Brush (12,000)	10,000
	Low pressure spray (1,200)	Immersion/Flooding ($1.4X10^6$)	1,200
		Low pressure spray (2,400)	800
	Wiping (93)	Immersion/Flooding ($1.4X10^6$)	93
		Low pressure spray (2,400)	90
	Foam (4,000)	Immersion/Flooding ($1.4X10^6$)	4,800
		Low pressure spray (2,400)	1,600
	Brush (22,000)	Immersion/Flooding ($1.4X10^6$)	22,000
		Low pressure spray (2,400)	2,000
	Sponge/Mesh/Wiping (190)	Immersion/Flooding (170)	90
		Trigger Pump (9,700)	190
	Low Pressure Spray (2,400)	Immersion/Flooding (170)	160
		Trigger Pump (9,700)	1,900
	Brush (45,000)	Immersion/Flooding (170)	170
		Trigger Pump (9,700)	8,000
	CIP (680)	CIP (680)	340
Food dispensing equipment	CIP(400)	CIP (810)	270

d. Occupational Post-Application Exposure

For most of the occupational scenarios, postapplication dermal exposure is not expected to occur or is expected to be negligible based on the application rates and chemical properties of these chemicals. The alkylbenzene sulfonates have a low vapor pressure ($5.1x10^{-10}$ to $6.02x10^{-15}$ mmHg), so that any standing solutions that may result in post application exposure were deemed negligible. For additional information, please see the Occupational and Residential Exposure Assessment for Alkylbenzene Sulfonates for the Reregistration Eligibility Decision document, dated July 6, 2006.

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 alkylbenzene sulfonates use sites and any associated uncertainties.

For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate Assessment of Alkylbenzene Sulfonates for the Reregistration Eligibility Decision and the Ecological Hazard and Environmental Risk Assessment of Alkylbenzene Sulfonates for the Reregistration Eligibility Decision document, dated July 12, 2006.

1. Environmental Fate and Transport

No fate studies for alkylbenzene sulfonates are available in US EPA's files. Thus, the Agency has relied on scientific literature and the Agency's EPI Suite model to obtain different environmental properties for the alkylbenzene sulfonates. The EPI Suite model predicts that alkylbenzene sulfonates are not likely to persist in water or microbial soils and sediments. The Agency also conducted a literature search to further support the output parameters that were provided by the EPI Suite model. Extensive literature are available that describe the fate and significance of alkylbenzene sulfonates in the environment from a long history of detergent use.

Environmental exposure modeling was not conducted for alkylbenzene sulfonic acids and sulfonates because the currently registered uses are indoor spray applications. Uses such as urinals and toilet bowls could result in minimal exposure to the environment when flushed, however, significant environmental exposure is not expected for the following reasons: total alkylbenzene sulfonate usage for these industrial applications is very minor - a very small percentage of the total pounds is used in antimicrobials; commercial only use precludes broad environmental exposures that might occur with residential use; applications are mostly sprayed on and allowed to air dry; alkylbenzene sulfonate breakdown and degrade rapidly in the environment; alkylbenzene sulfonates are significantly reduced by sewage treatment; and industrial water treatment requires a NPDES permit in order to discharge effluents.

2. Ecological Risk

The ecological risk assessment integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects.

Alkylbenzene sulfonates demonstrate low acute toxicity to birds, moderate acute toxicity to freshwater fish, and low to high acute toxicity to freshwater aquatic invertebrates depending on the length of the carbon chain. Supplemental acute studies indicate that alkylbenzene sulfonates are moderately toxic to freshwater fish and slightly to highly toxic to freshwater aquatic invertebrates depending on the length of the carbon chain. A summary of submitted data is provided in Table 13.

Table 13. Acute Toxicity of Alkylbenzene Sulfonates

Species	Chemical, % active ingredient (ai)	Endpoint	Toxicity Category (TGAI)	Satisfies Guidelines/ Comments	MRID
Birds					
Northern bobwhite *(Colinus virginianus)*	87.6%Carbon chain not identified. (Nacconal 90G used)	LD_{50} > 1382 mg/kg NOEL = 279 mg/kg	Slightly toxic	Yes. Acceptable. 14 day test	41143901
Freshwater Fish					
Fathead Minnow (*Pimephales promelas*)	14.0% (Carbon chain not identified.)	96hr LC50 = 3.4 mg/L	Moderately toxic	Yes. Supplemental study.	44260002
Rainbow trout *Oncorhynchus mykiss*)	65.0% C11, C12	96 hr LC50 = 1.68 mg/L	Moderately toxic	Yes. Supplemental study.	44260009
Freshwater Invertebrates					
Waterflea *(Daphnia magna)*	Not reported.	48-hr. EC_{50} = LAS-C10 = 29.5 mg/L, LAS-C12 = 6.84 mg/L, LAS-C14 = 0.80 mg/L, LAS-C16 = 0.20 mg/L.	C-10 = Slightly toxic, C14 = highly toxic.	Yes. Supplemental study.	47025025
Green Algae					
Selenastrum capricornutum	Not Reported. (Carbon chain not identified.)	96 hr. EC50 = 70.27 ppm	Slightly toxic	Supplemental study.	42439803

The alkylbenzene sulfonates are used as inert ingredients in agricultural herbicide formulations. Preplant incorporated and preemergence herbicide treatments are typically

applied once per year to the tilled, minimally tilled or no-tilled field before planting or before crop emergence in the spring. Spray applications are primarily via ground boom spray and occasionally by aircraft. Movement of the alkylbenzene sulfonates from the treated field to the aquatic environment can occur at the time of application due to spray drift, or following application via surface water/soil flow or by percolation to groundwater. The FIRST model has predicted a maximum potential concentration of 6.6 ppb alkylbenzene sulfonates in drinking water from inert agricultural uses. Available modeling and literature suggest that these chemicals will most likely biodegrade rapidly in soil due to microbial degradation. In addition, aquatic organisms are also not expected to be adversely affected by inert alkylbenzene sulfonates use acutely or chronically due to the low estimated level of alkylbenzene sulfonates in water.

3. Risk to Listed Species

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 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 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 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 then 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. The active ingredient uses of alkylbenzene sulfonic acids and sulfonates fall into this category for the following reasons:

1. The amount that will actually reach the environment is very small based on usage data for down-the-drain uses.
2. Use for toilets and urinals is limited (no home-owner or residential uses are registered).
3. Breakdown of alkylbenzene sulfonate in the environment and via sewage treatment is rapid and well documented in the literature.

The labeled antimicrobial uses of alkylbenzene sulfonic acids and sulfonates are not expected to result in significant environmental exposure. Therefore, no adverse effects (NE) to listed species are anticipated. Use of alkylbenzene sulfonates as inert ingredients in agricultural pesticide formulations is not expected to result in significant environmental exposure. Therefore, no adverse effects (NE) to listed species are anticipated.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

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 the generic (i.e., active ingredient-specific) data required to support reregistration of products containing alkylbenzene sulfonates as an active ingredient. The Agency has completed its review of these generic data and has determined that the data are sufficient to support reregistration of all supported products containing alkylbenzene sulfonates.

The Agency has completed its assessment of the dietary, residential, occupational, drinking water, and ecological risks associated with the use of pesticide products containing the active ingredient alkylbenzene sulfonates. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient alkylbenzene sulfonates, the Agency has sufficient information on the human health and ecological effects of alkylbenzene sulfonates 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 alkylbenzene sulfonates-containing products are eligible for reregistration provided that current data gaps and confirmatory data needs are addressed. Appendix A summarizes the uses of alkylbenzene sulfonates 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 alkylbenzene sulfonates 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

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decision for alkylbenzene sulfonates. During the public comment period on the risk assessments, which closed on June 19, 2006, the Agency received numerous comments from The DDBSA Steering Committee/Joint Venture (JV) and The Council for LAB/LAS Environmental Research (CLER) and the European Centre on Studies on LAB/LAS (ECOSOL) in response to EPA's draft risk assessment (RA) for alkylbenzene sulfonates. The comments submitted include areas of toxicology, chemical structure, risks, production volumes, and exposure. The Agency's responses to these comments are incorporated into the risk assessment and revised chapters, which are available on the U.S. Federal Government website at: www.regulations.gov (EPA-HQ-OPP-2006-0156). A Response to Comment document will be made available on the public docket in the future. In addition, comments received by the registrants during Phase I of the RED process, are available on the docket.

The Agency is providing a 60-day public comment period on this RED.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with alkylbenzene sulfonates. The Agency has concluded that the tolerance exemptions for the use of alkylbenzene sulfonates as an active and as an inert ingredient meet the FQPA safety standards and that the risk from dietary exposure (food sources only) is within the "risk cup." An acute aggregate assessment was not conducted because there are no adverse effects attributable to acute exposure. An intermediate-term aggregate assessment was not conducted because there are no residential exposures of this duration. In addition, because there are no long-term residential exposures, the chronic aggregate assessment only considered food and drinking water. Thus, only short-term and chronic aggregate assessments were conducted.

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, as well as aggregate exposure from food, drinking water and residential uses.

b. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with alkylbenzene sulfonates. The Agency has determined that the established tolerance exemptions for alkylbenzene sulfonates meet 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 it's use. In reaching this conclusion, the Agency has considered all available information on alkylbenzene sulfonates.

Typically, aggregate risk assessments are conducted for acute (1 day), short-term (1-30 days), intermediate-term (1-6 months) and chronic (6 months to lifetime) exposures. However, an acute aggregate assessment was not conducted because there are no adverse effects attributable to acute exposure of alkylbenzene sulfonates. An intermediate-term aggregate assessment was not conducted because there are no residential exposures of this duration. In addition, because there are no long-term residential exposures, the chronic aggregate assessment only considered food and drinking water. Thus, only short-term and chronic aggregate assessments were conducted. The short-term and chronic aggregate risk estimates associated with alkylbenzene sulfonates are well below the Agency's level of concern. Oral and inhalation exposure and risk estimates were conservatively combined for the aggregate risk assessment because these endpoints both identify adverse effects on body weight. The aggregate oral and inhalation risks are not of concern for adults or children. Dermal exposures were not considered in the risk assessment because a toxicological endpoint was not established.

c. Determination of Safety to Infants and Children

EPA has determined that the currently registered uses of alkylbenzene sulfonates, with changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors of the toxicity, use practices, and environmental behavior noted above for the general population, but also takes into account the possibility of increased susceptibility to the toxic effects of alkylbenzene sulfonates residues in this population subgroup.

No Special FQPA Safety Factor is necessary to protect the safety of infants and children. In determining whether or not infants and children are particularly susceptible to toxic effects from alkylbenzene sulfonates residues, the Agency considered the completeness of the 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 alkylbenzene sulfonates based on: (1) there is no concern for developmental neurotoxicity resulting from exposure to alkylbenzene sulfonates because there is no evidence alkylbenzene sulfonates will induce neurotoxic effects; (2) there is no quantitative or qualitative evidence of increased susceptibility to the fetus following *in utero* exposure in the prenatal developmental toxicity studies or to the offspring when adults are exposed in the two-generation reproductive study; and (3) 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 was 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, 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).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, alkylbenzene sulfonates may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

e. Cumulative Risks

Risks summarized in this document are those that result only from the use of alkylbenzene sulfonates. 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 as would 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 alkylbenzene sulfonates. 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/.

2. Tolerance Summary

Active Ingredient Uses

Exemptions from the requirement of a tolerance for the active food-contact sanitizer uses of these ingredients have been established in the 40 CFR 180.940(b) and (c).

Table 14. Tolerance Exemptions for Food Contact Sanitizer Uses (Active Uses)

Tolerance Exemption Expression/ Chemical Name	CAS No.	PC Code	40 CFR Citation	Use Pattern (Pesticidal)
Benzenesulfonic acid, dodecyl-	27176-87-0	098002	180.940 (b)	food contact sanitizing solutions for dairy processing equipment, and food processing equipment and utensils; end use concentration not to exceed 5.5 ppm NOTE: The Agency will be proposing a change to 40 CFR 180.940(b) to make the end use concentration not to exceed 400 ppm.
			180.940 (c)	food contact sanitizing solutions for food processing equipment and utensils; end use concentration not to exceed 400 ppm
Benzenesulfonic acid dodecyl-, sodium salt	25155-30-0	079010	180.940 (c)	food contact sanitizing solutions for food processing equipment and utensils; end use concentration not to exceed 430 ppm

Dodecylbenzenesulfonic acid (27176-87-0) and sodium dodecylbenzene sulfonate (25155-30-0) have uses in food-contact surface sanitizing solutions with tolerance exemptions as specified in 40 CFR 180.940 (b) and (c), and summarized in Table 14. Residues for these compounds are exempt from the requirement of a tolerance when used in accordance with good manufacturing practice as ingredients 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. Both dodecylbenzene sulfonic acid, and sodium dodecylbenzene sulfonate have limitations for the ready-to-use end-use concentration not to exceed 400 ppm and 430 ppm, respectively for food processing equipment and utensils. However, dodecylbenzene sulfonic acid has a much lower limitation of 5.5 ppm for use on dairy processing equipment. The Agency estimates that the 430 ppm limitation for the sodium salt is equivalent to approximately 400 ppm of the free acid form. The Agency will be proposing a change to the 40 CFR 180.940(b) to establish a maximum of 400 ppm for the end-use concentration of dodecylbenzenesulfonic acid, rather than the current limitation of 5.5 ppm. As previously stated, the Agency used the FDA milk truck model to estimate residues in milk that could result from the use of alkylbenzene sulfonates in the food processing equipment. The Agency assessed the maximum application rate of 400 ppm for dodecylbenzene sulfonates (as listed on the labels), although the current tolerance exemption has a limitation of 5.5 ppm for dairy processing equipment. This assessment indicated that risks are not of concern for all subpopulations.

Inert Ingredient Uses

Included in this document is the reassessment of the alkylbenzene sulfonates when used as an inert ingredient in pesticidal products. As noted previously, some of the inert functions of alkylbenzene sulfonates in the registered products are listed as solvent, surfactant, dispersant, detergent, or wetting agent. Some of these products are designated for use in agricultural settings (i.e., pre- and post-harvest and when applied to animals), where there is a potential for dietary exposure. The alkylbenzene sulfonates assessed in this document are constituents of a larger group of compounds that have a tolerance exemption as an inert ingredient in 40 CFR 180.910 and 180.930. As shown in Table 15, the tolerance exemption is listed as Alkyl (C8-C24) benzenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc salts.

Table 15. Tolerance Exemptions for Inert Use		
Tolerance Exemption Expression	**40 CFR Citation**	**Use Pattern**
Alkyl (C8-C24) benzenesulfonic acid and its ammonium, calcium, magnesium, potassium , sodium and zinc salts	180.910 (a)	Surfactants, related adjuvants of surfactants
	180.930 (a)	Surfactants, emulsifier, related adjuvants of surfactants

(a) Residues listed in 40 CFR §180.910 are exempted from the requirement of a tolerance when used as inert ingredients in pesticidal formulations when applied to growing crops or to raw agricultural commodities after harvest (i.e., pre- and post-harvest). Residues listed in 40 CFR §180.930 are exempted from the requirement of a tolerance when used as inert ingredients in pesticidal formulations when applied to animals only.

D. Regulatory Rationale

The Agency has determined that alkylbenzene sulfonates are eligible for reregistration provided that additional required data confirm this decision.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

The chronic dietary exposure estimates for both the active and inert ingredient uses are below the Agency's level of concern for all age groups. Therefore, no mitigation measures are necessary at this time.

b. Drinking Water Risk Mitigation

The chronic drinking water exposure estimates for the inert ingredient uses are below the Agency's level of concern. Significant drinking water exposure is not expected to result from the active ingredient uses of alkylbenzene sulfonates. Therefore, no mitigation measures are necessary at this time.

c. Residential Risk Mitigation

Residential risk estimates for the uses of alkylbenzene sulfonates as inert ingredients are below the Agency's level of concern. Therefore, no mitigation measures are needed at this time for these uses, as none present a risk of concern.

d. Occupational Risk Mitigation

i. Handler Risk Mitigation

The calculated short and intermediate-term inhalation MOEs are greater than 100, and therefore, are not of concern with the exception of the following scenarios:

- Short-Term and Intermediate-Term inhalation exposure from cleaning hard surfaces via wiping in the food handling category, inhalation MOE = 93.
- Short-Term and Intermediate-Term inhalation exposure from cleaning indoor hard surfaces via wiping and then following with sanitizing via immersion/flooding in the food handling premises category, inhalation MOE = 93.
- Short-Term and Intermediate-Term inhalation exposure from cleaning indoor hard surfaces via wiping and then following with sanitizing via low pressure spray in the food handling premises category, inhalation MOE = 90**.**
- Short-Term and Intermediate-Term inhalation exposure from cleaning indoor hard surfaces via sponge/mesh/wiping and then sanitizing via immersion/flooding in the food handling premises category, inhalation MOE = 90.

Due to the conservative nature of the assessment, risk estimates making a lot of assumptions, and the MOEs being so close to the target, the Agency does not have a risk concern for these scenarios.

ii. Post-Application Risk Mitigation

At this time, EPA does not foresee post-application exposures for the occupational uses of alkylbenzene sulfonates; therefore, no mitigation measures are necessary.

2. Environmental Risk Management

The Agency considers the uses of alkylbenzene sulfonates assessed in this RED to be unlikely to result in any appreciable exposure to terrestrial or aquatic organisms. Therefore, no risk mitigation measures are required.

3. 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 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 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 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 then 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 low toxicity of alkylbenzene sulfonates, 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

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

V. What Registrants Need to Do

The Agency has determined that alkylbenzene sulfonates are eligible for reregistration provided that additional data that the Agency intends to require confirm this decision. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For end-use products containing the active ingredient alkylbenzene sulfonates, the registrants need to submit the following items as there are no registered technical manufacturers:

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 Adam Heyward at (703) 308-6422 with questions regarding generic reregistration.

By US mail:
Document Processing Desk
Adam Heyward
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:
Document Processing Desk
Adam Heyward
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

For end-use products containing the active ingredient alkylbenzene sulfonates, the registrants need 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
Adam Heyward
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:
Document Processing Desk
Adam Heyward
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

A. Manufacturing Use Products

There are no currently registered alkylbenzene sulfonates manufacturing-use products. However, additional generic data requirements have been identified.

1. Additional Generic Data Requirements

The generic database supporting the reregistration of alkylbenzene sulfonates has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory data requirements. A generic data call-will be issued at a later date.

The risk assessment noted deficiencies in the surrogate inhalation exposure data available from the Chemical Manufacturers Association (CMA) data base. Therefore, the Agency is requiring confirmatory data to support the uses assessed with the CMA exposure data within this risk assessment. The risk assessment also noted that many of the use parameters (e.g., amount handled and duration of use) were based on professional judgments. Therefore, descriptions of human activities associated with the uses assessed are required as confirmatory. A 90-day nose-only rat inhalation study using DDBSA (Guideline 870.3465) is required due to limitations with the monkey inhalation study, which used 13% LAS, in addition to the presence of enzyme.

Table 16. Confirmatory Data Requirements for Reregistration

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
90-Day Inhalation – Rat	870.3465	82-4
Indoor Inhalation Exposure and Applicator Exposure Monitoring Data Reporting	875.1400 and 875.1600	234 and 236
Descriptions of Human Activity	875.2800	133-1
Product Use Information	875.1700/2700	N/A

2. Labeling for Technical and Manufacturing Use Products

There are no registered technical or manufacturing use products.

B. End-Use Products

1. Additional Product-Specific Data 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, then the study MRID numbers should be cited according to the

instructions in the Requirement Status and Registrants Response Form provided for each product.

A product-specific data call-in, outlining data requirements, will be sent to registrants at a later date. Possible efficacy studies that the Agency may call-in are listed in Table 17 below. The PDCI will be based upon current efficacy-related requirements for antimicrobial pesticide products, claims, or patterns of use. A summary of these requirements can be found on the Agency's Antimicrobials Science Policy website at http://www.epa.gov/oppad001/sciencepolicy.htm.

Table 17. Efficacy Data Requirements for Product Reregistration

Claim	Use Pattern	Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Sanitizer	(non-food contact surfaces – non-residual)	Sanitizer Test for Hard Inanimate Non—food contact surfaces	810.2100(l)	91-2(j)
Sanitizer	previously cleaned food-contact surfaces (non residual)	AOAC Germicidal and Detergent Sanitizers Method	810.2100 (m)(2)	91-2 (l)(2)
Disinfectant	Toilet bowl, urinal surfaces	AOAC Use Dilution Test (hard water and organic soil) Or AOAC Germicidal Spray Test Or AOAC Hard Surface Carrier Test (distilled water only)	91-7 (a) (1)	810.2600 (b) (1)
Virucidal Claim in Conjunction with Disinfectant Claim	Any site/application	Virucidal Activity Method used in conjunction with modifications of: AOAC Hard Surface Carrier Test (distilled water only) Or AOAC Germicidal Spray Test	810.2100(g)	91-2(f)
Fungicidal Claim	Any site/application	AOAC Fungicidal Test or AOAC Hard Surface Carrier Test (distilled water only) Or AOAC Germicidal Spray Products Test	810.2100(f)	91-2(e)

2. Labeling for End-Use Products that Contain Alkylbenzene Sulfonates as an Inert Ingredient

All products that contain alkylbenzene sulfonates as an inert ingredient and make a sanitization claim must contain an active ingredient that is a sanitizer. If a product containing alkylbenzene sulfonates as an inert ingredient makes a sanitization claim and does not contain an active ingredient that is a sanitizer, the sanitization claim will have to be removed from the label. If the registrant wishes to keep the sanitization claim, alkylbenzene sulfonates will need to be listed as an active ingredient rather than an inert ingredient. All relevant data will need to be submitted and reviewed in order to make this change.

VI. APPENDICES

Appendix A. Table of Use Patterns for Alkylbenzene Sulfonates

PC Code 079010

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications[1]	Use Limitations
Food handling/ storage establishments premises and equipment				
Eating Establishments & Equipment (utensils, cutting boards, counter tops, sinks, etc.), Food handling areas	Soluble Concentrate 1020-13	Brush or Spray	2 oz / gallon of water	Prepare fresh solutions daily
	Soluble Concentrate 71094-1 Ready to Use 71094-2	Immersion, flooding or spraying	1%(one pouch/ 8 gallons) to 2%(one pouch/ 4 gallons) One minute contact time	None Stated
Dairy and Food Processing Plants & Equipment, Food Contact	Soluble Concentrate 1020-13	Brush or Spray	2 oz / gallon of water	Prepare fresh solutions daily
	Soluble Concentrate 71094-1 Ready to Use 71094-2	Immersion, flooding or spraying	1%(one pouch/ 8 gallons) to 2%(one pouch/ 4 gallons) One minute contact time	None Stated
Fruit and Vegetable Rinses	Soluble Concentrate 71094-1 Ready to Use 71094-2	Immersion, gentle hand scrub	1%(one pouch/ 8 gallons) to 2%(one pouch/ 4 gallons) 2 to 5 minute wash	Prepare cleaning solution with potable water
Soft Ice Cream, Juice and Vending Machines	Soluble Concentrate 71094-1	Circulate in system	5 to 10 minute circulation to clean 2 to 5 minute circulation	Maintain sanitizer solution pH of 2.2-2.8; discard sanitizer if it becomes visibly dirty or its pH increases/ solution may not be

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications[1]	Use Limitations
			to sanitize	reused for sanitizing
	Ready to Use 71094-2			

[1] Application rate is given in terms of end-use product, not active ingredient.

Appendix A. Table of Use Patterns for Alkylbenzene Sulfonates

PC Codes 098002 and 190116

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications[2]	Use Limitations
Agricultural premises and equipment				
Dairy Farm milking machines, milk handling equipment and facilities	Soluble Concentrate 833-75 875-85 875-184 1270-254 4959-29 9152-18 64328-1 74210-1	Immersion, brush, spray, flushing or circulation	To clean: 1 oz. to 1.5-5 gallons of water To sanitize: 1 oz. to 1-6 gallons of water. 1-5 minute contact time. (200-400ppm)	Pre-clean and pre-soak prior to use. For cleaning follow with a potable water rinse. For sanitization, wash pre-cleaned surfaces with approved alkaline cleaner and potable water rinse before use.
	Soluble Concentrate 875-185	Immersion, brush, spray, flushing or circulation	1:30 to 1:40 dilution for foam cleaning and de-scaling	
			To sanitize: 1:200 dilution, ten minute contact time	

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications[2]	Use Limitations
Food handling/storage establishments premises and equipment				
Diary/Cheese processing plant equipment	Soluble Concentrate 150-61 833-75 875-85 875-184 1270-254 1677-169 2686-10 9152-18 19713-299 64328-1 65001-1 71695-1 74210-1	Immersion, brush, spray, flushing or circulation	To clean: 1 oz. to 1.5-5 gallons of water To sanitize: 1 oz. to 1-6 gallons of water. 1-5 minute contact time. (200-400ppm)	Pre-clean and pre-soak prior to use. For cleaning follow with a potable water rinse. For sanitization, wash pre-cleaned surfaces with approved alkaline cleaner and potable water rinse before use.
Diary/Cheese processing plant equipment	Soluble Concentrate 875-185	Immersion, brush, spray, flushing or circulation	1:30 to 1:40 dilution for foam cleaning and de-scaling To sanitize: 1:200 dilution, ten minute contact time	Pre-clean and pre-soak prior to use. For cleaning follow with a potable water rinse. For sanitization, wash pre-cleaned surfaces with approved alkaline cleaner and potable water rinse before use.
Ice Cream processing plant equipment	Soluble Concentrate 9152-18	Immersion, brush, spray, flushing or circulation	To sanitize: 1 oz. to two gallons of water, five minute contact time.	For sanitization, wash pre-cleaned surfaces with approved alkaline cleaner and potable water rinse before use.
	Soluble Concentrate 74210-1	Immersion, brush, spray, flushing or	To sanitize: 1 – 2 oz per 10 gallons of water, two minute contact time.	

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications[2]	Use Limitations
		circulation		
Egg processing and packing equipment and surfaces	Soluble Concentrate 1270-254	Circulation, flushing	To sanitize: 1 oz. to 6 gallons of water, one minute contact time.	For sanitization, wash pre-cleaned surfaces with approved alkaline cleaner and potable water rinse before use. NOTE: EPA Reg. No. 74210-1 has shell egg grading and egg products on its label but no specific directions for how to use the product on the site.
	Soluble Concentrate 74210-1	Immersion, brush, spray, flushing or circulation	To sanitize: 1 – 2 oz per 10 gallons of water, two minute contact time.	
Eating establishments equipment, glassware and utensils	Soluble Concentrate 833-75 875-184 1270-254 4959-29 64328-1	Immersion, brush, spray, flushing or circulation	To clean: 1 oz. to 1.5-5 gallons of water To sanitize: 1 oz. to 1-6 gallons of water. 1-5 minute contact time. (200-400ppm)	Pre-clean and pre-soak prior to use. For cleaning follow with a potable water rinse. For sanitization, wash pre-cleaned surfaces with approved alkaline cleaner and potable water rinse before use.
	Soluble Concentrate 875-185	Immersion, brush, spray, flushing or circulation	1:30 to 1:40 dilution for foam cleaning and de-scaling	
			To sanitize: 1:200 dilution, ten minute contact time	
Food processing equipment and surfaces	Soluble Concentrate 150-61 833-75 875-85	Immersion, brush, spray, flushing or circulation	To clean: 1 oz. to 1.5-5 gallons of water To sanitize: 1 oz. to 1-6 gallons of water. 1-5 minute contact time. (200-400ppm)	Pre-clean and pre-soak prior to use. For cleaning follow with a potable water rinse. For sanitization, wash pre-cleaned surfaces with approved alkaline cleaner and potable water rinse before use.
Food processing equipment and surfaces	Soluble Concentrate 875-184 1270-254	Immersion, brush, spray, flushing or	To clean: 1 oz. to 1.5-5 gallons of water To sanitize: 1 oz. to 1-6	Pre-clean and pre-soak prior to use. For cleaning follow with a potable water rinse.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications[2]	Use Limitations
	1677-169 2686-10 4959-29 7546-4 9152-18 19713-299 64328-1 65001-1 71695-1	circulation	gallons of water. 1-5 minute contact time. (200-400ppm)	For sanitization, wash pre-cleaned surfaces with approved alkaline cleaner and potable water rinse before use.
	Soluble Concentrate 875-185	Immersion, brush, spray, flushing or circulation	1:30 to 1:40 dilution for foam cleaning and de-scaling	
			To sanitize: 1:200 dilution, ten minute contact time	
Meat and poultry processing plants	Soluble Concentrate 833-75 875-184 1270-254 4959-29 64328-1 74210-1	Immersion, brush, spray, flushing or circulation	To clean: 1 oz. to 1.5-5 gallons of water To sanitize: 1 oz. to 1-6 gallons of water. 1-5 minute contact time. (200-400ppm)	Pre-clean and pre-soak prior to use. For cleaning follow with a potable water rinse. For sanitization, wash pre-cleaned surfaces with approved alkaline cleaner and potable water rinse before use.
	Soluble Concentrate 875-185	Immersion, brush, spray, flushing or circulation	1:30 to 1:40 dilution for foam cleaning and de-scaling	

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications[2]	Use Limitations
			To sanitize: 1:200 dilution, ten minute contact time	
Carbonated beverage and brewery processing equipment and surfaces	Soluble Concentrate 150-61 833-75 875-184 9152-18 19713-299 64328-1 65001-1 71695-1 74210-1	Immersion, brush, spray, flushing or circulation	To clean: 1 oz. to 1.5-5 gallons of water To sanitize: 1 oz. to 1-6 gallons of water. 1-5 minute contact time. (200-400ppm)	Pre-clean and pre-soak prior to use. For cleaning follow with a potable water rinse. For sanitization, wash pre-cleaned surfaces with approved alkaline cleaner and potable water rinse before use
	Soluble Concentrate 875-185	Immersion, brush, spray, flushing or circulation	1:30 to 1:40 dilution for foam cleaning and de-scaling To sanitize: 1:200 dilution, ten minute contact time	
Wineries, carbonated beverage and brewery processing equipment and surfaces	Soluble Concentrate 1270-254	Immersion, brush, spray, flushing or circulation	To clean: 1 oz. to 1.5-5 gallons of water To sanitize: 1 oz. to 1-6 gallons of water. 1-5 minute contact time. (200-400ppm)	Pre-clean and pre-soak prior to use. For cleaning follow with a potable water rinse. For sanitization, wash pre-cleaned surfaces with approved alkaline cleaner and potable water rinse before use

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications[2]	Use Limitations
Seafood processing plants	Soluble Concentrate 1270-254	Immersion, brush, spray, flushing or circulation	To sanitize: 1 oz. to 6 gallons of water, one minute contact time.	For sanitization, wash pre-cleaned surfaces with approved alkaline cleaner and potable water rinse before use.
Fruit and vegetable rinses	Soluble Concentrate 71695-1		1 oz. per 5 gallons of water. Rinse with potable water after the wash cycle.	Use a test kit to assure proper concentration of product in the wash water. At no time should the concentration of product exceed 2 oz. per 5 gallons of water.
Residential and public access premises				
Toilets, Porcelain Urinals and Shower Stalls	Soluble Concentrate/ Ready to Use 3625-279	Mop, brush or sponge	Ready to Use: Add 1 oz. to toilet bowl, ten minute contact time.	
			Concentrate: 1 oz. per gallon of water, ten minute contact time.	
	Soluble Concentrate 65001-1	Mop, brush or sponge	1 oz. per 5 gallons of water	

[2] Application rate is given in terms of end-use product, not active ingredient.

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

Guide to Appendix B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #4006 (alkylbenzene sulfonates) covered by this RED. It contains generic data requirements that apply to alkylbenzene sulfonates in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 4). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

(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

3. Bibliographic Citation (Column 5). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number

has been assigned. Refer to the Bibliography appendix for a complete citation of the 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	1,2,3	42439801
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process	1,2,3	42439801
830.1670	61-2b	Formation of Impurities	1,2,3	42439801
830.1700	62-1	Preliminary Analysis	1,2,3	42439801
830.1750	62-2	Certification of Limits	1,2,3	43729701; 43741101; 43752001; 43750401; 43748801; 43761801
830.1800	62-3	Analytical Method	1,2,3	42439802
830.6302	63-2	Color	1,2,3	00161997
830.6303	63-3	Physical State	1,2,3	43656401
830.6304	63-4	Odor	1,2,3	43656401
830.7200	63-5	Melting Point	1,2,3	00161997
830.7220	63-6	Boiling Point	1,2,3	Not required
830.7300	63-7	Density	1,2,3	43656401
830.7840 830.7860	63-8	Solubility	1,2,3	00161997
830.7950	63-9	Vapor Pressure		Waived
830.7370	63-10	Dissociation Constant in Water	1,2,3	00161997; 00161996

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)		Waived
830.7000	63-12	pH	1,2,3	00161997
830.6313	63-13	Stability	1,2,3	43656402; 43656403; 43656401; 43787401
830.6314	63-14	Oxidizing/Reducing Action		Not required
830.6315	63-15	Flammability		Not required
830.6316	63-16	Explodability		Not required
830.6317	63-17	Storage Stability	1,2,3	41221301
830.7100	63-18	Viscosity		Not required
830.6319	63-19	Miscibility		Not required
830.6320	63-20	Corrosion Characteristics		Not required
830.6321	63-21	Dielectric breakdown voltage		Not required
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity Test	1,2,3	41143901
850.2200	71-2	Avian Dietary Toxicity		Not required
850.1075	72-1	Acute Freshwater Fish (rainbow trout or bluegill sunfish)	1,2,3	44260002, 44260009

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.1010	72-2	Acute Freshwater Invertebrate (daphnia magna)	1,2,3	47025025
TOXICOLOGY				
870.1100	81-1	Acute Oral – Rat	1,2,3	43498402; 43498408; 43498430
870.1200	81-2	Acute Dermal – Rabbit	1,2,3	94032006
870.1300	81-3	Acute Inhalation – Rat	1,2,3	Open literature
870.2400	81-4	Primary Eye Irritation – Rabbit	1,2,3	43498405
870.2500	81-5	Primary Dermal Irritation – Rabbit	1,2,3	40359306
870.2600	81-6	Dermal Sensitization	1,2,3	Open literature
870.3100	82-1a	90-Day Feeding-Rodent	1,2,3	43498412; 43498402; 43498409; 43498413 & 43511401; open literature
	82-1b	90-Day Feeding-Non-Rodent		Not required
870.3200	82-2	21/28-Day Dermal Toxicity – Rat	1,2,3	43498411; Open literature
870.3250	82-3	90-day Dermal Toxicity – Rodent		Not required; Reserved
870.3465	82-4	90-Day Inhalation – Rat	1,2,3	Data gap
870.3700a		Developmental Toxicity – rodent	1,2,3	Open literature; 43498423; 43498424; 43498425; 43498426; 43511403
870.3700	83-3b	Teratogenicity – Rabbit	1,2,3	43498426

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.3800	83-4	Reproduction and Fertility Effects - 2 Generation Repro	1,2,3	43498416; Open literature
870.4100	83-1a	Chronic Feeding Toxicity – Rodent	1,2,3	43498416; Open literature
	83-1b	Chronic Feeding Toxicity - Non-Rodent (dog)		Not required
870.4200	83-2a	Oncogenicity – Rat	1,2,3	43498421; 43498422; 43498419; 43498420; 43498416; Open literature
	83-2b	Oncogenicity – Mouse		Waived
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity		Not required
870.5100		Bacterial reverse mutation test	1,2,3	Open literature; 43498429
870.5300		In Vitro mammalian cell gene mutation test	1,2,3	Open literature; 43498427
870.5265	84-2a	Gene Mutation – ames	1,2,3	43498428
870.5385	84-2b	Structural Chromosome Aberration	1,2,3	43498429; 43498428; Open literature
870.5395		Mammalian erythrocyte micronucleus test	1,2,3	Open literature
870.5450		Rodent dominant lethal assay	1,2,3	Open literature
	84-4	Other genotoxic effects	1,2,3	43498429
870.7485	85-1	General Metabolism	1,2,3	43498431; 43498410; Open literature
870.7600	85-2	Dermal Absorption	1,2,3	42565201; 43498407

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2800	133-1	Description of Human Activity	1,2,3	Data gap
875.1200 875.1600	233	Dermal Indoor Exposure	1,2,3	Waived
875.1400 875.1600	234	Inhalation Indoor Exposure	1,2,3	Data gap
875.1700 875.2700		Product Use Information	1,2,3	Data gap
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	1,2,3	Open literature

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The docket initially contained the April 19, 2006 preliminary risk assessment and the related supporting science documents. EPA then considered comments on the risk assessment and revised the risk assessment and supporting chapters as necessary. The revised risk assessment will be posted in the docket at the same time as the RED.

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

http://www.regulations.gov

These documents include:

- Alkylbenzene Sulfonates Preliminary Risk Assessment; Notice of Availability, 4/19/06.

Preliminary Risk Assessment and Supporting Science Documents (RED Supporting Documents):

- Alkylbenzene Sulfonates (ABS) Preliminary Risk Assessment for the Reregistration Eligibility Decision (RED) Document. PC Code: 079010, 190116 and 098002. Case No. 4006. DP Barcode: D323972
- Occupational and Residential Exposure Assessment for Alkylbenzene Sulfonates for the Reregistration Eligibility Decision Document (RED) (Active Uses). T. Milano. March 23. D327732
- Residential Exposure Inert Assessment of Alkylbenzene Sulfonates for the Reregistration Eligibility Decision Document (RED). T. Milano/C. Walls**,** March 23, 2006. D327733
- Environmental Fate Assessment of Alkylbenzene Sulfonates for the Reregistration Eligibility Document (RED). T. Milano. March 23, 2006. D323968
- Product Chemistry Science Chapter for Benzene Sulfonic Acid, C_{10}-C_{16} Derivatives and Sodium Salt. A. N. Shamim. March 2006. D323976.
- Ecological Hazard and Environmental Risk Assessment of Alkylbenzene Sulfonates for the Registration Eligibility Document (RED). R. Petrie. January 2006. D323970.
- Dietary Exposure Assessments for the Reregistration Eligibility Decision. R. Quick. March 23, 2006. D327731.
- Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision (RED) Document, A.Assaad/W.Dyksra/L.Scarano, March 23, 2006. D327886.
- Inert Ingredient Dietary Risk Assessment for Linear Alkyl Benzenesulfonate. K. Leifer. March 23, 2006. D324036

Revised Risk Assessment and Revised Supporting Science Documents (RED Supporting Documents):

- Alkylbenzene Sulfonates (ABS) Revised Risk Assessment for the Reregistration Eligibility Decision (RED) Document. PC Code: 079010, 190116 and 098002. Case No. 4006. DP Barcode: D330338
- Occupational and Residential Exposure Assessment for Alkylbenzene Sulfonates for the Reregistration Eligibility Decision Document (RED) (Active Uses). T. Milano. July 6, 2006. D330329
- Residential Exposure Inert Assessment of Alkylbenzene Sulfonates for the Reregistration Eligibility Decision Document (RED). T. Milano/C. Walls**,** July 6, 2006. D330330
- Product Chemistry Science Chapter for Benzene Sulfonic Acid, C_{10}-C_{16} Derivatives and Sodium Salt. A. N. Shamim. July 11, 2006. D330332.
- Ecological Hazard and Environmental Risk Assessment of Alkylbenzene Sulfonates for the Registration Eligibility Document (RED). R. Petrie. July 12, 2006. D330326.
- Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision (RED) Document, A.Assaad/W.Dyksra/L.Scarano, July 6, 2006. D330328.
- Environmental Fate Assessment of Alkylbenzene Sulfonates for the Registration Eligibility Document (RED). T. Milano. July 6, 2006. D323968.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)

MRID Studies

MRID 41143901 - Lloyd, D.; Grimes, J.; Jaber, M. (1989) Nacconol 90G: An Acute Oral Toxicity Study with the Bobwhite: Final Report: Wildlife International Ltd. Project No. 257-101. Unpublished study prepared by Wildlife International Ltd. 26p.

MRID 42439803 - Bollman, M.A. et. al. (1990) Report on the Algal Toxicity Tests of Selected Office of Toxic Substances (OTS) Chemicals. US EPA Environmental Research Laboratory. 179p.

MRID 43377801 - Physical/Chemical Properties Data on DDBSA and its Salts by John Todhunter, 1995. SRS International Corp., Study ID#: DDBS/63-13/Supplemental

MRID 43498403 Coate et al. (1978) Respiratory Toxicity of Enzyme Detergent Dust. Toxicol. Appl. Pharmacol., 45: 477-496.

MRID 43498410 Creswell et al. (1978) Toxicology Studies of Linear Alkylbenzene Sulfonate (LAS) in Rhesus Monkeys II. The Disposition of C14-LAS After Oral or Subcutaneous Administration. Toxicology, 11: 5-17.

MRID 43498413 Heywood et al. (1978) Toxicology Studies of Linear Alkyl Sulfonate (LAS) in Rhesus Monkeys I. Simultaneous Oral and Subcutaneous Administration for 28 Days. Toxicol. Appl. Pharmacol. 11: 245-250. (HERA)

MRID 43498416 Buehler, E., Newmann, E., and King, W. (1971) Two Year Feeding and Reproduction Study in Rats with Linear Alkylbenzene Sulfonate (LAS). Tox. Appl. Pharm. 18: 83-91. (HERA)

MRID 43498419 Takahasi et al. (1970) Effect of 4-Nitroquinoline-1-Oxide with Alkylbenzenesulfonate on Gastric Carcinogenesis in Rats. GANN: 61, 27-33.

MRID 43498420 Takahasi et al. (1969) Effect of Alkylbenzenesulfonate as a Vehicle for 4-Nitroquinoline-1-Oxide on Gastric Carcinogenesis in Rats. GANN: 8, 241-261.

MRID 43498424 Nomura, T et al. (1980) The Synthetic Surfactants AS and LAS Interrupt Pregnancy in Mice. Life Sciences, 26: 49-54. (HERA)

MRID 43498425 Nomura, T. et al. (1987) Killing of Preimplantation Mouse Embryos by AS and LAS. Mutation Research 190: 25-29. (HERA)

MRID 43498426 Palmer et al. (1975) Assessment of the Teratogenic Potential of Surfactants, (Part I), Toxicology 3: 91-106.

MRID 43498427 K. Inoue et al (1980) Food Cosmetic Toxicol. 18:289-296

MRID 43498428 J. Hope (1977) Absence of Chromosome Damage in the Bone Marrow of Rats Fed Detergent Actives for 90 Days. Mutation Research, 56: 47-50.

MRID 43498429 Inoue et al. (1980) Studies of In Vitro Cell Transformation and Mutagenicity by Surfactants and other Compounds, Food. Cosmet. Toxicol 18: 289-296. (HERA)

MRID 43498431 W. Michael (1968) Metabolism of Linear Alkylate Sulfonate and Alkyl Benzene Sulfonate. Toxicol. Appl. Pharmacol. 12: 473-485.

MRID 43511403 Palmer, et al. (1975) Assessment of the Teratogenic Potential of Surfactants, (Part III) - Dermal Application of LAS and Soap. Huntingdon Research Centre, Huntingdon, Great Britain. Study No. DDBSA JV-RP4-029. Toxicology 4: 171-181.

MRID 436564001 - Product Chemistry Data in support of Registration of Sodium Dodecylbenzenesulfonic Acid by John Todhunter and Kelly White, 1995: SRS International Corp. Lab ID# DD13SA JV/g63.13

MRID 44260002 - McKim, J. M.; Arthur, J.W.; Thorslund, T.W. (1975) Toxicity of Linear Alkylate Sulfonate Detergent to Larvae of Four Species of Freshwater Fish. USEPA, Nat. Water Qual. Lab., Duluth, MN. Bulletin of Environmental Contamination and Toxicology. Vol 14 (1) pg. 1-7.

MRID 44260009 - Calamari, D.; Marchetti, R. (1973) The Toxicity of Mixtures of Metals and Surfactants to Rainbow Trout (*Salmo gairdneri rich*.) Water Research. Vol. 7(10) pg. 1453-1464.

MRID 47025025 - Maki, A.W.; Bishop, W.E. (1979) Acute Toxicity Studies of Surfactants to *Daphnia magna* and *Daphnia pulex*. Archives of Environmental Contamination and Toxicology. Vol. 8, p. 599-612. Sponsored by The Proctor and Gamble Company USA, Ivorydale Technical Ctr., Cincinnati, OH.

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Cavalli, L., et. al. (1993). "LAS Removal and Biodegradation in a Wastewater Treatment Plant." Environmental Toxicology and Chemistry. Vol. 12. pp 1777-1788.

Fairchild, J. F., F. J. Dwyer, T. W. La Point, S. A. Burch, and C. G. Ingersoll. 1993. Evaluation of a Laboratory-Generated NOEC For Linear Alkylbenzene Sulfonate In Outdoor Experimental Streams. Environmental Toxicology and Chemistry. Vol. 12(10): 1763-1775. Symposium on Surfactants and Their Environmental Safety, 11th Annual Meeting, Society of Environmental Toxicology and Chemistry, Arlington, VA, Nov. 11-15, 1990.

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Lewis, M.A., C.A. Pittinger, D.H. Davidson and C.J. Ritchie. 1993. In Situ Response of Natural Periphyton To An Anionic Surfactant And An Environmental Risk Assessment For Phytotoxic Effects. Environmental Toxicology and Chemistry. Vol. 12(10): 1803-1812. Symposium on Surfactants and Their Environmental Safety, 11th Annual Meeting, Society of Environmental Toxicology and Chemistry, Arlington, VA, Nov. 11-15, 1990.

Mathur et al. (1992) Effect of Dermal Exposure to LAS Detergent and HCH Pesticide in Guinea Pigs: Biochemical and Histopathologic Changes in Liver and Kidney. J Toxicol Cutan Ocular Toxicol, 11(1): 3-13. (WHO 1996)

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Yoneyama et al. (1978) Effects of LAS on Incorporation of Acetate-1-14C in Liver Lipids in Rats. J Ann Rep Tokyo Metrop Res Lab Public Health, 29 (2): 55-57.

Websites:

http://chem.sis.nlm.nih.gov/chemidplus/jsp/ChemFull

"International Programme on Chemical Safety, Environmental Health Criteria 169, Linear Alkylbenzene Sulfonates and Related Compounds." World Health Organization. Geneva, 1996 http://inchem.org/documents/ehc/ehc/ehc169.htm.

World Health Organization (WHO). 1996. *Environmental Health Criteria Document for Linear Alkylbenzene Sulfonates and Related Compounds.* (EHC 169, available at http://www.inchem.org/documents/ehc/ehc/ehc169.htm)

Models and Internal Documents:

DEEM-FCID™ Program and Consumption Information - Version 2.1, Exponent, Inc., Washington, DC

The Estimation Programs Interface (EPI) Suite. Windows based suite of physical/chemical properties and environmental estimation models developed by the US EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) and Syracuse Research Institute (SRC). http://www.epa.gov/opptintr/exposure/docs/EPISuitedl.htm

Linear Alkyl Benzenesulfonate Modeling Input Parameters for FIRST and GENEEC

PiRat: http://www.epa.gov/opptintr/exposure/docs/pirat.htm

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USEPA. 1998. PHED Surrogate Exposure Guide. Estimates of Worker Exposure from the Pesticide Handler Exposure Database Version 1.1. Washington, DC: U.S. Environmental Protection Agency.

USEPA. 1999. Evaluation of Chemical Manufacturers Association Antimicrobial Exposure Assessment Study (CMA). Memorandum from Siroos Mostaghimi, Ph.D., USEPA, to Julie Fairfax.

Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the Alkylbenzene 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 at a later date.

Appendix G. Batching of Alkylbenzene Sulfonates Products for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency will complete the batching at a later date.

Appendix H. List of All Registrants Sent the Data Call-In

A list of registrants sent the data call-in will be posted at a later date.

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/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

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

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

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

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
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 (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf

8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit
www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit that 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' Web Site

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. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

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 Web site.

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 Web site: ace.orst.edu/info/nptn.

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:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. 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 CAS number if one has been assigned.