Model Alternatives Assessment

FINAL
ALTERNATIVES ASSESSMENT

Nonylphenol Ethoxylates (NPE) in All-Purpose Cleaners

As Required under
Division 4.5, Title 22, California Code of Regulations
Chapter 55. Safer Consumer Products

November 2013

Acknowledgments

On behalf of all of us working to advancing safer alternatives to chemicals of concern to human health or the environment and to avoiding regrettable substitutes, I hope that this report contributes to the growth and development of the field of alternatives assessment. Discussions of this report and others within the BizNGO Alternatives Assessment Work Group were invaluable to the process of completing this alternatives assessment.

-Eric Harrington

Table of Contents

Acronyms and Abbreviations

AA	acute aquatic toxicity; alternatives assessment
AES	alkyl ether sulfate
AOS	alpha olefin sulfonate
APE	alkylphenol ethoxylate
APG	alkyl polyglucose
AS	alkyl sulfate ester
ASTM	American Society for Testing and Materials
AT	acute toxicity
AWQC	Ambient Water Quality Criteria
B	bioaccumulation
BCF	bioconcentration factor
BizNGO	BizNGO Working Group for Safer Chemicals and Sustainable Materials
BOD	biochemical/biological oxygen demand
bw	body weight
C	degrees Celsius/Centigrade; carbon; carcinogenicity
CA	chronic aquatic toxicity
CA SCP	California Safer Consumer Product (regulations)
CAN/CGSB	Canadian General Standards Board
CAS	Chemical Abstracts Service
CASRN	Chemical Abstracts Service Registry Number
CHA	comparative hazard assessment
CNO	coconut oil
CSMA	Chemical Specialties Manufacturers Association
D	developmental toxicity
d	day
deca-BDE	decabromodiphenyl ether
DfE	US EPA Design for the Environment Program
DG	data gap
DOC	dissolved organic carbon
DOT	US Department of Transportation
DTSC	California Department of Toxic Substances Control
E	endocrine activity

EC_{50}	half maximal effective concentration
ED	endocrine disruptor
EMR	Energy of material resources
EO	ethylene oxide
EU	European Union
F	flammability
Fp	flash point
GHS	Globally Harmonized System for Hazard Communication
GJ	gigajoules
GLP	good laboratory practice
H	high
HBCDD	hexabromocyclododecane
HPV	High Production Volume
IPCS	Institute of Peace and Conflict Studies
IrE	eye irritation/corrosivity
IrS	skin irritation/corrosivity
kg	kilogram
K_{ow}	octanol/water partition coefficient
L	liter; low
LAE	linear alcohol ethoxylate
LAS	linear alkylbenzene sulfonate
LC_{50}	median lethal concentration
LCI	life cycle inventory
LD_{50}	median lethal dose
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
M	mutagenicity
M	moderate
mg	milligram
MITI	Ministry of International Trade and Industry, Japan
N	neurotoxicity
NA	not available
NGO	non-governmental organization
NOAEL	no observed adverse effect level

NOEC	no observed effect concentration
NOEL	no observed effect level
NP	nonylphenol
NPE	nonylphenol ethoxylates
NPEC	nonylphenol ether-carboxylate
Oc	oleochemical
OECD	Organization for Economic Cooperation and Development
OPE	octylphenol ethoxylate
OSPAR	Oslo and Paris Conventions
P	persistence
PAA	preliminary alternatives assessment
PBT	persistent, bioaccumulative, and toxic
Pc	petrochemical
PEG	polyethylene glycol
PKO	palm kernel oil
PO	palm oil
ppm	parts per million
R	reproductive toxicity
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical Substances
Rx	reactivity
SIN	Substitute It Now (List)
SnR	respiratory sensitization
SnS	skin sensitization
SPC	sulfophenyl carboxylates
ST	systemic toxicity
STP	sewage treatment plan
T	toxic
ThCO2	theoretical carbon dioxide production
ThOD	theoretical oxygen demand
TM	trademark
TRSA	Textile Rental Services Association of America
U	undetermined
UN	United Nations
US EPA	United States Environmental Protection Agency

UVCB	unknown or variable compositions, complex reaction products and biological materials
vH	very high
vL	very low
vPT	very persistent and toxic
WHO	World Health Organization
µg	microgram

About this Report

One of the environmental and public health challenges facing industry is the reduction of "substances (or chemicals) of concern" in products. In the process of assessing viable alternatives to substances of concern, an important consideration is transitioning to a product that has the same or better performance properties, economic feasibility, and life cycle benefits, but has no substances of concern in any phase of the life cycle. When such a transition is not possible, the next step is to look at all potential alternatives and systematically define which would be as good or better than the existing product that contains a substance of concern.

To address these issues, the California Department of Toxic Substances Control (DTSC) issued the Safer Consumer Product Regulations (CA SCP regulations) in 2013, which require businesses to assess alternatives for chemicals of concern in priority products. The regulations require "responsible entities," which include manufacturers, importers, assemblers, and/or retailers, of a "priority product," that is, a consumer product containing a chemical of concern, to complete an alternatives analysis to determine whether feasible alternatives are available to minimize public health and environmental impacts. "Alternatives analysis" is synonymous with the term "alternatives assessment" and is defined as a process for identifying, comparing and selecting safer alternatives to chemicals of concern, including those in materials, processes or technologies, on the basis of their hazards, performance, and economic viability. The process is intended to ensure that chemicals of concern are replaced with safer alternatives that are not likely to be later regretted.

The CA SCP regulations divide the alternatives analysis into two stages. The primary components of Stage 1 are: examining the product's and chemical of concern's function and performance requirements; identifying candidate alternatives; identifying relevant comparison factors (for example, environmental, human health, and physicochemical properties); assessing human and environmental health hazards of concern; and completing a work plan and associated timeline for completion and submission of the Stage 2 assessment. Stage 2 includes a broader assessment of lifecycle impacts not addressed in Stage 1 and an assessment of economic and technical feasibility.

BizNGO, a collaboration of leaders from businesses, environmental groups, universities, and governments, initiated a demonstration project to conduct an alternatives assessment per the CA SCP regulations. Nonylphenol ethoxylate (NPE) in all-purpose cleaners was selected as the chemical of concern and priority product combination for the assessment. An all-purpose cleaner is one that works on multiple surfaces and accomplishes many types of cleaning needs; a familiar example of an all-purpose cleaner is Formula 409®.

NPE in all-purpose cleaners was chosen for this demonstration project for three reasons. First, known significant ecological hazards are associated with NPE and degradation compounds such as nonylphenol (NP). Second, the CA SCP regulations are anticipated to focus on consumer goods manufactured and sold in CA in widespread use for example in "household applications" versus industrial use. Third, household cleaners are formulated chemical products, which will likely be prioritized for consideration under the CA CSP regulations and which include inherent challenges in the assessment of alternatives.

This model alternatives assessment is not intended to present new information on alternatives to NPE. Rather it uses existing information to illustrate how the requirements for an alternatives assessment under the draft regulations could be met. This model assessment will be used to inform public comments to CA DTSC as it develops its CSP compliance guidance document. The analysis summarized in

this report *is not tied to any real or specific company or product*.

At the time of this demonstration project, CA DTSC had not developed compliance assessment guidance and protocols. Thus this report follows the format outlined only in the CA SCP regulations**. Future assessments need to follow compliance guidance issued by the California Department of Toxic Substances Control (DTSC), found on its website: http://www.dtsc.ca.gov/scp/.** This report includes both Stage 1 and Stage 2 assessments. However, given schedules and submission guidelines stipulated in the regulations, in practice the two stages would be submitted separately.

A summary of results and lessons learned to inform the practice of alternatives assessment under the CA SCP regulations, are described in the last section of this report.

EXECUTIVE SUMMARY

This model alternatives assessment (AA) for nonylphenol ethoxylates (NPE) in all-purpose cleaners has been completed in accordance with the California Safer Consumer Products regulations, found in Chapter 55, Division 4.5 of Title 22, California Code of Regulations.

The California Department of Toxic Substances Control (DTSC) listed all-purpose cleaning products containing NPE as a Priority Product under the Safer Consumer Products regulations, with the NPE being the designated Chemical of Concern. Accordingly, this AA has been prepared to comply with the regulations and, in the process, to identify and evaluate potential alternatives to all-purpose cleaning products containing nonylphenol ethoxylates.

As NPE clearly requires replacement, mainly due to the environmental toxicity of the primary degradate (nonylphenol, or NP), the objective of this AA is to identify an appropriate alternative chemical(s) as a substitute surfactant. Technically and economically feasible alternatives do exist, as evidenced by the plethora of products already in commerce that do not contain NPE as a surfactant.

Functional requirements for all-purpose cleaning products include cleaning a surface by wetting it, then suspending, dissolving, or otherwise separating the soil to be removed so that it is not redeposited.

Performance of all-purpose cleaning products is not standardized but is evaluated through testing according to procedures established by manufacturers or trade associations, consumer or independent testing organizations, or governmental agencies.

There are no legal requirements for the performance of all-purpose cleaning products.

The scope of alternatives considered for this AA was based on information gathered by the US EPA Design for the Environment Program (DfE) in its 2012 report *Alternatives Assessment for Nonylphenol Ethoxylates*. The DfE NPE Alternatives Assessment identified nine representative alternatives, including one, octylphenol ethoxylate, which was not considered here due to a toxicological profile more hazardous than NPE. The remaining eight alternatives considered by the US EPA are listed in Table A.

Table A: NPE Alternatives Based on EPA's 2012 Alternatives Assessment Report

CHEMICAL CLASS	REPRESENTATIVE CHEMICAL NAME	CASRN
Sorbitan ester	Sorbitan monostearate	1338-41-6
Alkyl sulfate ester (AS)	Sodium lauryl sulfate	151-21-3
Ethoxylated/ propoxylated alcohols	Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether)	64366-70-7
Linear alcohol ethoxylate (LAE)	C12-15 alcohols, ethoxylated (9EO)	68131-39-5
Linear alkylbenzene sulfonate (LAS)	Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt	68411-30-3
Linear alcohol ethoxylate (LAE)	C9-11 alcohols, ethoxylated (6EO)	68439-46-3
Alkyl polyglucose (APG)	D-glucopyranose, oligomeric, decyloctyl glycosides	68515-73-1
Alkyl ether sulfate (AES)	Polyoxy (1,2-ethanediyl), alpha-sulfo-omega-dodecyloxy-, sodium salt	9004-82-4

Factors considered for as relevant for compliance with the Safer Consumer Product regulations, along with associated exposure pathways and life cycle segments, were identified as: adverse environmental impact, adverse public health impact, environmental fate, materials and resource consumption impact (included as part of multimedia life cycle impacts), physical chemical hazards, multimedia life cycle

impacts, product function and performance impacts, and economic impacts. All potential alternatives considered were deemed to be equivalent or superior to NPEs with regard to technical and performance aspects. Table B summarizes the assessment of relevancy of the various factors that were required to be considered in the AA.

Table B: Assessment Factors Required to be Considered for Relevance

RELEVANT ASSESSMENT FACTORS		RELEVANT?	ANALYSIS METHOD
ADVERSE ENVIRONMENTAL IMPACTS	*Air quality impact*	NO	NONE
	Ecological impact	YES	GreenScreen®
	Soil quality impact	NO	NONE
	Water quality impact	NO	NONE
	Potential for exceedance of standards	NO	NONE
ADVERSE PUBLIC HEALTH IMPACT	*Carcinogenicity*	YES	GreenScreen®
	Developmental toxicity	YES	GreenScreen®
	Reproductive toxicity	YES	GreenScreen®
	Cardiovascular toxicity	YES	GreenScreen®
	Dermatotoxicity	YES	GreenScreen®
	Endocrine toxicity	YES	GreenScreen®
	Epigenetic toxicity	YES	GreenScreen®
	Genotoxicity	YES	GreenScreen®
	Hematotoxicity	YES	GreenScreen®
	Digestive system toxicity	YES	GreenScreen®
	Immunotoxicity	YES	GreenScreen®
	Musculoskeletal toxicity	YES	GreenScreen®
	Nephrotoxicity	YES	GreenScreen®
	Neurodevelopmental toxicity	YES	GreenScreen®
ADVERSE WASTE AND END-OF-LIFE IMPACTS		MEASURED BY OTHER FACTORS	NONE
ENVIRONMENTAL FATE	*Persistence and bioaccumulation*	YES	GreenScreen®
PHYSICAL CHEMICAL HAZARDS	*Reactivity and flammability, etc.*	YES	GreenScreen®
PHYSICAL PROPERTIES	*Density, viscosity, vapor pressure, etc.*	TO THE EXTENT THAT THEY AFFECT OTHER FACTORS	NONE
MULTIMEDIA LIFE CYCLE IMPACTS	*Material extraction, manufacturing production, transportation, use, end-of-life*	YES	Life Cycle Inventory; qualitative assessment
PRODUCT FUNCTION AND PERFORMANCE IMPACTS	*Product function, performance*	YES	Qualitative assessment
ECONOMIC IMPACTS	*Public health and environmental costs, costs to government agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, protecting natural resources, water quality, and wildlife*	YES	Qualitative assessment

As is shown in the table, these relevant factors were deemed to be addressable by using a comparative chemical hazard screening process; in particular, the GreenScreen® methodology. The results of this process are shown in Table C. In addition to the eight alternatives from the US EPA AA, this table includes NPE and NP (as a transformation product of NPE).

Table C: GreenScreen® Hazard Assessment Results

		Group I Human						Group II Human						Ecotoxicity				Fate		Physical	
		C	M	R	D	E	AT	ST		N		SnS	SnR	IrS	IrE	AA	CA	P	B	Rx	F
								single	repeated	single	repeated										
Chemical	**CASRN**																				
Nonylphenol ethoxylate	127087-87-0	**L**	DG	**M**	DG	*H*	**M**	**M**	DG	DG	DG	DG	DG	**H**	**vH**	**H**	**H**	**M**	DG	**L**	**L**
Nonylphenol	84852-15-3	DG	**L**	DG	DG	H	M	**DG**	**M**	DG	DG	DG	DG	**vH**	**vH**	**vH**	**H**	*vH*	*H*	**L**	**L**
Sorbitan monostearate	1338-41-6	**L**	**L**	DG	DG	DG	**L**	DG	L	DG	DG	DG	DG	**H**	DG	**H**	**H**	**L**	*vL*	**L**	**L**
Sodium lauryl sulfate	151-21-3	**L**	**L**	**L**	**L**	DG	**H**	*M*	**M**	DG	DG	**L**	DG	**H**	**vH**	**vH**	**H**	**vL**	**vL**	**L**	**H**
Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether)	64366-70-7	DG	DG	DG	DG	DG	DG	DG	DG	DG	DG	DG	DG	DG	**vH**	**M**	*M*	**L**	DG	**L**	**L**
C12-15 alcohols, ethoxylated (9EO)	68131-39-5	**L**	**L**	DG	DG	DG	**M**	DG	DG	DG	DG	**L**	DG	**H**	**vH**	**vH**	**H**	**vL**	**L**	**L**	**L**
Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt	68411-30-3	**L**	**L**	DG	DG	**L**	**M**	DG	DG	DG	DG	**L**	DG	**H**	**H**	**H**	**H**	**vL**	**L**	**L**	**L**
C9-11 alcohols, ethoxylated (6EO)	68439-46-3	**L**	**L**	**L**	DG	DG	*M*	DG	DG	DG	DG	**L**	DG	**H**	**vH**	**H**	**H**	**vL**	DG	**L**	**L**
D-glucopyranose, oligomeric, decyloctyl glycosides	68515-73-1	DG	L	L	L	DG	L	DG	L	DG	DG	L	DG	H	vH	M	M	vL	*L*	**L**	**L**
Polyoxy (1,2-ethanediyl), alpha-sulfo-omega-dodecyloxy-, sodium salt	9004-82-4	L	L	L	L	DG	M	DG	DG	DG	DG	L	DG	H	vH	vH	vH	L	DG	**L**	**L**

The resulting GreenScreen® draft benchmark scores are shown below in Table D. NP does not appear in this table as it is only a contributor to the benchmarking of NPE.

Table D: Draft GreenScreen Benchmark Scores

CHEMICAL	DRAFT BENCHMARK	REASON
Nonylphenol ethoxylates	1	Draft Benchmark Score = 1 for NP transformation product
Sorbitan monostearate	U	Does not meet minimum data requirements for Group 1 or Group II Human Health endpoints
Sodium lauryl sulfate	2	GreenScreen® Criterion 2f: Very High Eye Irritation
Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether)	U	Does not meet minimum data requirements for Group I Human Health, Group II Human Health, or Environmental Fate endpoints
C12-15 alcohols, ethoxylated (9EO)	U	Does not meet minimum data requirements for Group I Human Health
Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt	2_{DG}	GreenScreen® Criterion 3b: Moderate (or High) Ecotoxicity (Acute and Chronic Aquatic Toxicity); Criterion 3c: Moderate (or High) Group II Human Toxicity (Eye and Skin Irritation) Meets the hazard classification requirements of BM3 based on all available data but does not achieve the minimum data requirements for BM3 for Group I Human and Group II Human endpoints
C9-11 alcohols, ethoxylated (6EO)	U	Does not meet minimum data requirements for Environmental Fate endpoints
D-glucopyranose, oligomeric, decyloctyl glycosides	2_{DG}	GreenScreen® Criterion 3b: Moderate (or High) Ecotoxicity (Acute and Chronic Aquatic Toxicity); Criterion 3c Moderate (or High) Group II Human Toxicity (Eye Irritation) Meets the hazard classification requirements of BM3 based on all available data but does not achieve the minimum data requirements for BM3 for Group I Human and Group II Human endpoints
Polyoxy (1,2-ethanediyl), alpha-sulfo-omega-dodecyloxy-, sodium salt	U	Does not meet minimum data requirements for Environmental Fate endpoints

Comparison of the relevant factors between NPE and the various alternatives on a qualitative basis (based on the previous hazard assessment table data) results in Table E, wherein each factor is compared and assigned a rating as to whether it is better (+), worse (-), or equivalent (=) to NPE for each alternative. Where there are data gaps, a "?" is assigned to indicate that the relative comparison is unknown. If NPE has a data gap, and data exist for any of the alternatives, then those data are assumed to be better. Simple color-coding shows at a glance the relative comparisons: red means worse, green means better, and gray means unknown. A glance shows that there are a lot of unknowns, but for the most part the alternatives are generally better than NPE.

Table E: Comparison of Alternatives

RELEVANT ASSESSMENT FACTORS		NPE (REFERENCE)	COMPARISON TO NPE (+ better, = similar, - worse, ? unknown)							
			Sorbitan monostearate	Sodium lauryl sulfate	Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether)	C12-15 alcohols, ethoxylated (9EO)	Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt	C9-11 alcohols, ethoxylated (6EO)	D-glucopyranose, oligomeric, decyloctyl glycosides	Polyoxy (1,2-ethanediyl), alpha-sulfo-omega-dodecyloxy-, sodium salt
ADVERSE ENVIRONMENTAL IMPACT	*Acute ecotoxicity*	H	=	-	+	-	=	=	+	-
	Chronic ecotoxicity	H	=	=	+	=	=	=	+	-
	Carcinogenicity	L	=	=	?	=	=	=	?	=
	Mutagenicity	UNK*	+	+	?	+	+	+	+	+
	Reproductive toxicity	M	?	+	?	?	?	+	+	+
	Developmental toxicity	UNK*	?	+	?	?	?	?	+	+
	Endocrine activity	H	?	?	?	?	+	?	?	?
	Acute mammalian toxicity	M	+	-	?	=	=	=	+	=
ADVERSE PUBLIC HEALTH IMPACT	*Systemic toxicity – single dose*	M	?	=	?	?	?	?	?	?
	Systemic toxicity – repeated dose	UNK*	+	+	?	?	?	?	+	?
	Neurotoxicity – single dose	UNK	?	?	?	?	?	?	?	?
	Neurotoxicity – repeated dose	UNK	?	?	?	?	?	?	?	?
	Skin sensitization	UNK*	?	+	?	+	+	+	+	+
	Respiratory sensitization	UNK	?	?	?	?	?	?	?	?
	Skin irritation	H	=	=	?	=	=	=	=	=
	Eye irritation	vH	?	=	=	=	+	=	=	=
ENVIRONMENTAL FATE	*Persistence*	M	+	+	+	+	+	+	+	+
	Bioaccumulation	H*	+	+	?	+	+	?	+	?
PHYSICAL CHEMICAL HAZARDS	*Reactivity*	L	=	=	=	=	=	=	=	=
	Flammability	L	=	-	=	=	=	=	=	=
MULTIMEDIA LIFE CYCLE		UNK	?	?	?	?	?	?	?	?
PRODUCT FUNCTION AND PERFORMANCE IMPACTS		UNK	=	=	=	=	=	=	=	=
ECONOMIC IMPACTS		UNK	?	?	?	?	?	?	?	?

* If NPE has a data gap and alternatives have data, those data are assumed to be better than NPE

**NP degradate has high bioaccumulation and is used for comparison purposes

The hazard assessment and benchmarking process led to the following conclusions:

- NPE is a chemical of very high concern whose use should be avoided, having been ranked as a Draft Benchmark 1 chemical.
- Sorbitan monostearate (CASRN 1338-41-6), C12-15 alcohols, ethoxylated (9EO)(CASRN 68131-39-5), Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether)(CASRN 64366-70-7), C9-11 alcohols, ethoxylated (6EO)(CASRN 68439-46-3), and Polyoxy (1,2-ethanediyl), alpha-sulfo-omega-dodecyloxy-, sodium salt (CASRN 9004-82-4) do not meet the minimum data requirements and should not be considered further until new data is available to fill in the gaps.
- Sodium lauryl sulfate (CASRN 151-21-3) is assessed as a chemical which may be used, but for which safer substitutes should be identified (Draft Benchmark 2).
- Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt (CASRN 68411-30-3) and D-glucopyranose, oligomeric, decyloctyl glycosides (CASRN 68515-73-1) are also assessed as chemicals which may be used, but for which safer substitutes should be identified, but only due to lack of sufficient data (Draft Benchmark 2_{DG}).

RECOMMENDATION: Considering the relative draft benchmark scores, the two Draft Benchmark 2_{DG} alternatives are recommended for further assessment. In the event that these are determined to be unsuitable for some reason(s), then the Draft Benchmark 2 alternative should be evaluated.

The following actions will be completed upon approval of this AA:

- Reformulation studies to make final surfactant determination
- Submittal of revised Final Alternatives Assessment report
- Manufacturing of new formulation
- Roll-out of reformulated product

Depending on the needs for capital modifications to production facilities, these activities may be completed within two years.

This AA has been completed compliant with all pertinent aspects of the Safer Consumer Products regulations. It has been completed in sufficient breadth and depth to ensure that the recommended alternative(s) are protective of human health and the environment, as discussed in the assessment.

This page intentionally left blank

STAGE 1 ALTERNATIVES ANALYSIS

Specific guidance for all future assessment should follow the CA DTSC alternatives analysis guide: http://www.dtsc.ca.gov/scp/

Stage 1 of the alternatives assessment per CA SCP regulations included in this report include the following components.

- Identify the product requirements and function of the chemical of concern. Specific considerations include:
    - identify functional, performance, and legal requirements; identify the role of the chemical of concern; determine the requirements/necessity of the chemical of concern, including its possible elimination (if appropriate).
- Identify candidate alternatives. Specific considerations include:
    - identify and consider a broad range of alternatives; research and evaluate viable alternatives for consideration.
- Identify relevant comparison factors (for example, environmental, human health, and physicochemical properties). Specific considerations include:
    - factors that make a material contribution to one or more adverse impacts and a difference in contributing to such impacts between the priority product and its alternatives.
- Initial evaluation and screening of alternatives. Specific considerations include:
    - those identified above, (relevant comparison factors) and identify viable alternatives for further consideration in Stage 2 assessment.
- Consideration of additional information.
- A work plan and associated timeline relevant to completion and submission of the Stage 2 assessment.

Template for California Safer Consumer Products Regulations, Stage 1 and 2 Submission: Preparer Information

Preparer Data

Name	Eric Harrington
Organization	Green Advantage Consultants
Address	
Telephone	
Email	

Responsible Entity Data

Organization	***
Representative	***
Address	***
Telephone	***
Email	***

Other Involved Parties

Name	Organization	Role
***	***	***

Comment Process

This document has been posted on the website of the California Department of Toxic Substances Control (DTSC)at [URL]. It is available for public review and comment for a period of 45 days beginning [date]. Comments may be submitted in writing or electronic form to the person named in "Preparer Data" above. All comments submitted to the preparer shall be simultaneously submitted to the DTSC by [***] at [***].

Certification and Signatures

"I certify that this document and all attachments were prepared or compiled under my direction or supervision to assure that qualified personnel properly gathered and evaluated the information submitted. Based on my inquiry of the person(s) directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that submitting false information or statements is a violation of law."

Responsible Entity	Signature	***	Date	***
Preparer	Signature	***	Date	***

***As this is a model alternatives assessment, and not tied to any specific company or product, this information is not provided here.

Template for California Safer Consumer Products Regulations, Stage 1 and 2 Submission: Responsibility Entity and Supply Chain Information

Manufacturer Data	
Manufacturer	***
Headquarters Address	***
Responsible Representative	***
Address	***
Telephone	***
Email	***
Website	***
Importer Data	
Importer	***
Headquarters Address	***
Responsible Representative	***
Address	***
Telephone	***
Email	***
Website	***
California Customer Identification	
Organization	***
Contact Person	***
Address	***
Telephone	***
Email	***
Direct Outlet Identification	
Organization	***
Contact Person	***
Address	***
Telephone	***
Email	***

***As this is a model alternatives assessment, and not tied to any specific company or product, this information is not provided here.

1. Priority Product Information

Brand Names and/or Product Names	***
Products in Which Priority Product is Used as a Component	***
Chemical of Concern	nonylphenol ethoxylates (NPE)
Material Safety Data Sheet Reference	***

***As this is a model alternatives assessment, and not tied to any specific company or product, this information is not provided here.

1.1 Functional Requirements

Various types of cleaners are on the market for household, business, or institutional use, and these can be classified as follows:[1]

- General purpose/all-purpose: surface cleaners labeled as multipurpose, or clearly intended for use in a variety of applications, including multi-purpose spray cleaners, floor or wall cleaners, disinfecting cleaners, cleaner-degreasers, and concentrated cleaners.
- Bathroom cleaners: cleaners intended primarily for use on bathroom surfaces, labeled as bathroom cleaners, or which mention specific bathroom surfaces, including tub and tile cleaners, mildew stain removers, shower cleaners, and disinfecting bathroom cleaners.
- Disinfectants (excluding disinfecting cleaners): products which claim to disinfect surfaces but not necessarily to clean, including liquid, spray, or concentrated germicides.
- Scouring cleansers: surface cleaners combining with an abrasive, including scouring powders, scouring pastes or liquids.
- Glass cleaners: cleaners specifically for glass, including pump spray, aerosol, or liquid glass cleaners.
- Carpet/upholstery cleaners: cleaners specifically designed for use on fabrics that cannot be removed for laundering or dry cleaning, including liquids, foams, or dry powders, inclusive of products for use in rental machines.
- Spot/stain removers: products designed to remove spots, excluding bleaches, but including cleaning fluids, stain sticks, and enzyme spot removers.
- Toilet bowl cleaners: products designed specifically to clean the toilet bowl and which have no intended other use, including liquid or crystal acid-based cleaners, and detergent cleaners.
- Automatic toilet cleaners: products which are placed in the toilet tank and which drip or dissolve, providing continuous cleaning of the bowl, including blocks, tablets, controlled release bottles.

Of this spectrum of cleaning product types, the category of all-purpose cleaners is the Priority Product that is the subject of this AA. All-purpose cleaners are designed to clean many different types of washable surfaces, and product directions reveal the types of surfaces for which specific cleaners should be used and for which ones their use should be avoided. The benefit of an all-purpose cleaner is that it

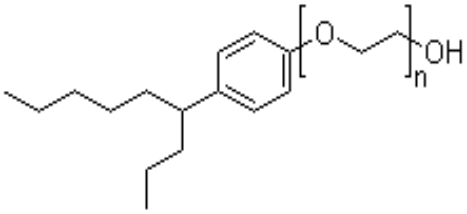
[1] Davis, G.A. et al. Household Cleaners: Environmental Evaluation and Proposed Standards for General Purpose Household Cleaners. University of Tennessee Center for Clean Products and Clean Technologies. July 1992. http://isse.utk.edu/ccp/pubs/pdfs/HouseholdCleaners-wofigsandapps.pdf. Accessed May 2013.

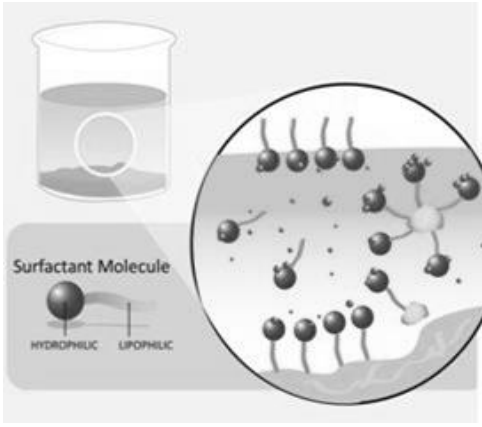
provides consumers with one cleaner that can be used in most areas of a home or office. All-purpose cleaners can frequently be used to mop, clean countertops, clean bathroom surfaces, and more.

The function of detergency or cleaning is a complex combination of functions. The surface to be cleaned and the soil to be removed must initially be wetted and the soils suspended, solubilized, dissolved or separated in some way so that the soil will not just redeposit on the surface being cleaned.

All-purpose cleaners may use many different types of ingredients, such as detergents, grease-cutting agents, solvents, surfactants, and disinfectants. Each ingredient in a formulation has a function in making a product work - whether it is to aid in cleaning by reducing surface tension (surfactants), dissolve or suspend materials (solvents), reduce water hardness (chelating agents), or provide a scent (fragrances).[2] In general, there are five types of ingredients found in household cleaners: surfactants, builders, solvents, antimicrobials, and miscellaneous. Surfactants are the wetting and foaming agents that form the basis for most aqueous cleaners. Builders are used to enhance the work of the surfactants by adjusting or maintaining solution pH, softening water, or manipulating foam height. Solvents assist in the dissolution of oil and grease. Antimicrobials are pesticides that kill bacteria, fungus, or mildew, and sometimes the same materials are used in smaller amounts as preservatives. All other ingredients are categorized as "miscellaneous" and include abrasives, fragrances, dyes, thickeners, hydrotopes (substances which keep a mixture from separating), preservatives, and anything else.

The Chemical of Concern is NPE. NPEs are nonionic surfactants that are part of the broader category of surfactants known as alkyphenol ethoxylates (APEs). NPEs are considered workhorse surfactants given their cost-effectiveness and high performance in multiple applications.[3] Although the structure of the carbon chain on the left can vary, a typical molecular structure for NPE is shown below, with 'n' corresponding to the number of repeating ethoxylates added to the molecule (n typically ranges from 4-80 in commercial formulations).





A surfactant, usually dissolved in water, does the primary work in the cleaning process as it helps to remove dirt, oil, and grease from a surface by enabling the cleaning solution to fully wet the soiled surface so the contaminant can be more easily removed, and then emulsifying or dispersing the contaminant in such a way that it is not redeposited on the surface. This is done by lowering the interfacial surface tension between the cleaning solution and the soil, and between the soil and the surface, making it easier to

[2] US Environmental Protection Agency. DfE's Standard and Criteria for Safer Chemical Ingredients. August 20, 2012. http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Standard

[3] U.S. Environmental Protection Agency, Design for the Environment Program. DfE Alternatives Assessment for Nonylphenol Ethoxylates. May 2012. http://www.epa.gov/dfe/pubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf Accessed 7/11/2012.

remove the soil and keep it removed. The hydrophilic head of the surfactant molecule remains in the water and it pulls the stains towards the water, away from the surface. The surfactant molecules surround the soil particles, break them up, force them away from the surface, and then suspend them so they can be removed.

1.2 Performance Requirements

1.2.1 Cleaner Performance

All-purpose cleaners are intended to clean a wide variety of soils on a wide variety of surfaces. As such, a single performance test or standard is difficult to specify. With so many different types of cleaners on the market with a wide variety of ingredients, it is impossible to predict performance based simply upon product ingredients.

Performance of all-purpose cleaners can be measured by tests established by manufacturers or trade associations, consumer or testing organizations, or governmental agencies. The primary purpose of the testing is to ensure that the cleaner is capable of removing the type of contaminant that it is intended to remove.

In their DfE Standard for Safer Cleaning Products, the US EPA specifies that, for all-purpose cleaners, "The product must remove at least 80% of the particulate or greasy soils, as appropriate, when tested according to American Society for Testing and Materials (ASTM) G122, DCC-17, CAN/CGSB 2-GP-11 Method 20.3 or an equivalent method agreed upon by DfE."

Another example is the European Union "Framework for testing the performance of all-purpose cleaners, window cleaners and sanitary cleaners,"[4] which allows for either an adequate and verifiable laboratory test, or an adequate and verifiable consumer test. However, the framework does not specify quantifiable performance, stating only that the method of measurement and the scoring system must be decided in advance.

Manufacturers have developed their own internal performance tests, but these are rarely shared. Several associations have done so as well, but none have set standards of performance.

The Chemical Specialties Manufacturers Association (CSMA), a trade association for manufacturers of cleaners (now known as the Consumer Specialty Products Association), developed a test method for the performance of all-purpose cleaners: CSMA DCC-04 for Hard Surface Cleaners (July 1973). This test evaluates the relative efficiency of aqueous cleaners on painted surfaces using representative soils, a specific cleaning apparatus, and a panel of judges.

Performance characteristics of the cleaning product using alternative surfactants were not evaluated. In any case, the parameters of the mixture would be adjusted to achieve the required performance, so it was assumed that, with respect to using alternative surfactants, all of the alternatives would be equivalent.

1.2.2 Surfactant Performance

The surfactant industry provides compounds for a large range of applications in industries ranging from

[4] See: http://ec.europa.eu/environment/ecolabel/ecolabelled_products/categories/purpose_cleaners_en.htm

detergents to cosmetics to food to pharmaceuticals, among others. These various applications require a large number of different tests depending on the end-use property of the product. Three primary test applications measure the emulsifying power, dispersing power, and foamability.

Emulsifying power refers to the capability of the surfactant to help form an emulsion, which is a mixture of two or more liquids that are normally immiscible (unblendable). This principle is exploited in soap to remove grease for the purpose of cleaning. Emulsifying power can be measured by the production of a standard emulsion and the study of emulsion stability through visual observation. The emulsification method (time and speed of agitation) and the composition of the emulsion (nature and volume fraction of the dispersed phase) are set by the test method. The efficiency of the surfactant corresponds to the measurement of the emulsion stability compared to a reference emulsion.

Dispersing power is the ability of the surfactant to help form a dispersion when it is added to a suspension of solid particles in a liquid to improve the separation of particles and to prevent settling or clumping. Dispersing power can be measured by controlling and comparing the suspension stability depending on the concentration and the nature of the surfactant, as for emulsions. This test is usually done by a visual observation of the sedimentation of the product analyzed. The control of the dispersing efficiency is often left to visual inspection and comparison with a reference dispersion.

Foamability is the ability of the product to form foam, which is not as important in an all-purpose cleaner as emulsifying power and dispersing power.

Performance characteristics of the surfactant alternatives were not evaluated, as the performance of concern is that of the cleaning product as a whole.

1.3 Legal Requirements

There are no legal requirements for performance of all-purpose cleaners.

1.4 Role of Chemical of Concern in Meeting Product Requirements

The role of the Chemical of Concern is to provide the primary function of cleaning - removal of soil and grease from the surface to be cleaned. Either the Chemical of Concern or an alternative chemical are necessary to meet the product functional requirements. Therefore, it is required that alternatives be identified and evaluated according to relevant comparison factors.

2. Scope and Comparison of Alternatives

2.1 Identification of Alternatives

As surfactants are a necessary ingredient to achieve the performance requirements of an all-purpose cleaner, either NPE or a substitute chemical is required. It is not possible to meet performance requirements by eliminating the surfactant from the products.

Typically, surfactants are interchanged by type - a nonionic for a nonionic, a cationic for a cationic, etc. However, it is possible to formulate a product with one or another. That is, a hard surface cleaner can be formulated based on a nonionic, an anionic, or a mixture of surfactants. As a nonionic surfactant, the most likely alternatives for NPE are other nonionic surfactants. However, substitutions are not typically "drop-in" replacements, and formulations must be adjusted to accommodate the new surfactant.

This AA adopts the alternatives to NPE identified by the US EPA in their 2012 DfE Alternatives Assessment for Nonylphenol Ethoxylates.[5] US EPA identified nine representative alternatives to NPE surfactants, including one – octylphenol ethoxylate (OPE10) – which will not be considered herein due its more-hazardous toxicological profile (as characterized by US EPA).

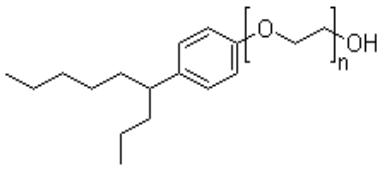
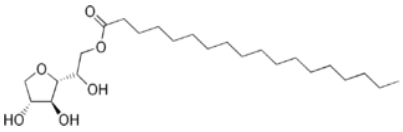
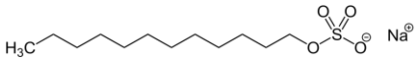
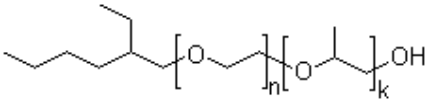
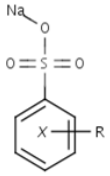
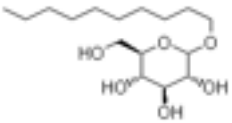
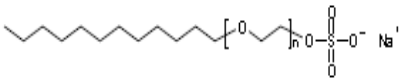
These alternatives are not all drop-in substitutes, and may need to be blended in order to achieve the necessary functionality. US EPA selected these alternatives as representative members of their particular class of surfactants and they are certainly not a comprehensive list. Selection criteria included availability of data sufficient to allow the drawing of defensible conclusions and frequent use in DfE-recognized formulations.

NOTE: Throughout this document, it should be understood that the actual alternatives being evaluated are all-purpose cleaners with a substitute surfactant. However, for the sake of simplicity, this AA discusses the alternatives as the potential substitute surfactants themselves.

The nine alternatives (including NPE) to be evaluated in this AA are listed in Table 1.

[5] US Environmental Protection Agency. DfE Alternatives Assessment for Nonylphenol Ethoxylates. May 2012. http://www.epa.gov/dfe/pubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf

Table 1. NPE Alternatives

CHEMICAL CLASS	REPRESENTATIVE CHEMICAL NAME	CASRN	DESCRIPTION	TYPE	MOLECULAR STRUCTURE
Alkylphenol ethoxylates (APE)	Nonylphenol ethoxylate	127087-87-0	white to yellow solid, or clear to cloudy liquid, depending on molecular weight	non-ionic	
Sorbitan ester	Sorbitan monostearate	1338-41-6	White to tan waxy solid	nonionic	
Alkyl sulfate ester (AS)	Sodium lauryl sulfate	151-21-3	White or cream-colored solid	anionic	
Ethoxylated/ propoxylated alcohols	Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether)	64366-70-7	Colorless to yellow liquid	nonionic	
Linear alcohol ethoxylate (LAE)	C12-15 alcohols, ethoxylated (9EO)	68131-39-5	Colorless liquid	nonionic	CH_3-$(CH2)_{n=12-15}$-CH_2-$(O$-CH_2-$CH_2)_9$-OH
Linear alkylbenzene sulfonate (LAS)	Benzenesulfonic acid, C10-13 alkyl derivatives, sodium salt	68411-30-3	Solid	anionic	
Linear alcohol ethoxylate (LAE)	C9-11 alcohols, ethoxylated (6EO)	68439-46-3	Colorless liquid	nonionic	CH_3-$(CH2)_{n=9-11}$-CH_2-$(O$-CH_2-$CH_2)_6$-OH
Alkyl polyglucose (APG)	D-glucopyranose, oligomeric, decyloctyl glycosides	68515-73-1	Colorless to light yellow liquid	nonionic	
Alkyl ether sulfate (AES)	Polyoxy (1,2-ethanediyl), alpha-sulfo-omega-dodecyloxy-, sodium salt	9004-82-4	Solid	anionic	

2.2 Identification of Relevant Comparison Factors

Comparison factors are relevant if they:

- Make a material contribution to one or more adverse public health impacts, adverse environmental impacts, adverse waste and end-of-life effects, and/or materials and resource

consumption impacts associated with the priority product and/or one or more alternatives under consideration; and
- There is a material difference in the factor's contribution to such impact(s) between the priority product and one or more alternatives under consideration and/or between two or more alternatives.

Factors to be considered for relevancy and compliance with the Safer Consumer Product regulations, along with their associated exposure pathways and life cycle segments, include the following:

- Adverse environmental impacts;
- Adverse public health impacts;
- Adverse waste and end-of-life effects;
- Environmental fate;
- Materials and resource consumption impacts;
- Physical chemical hazards;
- Physicochemical properties;
- Multimedia life cycle impacts;
- Product function and performance impacts; and
- Economic impacts.

None of these factors required quantitative analysis to determine relevancy; qualitative evaluation was sufficient.

Identification of relevant exposure pathways (for public and/or aquatic, avian, or terrestrial animal or plant organism exposures) considered both chemical quantity information and exposure factors.

Chemical quantity information did not provide a significant difference in the alternatives. Surfactants generally comprise about 2-5% of the formulation weight, and thus any changes in formulation may only comprise a small difference in the quantities of the NPE or alternative replacement chemicals necessary to manufacture the priority product. Until a product is definitively reformulated, it is not possible to estimate the volume or mass of the Chemical(s) of Concern or alternative replacement chemical(s) that is/are or would be placed into the stream of commerce in California as a result of the priority product and each alternative under consideration.

Exposure factors, as listed below (per the regulations), were not considered to be significantly different for any of the alternatives:

- Market presence of the product, including:
  - Statewide sales by volume;
  - Statewide sales by number of units; and/or
  - Intended product use(s), and types and age groups of targeted customer base(s).
- The occurrence, or potential occurrence, of exposures to the Chemical of Concern in the product.
- The household and workplace presence of the product, and other products containing the same Chemical of Concern that are the basis for considering the listing of the product-chemical combination as a Priority Product.
- Potential exposures to the Chemical of Concern in the product during the product's life cycle, considering:

- Manufacturing, use, storage, transportation, waste, and end-of-life management practices and the locations of these practices;
- Whether the product is manufactured or stored in, or transported through, California solely for use outside of California;
- Whether the product is placed into the stream of commerce in California solely for the manufacture of one or more of the products exempted from the definition of "consumer product" specified in Health and Safety Code section 25251;
- The following types of uses:
  - Household and recreational use;
  - Sensitive subpopulation potential use of, or exposure to, the product; and/or
  - Workers, customers, clients, and members of the general public who use, or otherwise come in contact with, the product or releases from the product in homes, schools, workplaces, or other locations;
- Frequency, extent, level, and duration of potential exposure for each use scenario and end-of-life scenario;
- Containment of the Chemical of Concern within the product, including potential accessibility to the Chemical of Concern during the useful life of the product and the potential for releases of the Chemical of Concern during the useful life and at the end-of-life;
- Engineering and administrative controls that reduce exposure concerns associated with the product; and/or
- The potential for the Chemical of Concern or its degradation products to be released into, migrate from, or distribute across environmental media, and the potential for the Chemical of Concern or its degradation products to accumulate and persist in biological and/or environmental compartments or systems.

2.2.1 Adverse Environmental Impact

Adverse environmental impact **is** a relevant factor. This factor includes air quality impacts, ecological impacts, soil quality impacts, water quality impacts, as well as potential for exceedance of state or Federal regulatory standards relating to protection of the environment.

Adverse air quality impacts means indoor or outdoor emissions of any of the following that have potential adverse impacts: greenhouse gases, nitrogen oxides, certain particulate matter, ozone-depleting substances, sulfur oxides, or ozone-forming compounds. These are not relevant factors.

Ecological impacts include adverse effects to aquatic, avian, or terrestrial animal or plant organisms or microbes, including, among other impacts, acute or chronic toxicity - the primary concern with NPE and NP. The potential for NPE or its degradation products (primarily NP) to be released into, migrate from, or distribute across environmental media, and the potential to accumulate and persist in biological and/or environmental compartments or systems is high. Cleaning products are designed to be released to the environment either by rinsing into the sewer and eventually to the aquatic system, or by disposal of solid wipes into the municipal solid waste system. The environmental toxicity of NP is extremely high and is the primary justification for listing NPE as a Chemical of Concern. Environmental discharges from the manufacturing site are also potential sources of environmental impact, especially to the aquatic environment due to spills, leaks, discharge of equipment cleaning solutions, etc. These may be direct releases to the terrestrial or aquatic environment, or indirect releases through a wastewater treatment plant. As will be seen in the analysis, ecological impacts comprise a significant material difference

between NPE and its alternatives.

Adverse soil quality impacts include compaction or other structural changes, erosion, loss of organic matter, or sealing (meaning covering or changing to become impermeable). These are not relevant factors.

Adverse water quality impacts include increase in biological oxygen demand, increase in chemical oxygen demand, increase in temperature, increase in total dissolved solids, and introduction or increase of specific pollutants listed under various state and Federal regulatory regimes. These are not expected to be relevant factors.

Potential for exceedances of regulatory standards is also not expected to be a relevant factor.

2.2.2. Adverse Public Health Impact

Adverse public health impact (including occupational health) **is** a relevant factor. It includes the following hazard endpoints: carcinogenicity, developmental toxicity, reproductive toxicity, cardiovascular toxicity, dermatotoxicity, endocrine toxicity, epigenetic toxicity, genotoxicity, hematotoxicity, digestive system toxicity, immunotoxicity, musculoskeletal toxicity, nephrotoxicity, neurodevelopmental toxicity, neurotoxicity, ocular toxicity, ototoxicity, reactivity in biological systems, respiratory toxicity, and others. Use of cleaning products in the home or workplace creates multiple exposure pathways for NPE for both adults (most likely to be the primary user) and children (who comprise a sensitive subpopulation and may also be the user on occasion, but may also be exposed incidentally to chemical residues on surfaces or through accidental inhalation, ingestion, etc.). Exposure pathways may include inhalation, ingestion, or dermal contact. Workers may also be exposed to much larger amounts of NPE in the formulation process, and the potential exposure pathways are the same. As will be seen in the analysis, ecological impacts comprise a significant material difference between NPE and its alternatives, although less significant than for ecological impacts.

2.2.3 Adverse Waste and End-of-Life Impact

Adverse waste and end-of-life impact includes the waste materials and byproducts generated during the life cycle of the product, and the associated adverse effects due to any of the following:

- volume or mass generated;
- special handling required;
- effects on solid waste and wastewater disposal and treatment;
- discharge or disposal to storm drains or sewers that affect operation of wastewater or storm water treatment facilities; or
- release to the environment.

These **are not** directly-relevant factors. All-purpose cleaning products are designed to be released into the environment through air, water, or soil pathways, and may result in an adverse environmental impact, which is a relevant factor. End-of-life is either the same as end-of-use, or disposal of leftover amounts of cleaning products. The latter would constitute an insignificant fraction of the municipal

solid waste stream or the sanitary sewage stream, depending on the disposal pathway.

2.2.4 Environmental Fate

Environmental fate **is** a relevant factor. The potential for NPE or its degradation products (primarily NP) to be released into, migrate from, or distribute across environmental media, and the potential to accumulate and persist in biological and/or environmental compartments or systems is high. Cleaning products are designed to be released to the environment either by rinsing into the sewer and eventually to the aquatic system, or by disposal of solid wipes into the municipal solid waste system. The environmental toxicity of NP is extremely high and is the primary justification for listing NPE as a chemical of concern and making environmental fate a relevant factor. As will be seen in the analysis, ecological impacts comprise a significant material difference between NPE and its alternatives.

2.2.5 Materials and Resource Consumption Impact

Materials and resource consumption impact **is** a relevant factor. Chemicals for manufacturing of the alternative surfactants are drawn from multiple sources, both organic and inorganic. One significant difference is that some are primarily based upon petroleum feedstocks, while others are primarily based on renewable (plant-based) feedstocks. As such, impacts are likely materials consumption, energy consumption, water use, land use, and greenhouse gas emissions - all of which are generally assessed through the life cycle assessment process. This factor will be addressed under Multimedia Life Cycle Impacts.

2.2.6 Physical Chemical Hazards

Physical chemical hazards **are** a relevant factor. Potential hazards such as flammability and reactivity, if present, would constitute a risk to any population exposed to the priority product and the chemical of concern. One aspect that should be evaluated is whether the hazard is still present when the chemical of concern is diluted into the priority product during the formulation process, which is generally not the case in this situation.

2.2.7 Physicochemical Properties

Physicochemical properties **are** relevant factors to the extent that they contribute to the presence of relevant environmental and human health hazards (and are thus covered in that area of assessment). Other than that, the surfactant alternatives are used in similar amounts in the priority products, and would not significantly increase or decrease the quantities necessary to manufacture the product. Neither would they be likely to affect the market presence, the occurrence of exposures, household or workplace presence, or potential exposures during the life cycle of the product (to any extent not covered under environmental and human health hazards).

2.2.8 Multimedia Life Cycle Impact

Multimedia life cycle impacts **are** a relevant factor. "Multimedia" refers to effects on atmospheric, aquatic, and terrestrial environments. "Life cycle" generally refers to the path that materials and energy follow in the manufacture and use of products. Life cycle impacts that are commonly evaluated for each phase of product life include global warming, stratospheric ozone depletion, acidification, eutrophication, photochemical smog, terrestrial toxicity, aquatic toxicity, human health, resource depletion, land use, and water use. The general life cycle of a typical product is pictured in Figure 1.

Figure 1: General Product Life Cycle

In the case of cleaners and their surfactants, disposal and recycling is generally equivalent to discharge to the environment. A comprehensive 1995 European life cycle inventory study, which looked at the production of major surfactants then used in European detergent products, included energy and material requirements as well as environmental emissions and solid waste associated with all phases of surfactant production. The study showed that each surfactant system has an impact on the environment through the consumption of a wide variety of resources, including crude oil, natural gas, agricultural products, and minerals for material feedstock, energy generation, and transportation purposes, as well as environmental releases during the production and transport life cycle phases.[6] This study did not convert the life cycle inventory into life cycle impacts as would have been done in a full life cycle assessment.

2.2.9 Product Function and Performance Impacts

Product function and performance impacts **are**, by regulation, considered to be relevant factors. This assessment will evaluate the useful life, function, and performance of the Priority Product and the alternatives being considered, as well as whether an alternative exists that is functionally acceptable, technically feasible, and economically feasible.

2.2.10 Economic Impacts

Economic impacts **are**, by regulation, considered to be relevant factors. This assessment will evaluate and monetize (if possible) the public health and environmental costs, as well as the costs to government

[6] Stalmans, M., et al. Franklin & Associates. European Life-Cycle Inventory for Detergent Surfactants Production. Tenside Surf. Det. 1995;32(2):84-109.

agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife.

2.3 Evaluation and Screening of Alternative Replacement Chemicals

Alternative replacement chemicals were evaluated and screened using a multi-step process. First, a hazard screening was conducted. This was initially conducted during the preparation of the PAA, and did not change during preparation of the FAA. Second, additional relevant factors were added that were not required to be included in the PAA originally:

- multimedia life cycle impacts
- product function and performance impacts
- economic impacts

2.3.1 Hazard Screening

The alternatives were screened using the following relevant factors:

- adverse environmental impacts
- adverse public health impacts
- environmental fate
- physical chemical hazards

Comparative chemical hazard assessment was the method used for the preliminary evaluation and screening of the alternatives to NPE. The specific methodology for conduct of the hazard assessment was the GreenScreen®, which is a chemical hazard assessment protocol which evaluates chemicals and their transformation products (either independently or as part of a formulated or fabricated product) and assigns a benchmark score ranging from 1 (worst) to 4 (best) (see Appendix 2 for a more detailed description of the GreenScreen®). The GreenScreen® addresses adverse environmental impacts (Ecotoxicity), adverse public health impacts (Group I Human and Group II Human), environmental fate (Fate), and physical-chemical hazards (Physical), thus evaluating all of the relevant factors previously identified. Although the US EPA AA did a hazard assessment, it was based on the Design for the Environment (DfE) safer surfactant criteria, which do not include human health endpoints. They considered that, for detergent surfactants, environmental endpoints were the ones most relevant to hazard assessment and identification of safer alternatives. As public health impacts are considered relevant factors in this AA, human health endpoints were considered and evaluated.

Table 2 summarizes the data developed using the hazard assessment methodology. The alphabetic hazard ratings in Table 2 were assigned per a two-step process. Initially, some ratings were assigned per the results of a GreenScreen® List Translator assessment process, which uses a computerized process to assess chemical CAS numbers against various specified lists and assigns hazard ratings per the predetermined GreenScreen® algorithm. Literature was then reviewed to obtain data, which was then compared against the values in the GreenScreen® Version 1.2 Criteria.[7] No new data was generated for this alternatives assessment. In addition to the eight alternatives from the US EPA AA, this table

[7] Clean Production Action. GreenScreen® for Safer Chemicals Version 1.2 Criteria. 2012.

includes NPE and NP (as a transformation product of NPE).

Normally, summary data for any persistent/recalcitrant transformation products would accompany the summary data for each alternative. However, according to US EPA, only NPE has any transformation products that are persistent/recalcitrant - nonylphenol - so this is the only alternative for which transformation products were evaluated.

Appendix 3 contains the data upon which Table 2 is based, including references to the sources of all of the data.

Table 2: Hazard Assessment Summary

		Group I Human						Group II Human						Ecotoxicity		Fate		Physical	
		C	M	R	D	E	AT	ST		N		SnS	SnR	IrS	IrE	AA	CA	P	B	Rx	F
								single	repeated	single	repeated										
Chemical	**CASRN**																				
Nonylphenol ethoxylate	127087-87-0	L	DG	M	DG	*H*	M	M	DG	DG	DG	DG	DG	H	vH	H	H	M	DG	L	L
Nonylphenol	84852-15-3	DG	L	DG	DG	H	M	DG	M	DG	DG	DG	DG	vH	vH	vH	H	*vH*	*H*	L	L
Sorbitan monostearate	1338-41-6	L	L	DG	DG	DG	L	DG	L	DG	DG	DG	DG	H	DG	H	H	L	*vL*	L	L
Sodium lauryl sulfate	151-21-3	L	L	L	L	DG	H	*M*	M	DG	DG	L	DG	H	vH	vH	H	vL	vL	L	H
Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether)	64366-70-7	DG	DG	DG	DG	DG	DG	DG	DG	DG	DG	DG	DG	DG	vH	M	*M*	L	DG	L	L
C12-15 alcohols, ethoxylated (9EO)	68131-39-5	L	L	DG	DG	DG	M	DG	DG	DG	DG	L	DG	H	vH	vH	H	vL	L	L	L
Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt	68411-30-3	L	L	DG	DG	L	M	DG	DG	DG	DG	L	DG	H	H	H	H	vL	L	L	L
C9-11 alcohols, ethoxylated (6EO)	68439-46-3	L	L	L	DG	DG	*M*	DG	DG	DG	DG	L	DG	H	vH	H	H	vL	DG	L	L
D-glucopyranose, oligomeric, decyloctyl glycosides	68515-73-1	DG	L	L	L	DG	L	DG	L	DG	DG	L	DG	H	vH	M	M	vL	*L*	L	L
Polyoxy (1,2-ethanediyl), alpha-sulfo-omega-dodecyloxy-, sodium salt	9004-82-4	L	L	L	L	DG	M	DG	DG	DG	DG	L	DG	H	vH	vH	vH	L	DG	L	L

Applying the GreenScreen® algorithms for assigning benchmarks to each chemical alternative), Table 3 was generated. NP does not appear in Table 3 as it is only a contributor to the benchmarking of NPE.

Table 3: Draft GreenScreen® Benchmarks

CHEMICAL	DRAFT BENCHMARK	REASON
Nonylphenol ethoxylates	1_{TP}	Draft Benchmark Score = 1 for NP transformation product
Sorbitan monostearate	U	Does not meet minimum data requirements for or Group 1 or Group II Human Health endpoints
Sodium lauryl sulfate	2	GreenScreen® Criterion 2f: Very High Eye Irritation
Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether)	U	Does not meet minimum data requirements for Group I Human Health, Group II Human Health, or Environmental Fate endpoints
C12-15 alcohols, ethoxylated (9EO)	U	Does not meet minimum data requirements for Group I or Group II Human Health
Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt	2_{DG}	GreenScreen® Criterion 3b: Moderate (or High) Ecotoxicity (Acute and Chronic Aquatic Toxicity); Criterion 3c: Moderate (or High) Group II Human Toxicity (Acute Mammalian Toxicity, Eye and Skin Irritation) Meets the hazard classification requirements of BM3 based on all available data but does not achieve the minimum data requirements for BM3 for Group I Human and Group II Human endpoints
C9-11 alcohols, ethoxylated (6EO)	U	Does not meet minimum data requirements for Group II Human or Environmental Fate endpoints
D-glucopyranose, oligomeric, decyloctyl glycosides	2_{DG}	GreenScreen® Criterion 3b: Moderate Ecotoxicity (Acute and Chronic Aquatic Toxicity); Criterion 3c Moderate (or High) Group II Human Toxicity (Skin and iEye Irritation) Meets the hazard classification requirements of BM3 based on all available data but does not achieve the minimum data requirements for BM3 for Group I Human and Group II Human endpoints
Polyoxy (1,2-ethanediyl), alpha-sulfo-omega-dodecyloxy-, sodium salt	U	Does not meet minimum data requirements for Group II Human or Environmental Fate endpoints

RECOMMENDATION: Considering the relative draft benchmark scores, the two Draft Benchmark 2_{DG} alternatives are recommended for further assessment. In particular, it may be valuable to conduct further literature research in an attempt to fill the data gaps that prevent assessment of these chemicals as Draft Benchmark 3 chemicals. In the event that these are determined to be unsuitable for some reason(s), then the Draft Benchmark 2 alternative should be evaluated.

3. Final Alternatives Assessment Work Plan and Proposed Implementation Schedule

ACTION ITEM	DESCRIPTION	SCHEDULED COMPLETION DATE*
Re-evaluation of relevant factors from Preliminary Alternatives Assessment	Relevant factors identified in the Preliminary Alternatives Assessment will be reviewed and changes will be documented.	4
Review of production function and performance factors	The Performance Evaluation Module (Level X) of the Draft Eight State Alternatives Assessment Guidance Document will be used as a guideline.	8
Consideration of Materials and Resource Consumption Impacts	Existing Life Cycle Inventories/Life Cycle Assessments will be reviewed for relevant data. Results will be summarized.	12
Review of economic factors	It is anticipated that one or more of the alternatives will be selected for substitution of the chemical of concern; therefore, the economic impacts are expected to be positive from a burden shifting perspective. Economic factors, as specified in the regulations, will be researched and evaluated.	16
Comparison of Priority Product and alternatives/alternative selection decision	The Priority Product and the alternatives will be compared based on the relevant factors, and one or more alternatives will be selected as the recommended option. Relevant factors will include factors identified in the PAA, but not included in the comparison of alternatives in the PAA, plus relevant function and performance and economic factors.	20
Submittal of Final Alternatives Assessment report	The scheduled submission date is as required by regulation.	26**

* weeks after receipt of Notice of Compliance for Preliminary Alternatives Assessment from DTSC
**DTSC requires submittal within 52 weeks

STAGE 2 ALTERNATIVES ANALYSIS

Specific guidance for all future assessment should follow the CA DTSC alternatives analysis guide: http://www.dtsc.ca.gov/scp/

Stage 2 of the alternatives assessment per CA SCP regulations in this report include the following components:

- Evaluation of Other Relevant Factors Not Addressed in Stage 1. Specific considerations include:
    - adverse impacts and multimedia life cycle impacts;
    - product function and performance; and
    - economic impacts.
- Compare the Priority Product to Alternatives. Specific considerations include:
    - performance of alternatives with respect to all relevant factors included in the assessment (e.g., hazard, consideration of exposure pathways, multimedia life cycle impacts, performance, economic feasibility).
- Additional Considerations
- Alternative Selection Decision

4. Evaluation and Screening of Alternatives – Factors Not Considered in Stage 1

4.1 Multimedia Life Cycle Impacts

"Multimedia" refers to effects on atmospheric, aquatic, and terrestrial environments. "Life cycle" generally refers to the path that materials and energy follow in the manufacture and use of products. Life cycle impacts that are commonly evaluated for each phase of product life include global warming, stratospheric ozone depletion, acidification, eutrophication, photochemical smog, terrestrial toxicity, aquatic toxicity, human health, resource depletion, land use, and water use.

Although the use of substitute surfactants will require reformulation of the cleaning product, this should not affect other ingredients in the formulation (unless the ingredients are incompatible in some way or the new combination affects performance, requiring a substitution of other ingredients) except for variations in relative percentages in composition. Therefore, the assessment of life cycle factors only looks at the surfactants that are being considered as alternatives to NPE.

Two life cycle inventory (LCI)(meaning that material and energy flows were tabulated, but not converted to environmental impacts such as global warming potential or aquatic toxicity) studies, one conducted in Europe and published in 1995[8] and one conducted two years earlier in the US,[9] were performed on a group of surfactants, which included all of the alternatives being considered in this alternatives assessment, with the exception of sorbitan monostearate and ethoxylated/propoxylated alcohols (no other life cycle studies were found). These studies were limited to consideration of a cradle-to-(factory) gate scope, and do not include the use phase or end-of-life phase of the life cycle.

The comprehensive 1995 European study, which looked at the production of major surfactants then used in European detergent products, included energy and material requirements as well as environmental emissions and solid waste associated with all phases of surfactant production (cradle-to-gate). The study showed that each surfactant system has an impact on the environment through the consumption of a wide variety of resources, including crude oil, natural gas, agricultural products, and minerals for material feedstock, energy generation, and transportation purposes, as well as environmental releases during the production and transport life cycle phases.[10] This analysis of the impact of the relevant life cycle factors depends on the existing data presented in this study, and the limitations thereof.

The following excerpts from the study describe the limitations of the data and the ability to compare data for different surfactant systems.

> "All data in this study are expressed per 1000 kg surfactant produced. It must be emphasized, however, that it is in general not meaningful to compare surfactants on a weight basis. The surfactants examined in this study cover a variety of different structural and functional types and show a range of different surfactant properties and

[8] Stalmans, M., et al. Franklin & Associates. European Life-Cycle Inventory for Detergent Surfactants Production. Tenside Surf. Det. 1995;32(2):84-109.

[9] Hunnicutt, M. Environmental Life-Cycle Inventory of Detergent-Grade Surfactant Sourcing and Production. Vol. 70 [1], JAOCS (1993).

[10] Stalmans, M., et al. Franklin & Associates. European Life-Cycle Inventory for Detergent Surfactants Production. Tenside Surf. Det. 1995;32(2): 84-109

formulation characteristics. Detergent preparations are complex multi-component systems, designed to deliver specific cleaning properties under particular conditions. The surfactants used in any formulation are carefully chosen to achieve the desired performance with lowest total chemical consumption and environmental loading per wash. As a result, it is generally not possible to replace one surfactant type by another without changing other components of the preparation, or altering the performance characteristics. Thus, it must be emphasized that i! is inappropriate to make direct comparisons between all surfactants simply on the basis of their weight."

"The most relevant functional unit for detergent surfactants must be one which fully incorporates the actual washing, formulation and other performance characteristics. Assessment of such characteristics is a specialized undertaking and one which must not only consider the surfactants themselves and their blends but the products in which they are deployed and the conditions under which they are used. This performance necessarily involves judgmental criteria, for example, on the relative importance of different laundry dirt and soils or on consumer habits and thus requires careful interpretation and characterization definitions. When comparing and assessing detergent formulations, all relevant criteria must be taken into account including the characteristics of other detergent ingredients. Thus, a single functional unit that applies for all studied surfactants, cannot be developed. In general, the outcome of comparisons between surfactants is highly dependent on the normalization basis selected."

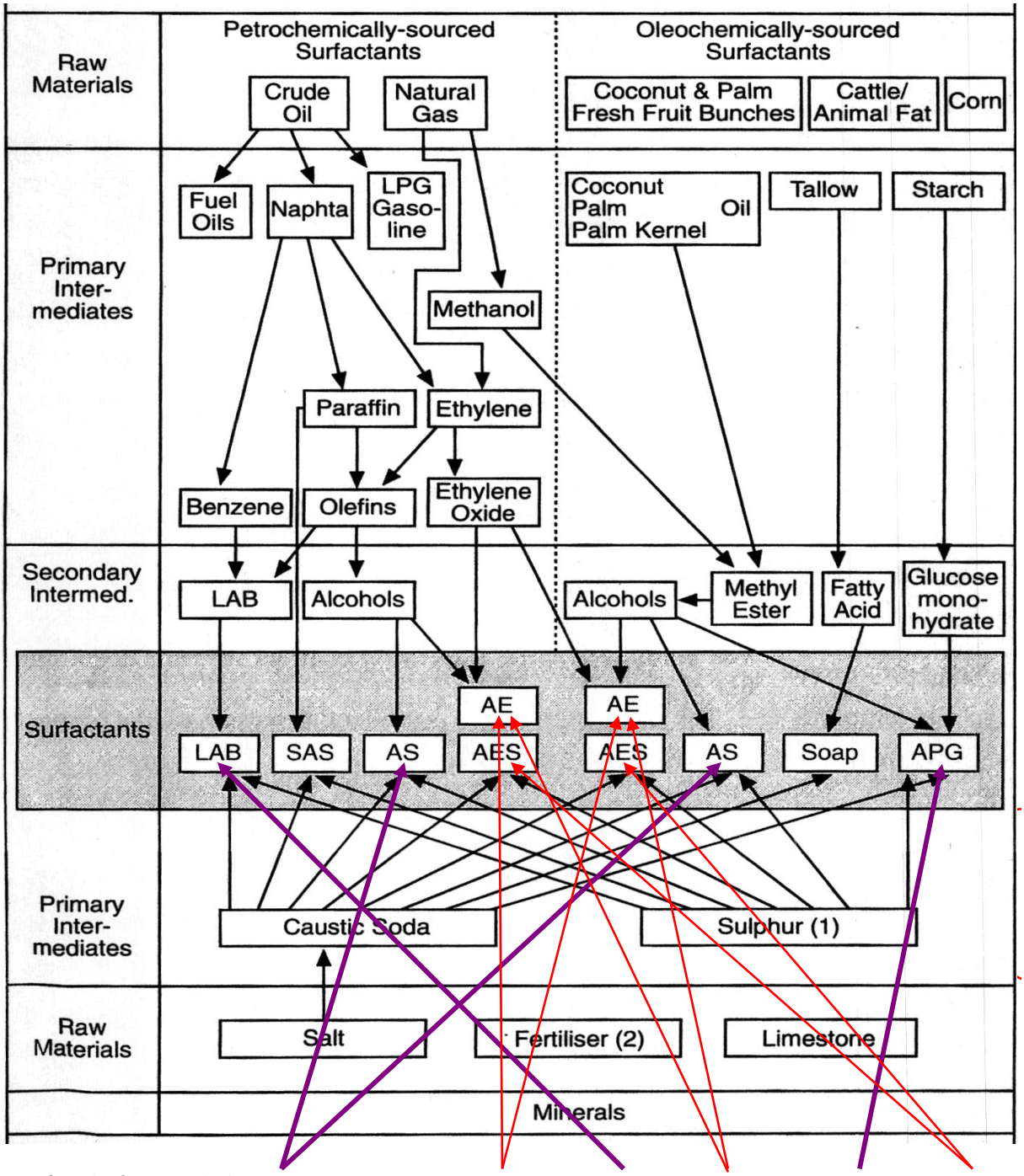
"The main value of the surfactant LCI inventory compiled here will be to identify opportunities for improvement within each individual surfactant system rather than to make direct comparisons between surfactants. In order to achieve this, a pragmatic, operationally defined Functional Unit was used in this study by expressing all data on the basis of 1000 kg of surfactants."

"The results of this surfactant LCI depend on the scenario looked at and the assumptions made. A simplistic interpretation of the results, though tempting, is not realistic and should not be attempted without careful consideration of the boundaries and frame conditions. As explained earlier, it remains inappropriate to make direct comparisons between all surfactants simply on the basis of their weight. The LCI data should be used mainly to identify opportunities for improvement within each individual surfactant system rather than to attempt direct comparisons between them."

Therefore, without being able to establish a functional unit based on equivalent performance, any conclusions that are drawn may not be valid. On the other hand, they may be the best available for use in further analyses.

The following diagram (Figure 2), courtesy of the 1995 study, shows the manufacturing process for most of the surfactant alternatives under consideration. It shows that surfactants can be divided into those derived from petrochemical sources and those derived from oleochemical sources (plant or animal-based), although some may be produced by either route.

Figure 2: Manufacturing Process for Most Surfactant Alternatives Under Consideration



Alternatives Surfactants: CAS#s

127087-87-0 (not included)	**1338-41-6** (not included)	**151-21-3**	**64366-70-7** (not included)	**68131-39-5**	**68411-30-3** (LAB is precursor to LAS)	**68439-46-3**	**68515-73-1**	**9004-82-4**

Heavy purple lines are associated with alternatives still under consideration. Lighter red lines are associated with alternatives that have been eliminated from further consideration.

Tables 4 and 5 and Figures 2 and 3 summarize the data from the 1995 study for the pertinent data. A discussion of each life cycle phase follows the tables and charts.

Table 4: Resource Usage for Surfactant Production

SURFACTANT TYPE	RAW MATERIAL USAGE (kg)	ENERGY RESOURCE USAGE (kg)
LAS (Pc)	1040	515
AS (Pc)	991	668
AS (PKO)	1982	915
AS (CNO)	2250	538
AS (PO)	1991	836
APG (PKO)	1973	933
APG (CNO)	2147	685

Figure 2: Surfactant Production Raw Material Usage (kg)

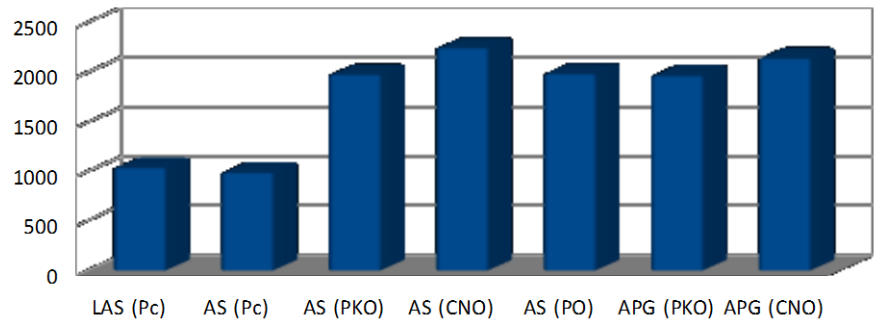


Figure 3: Surfactant Production – Energy Resource Usage (kg)

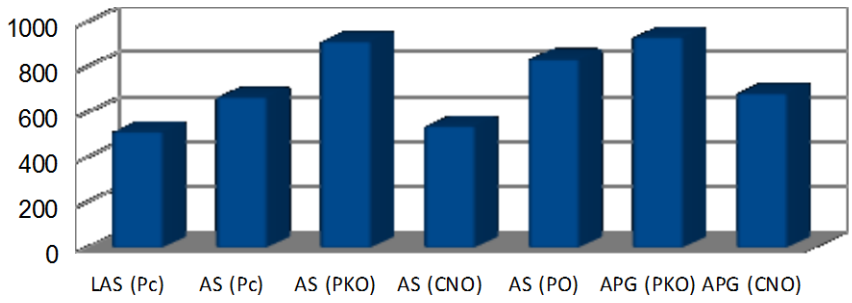


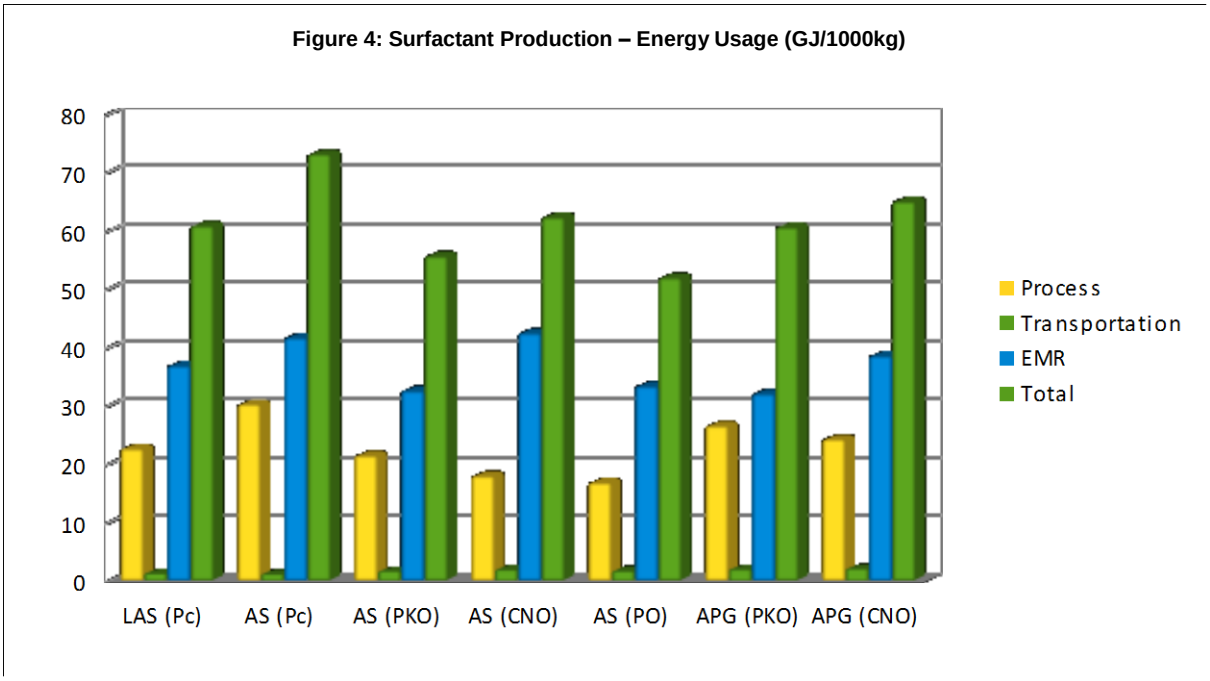
Table 5: Energy Requirements for Surfactant Production

SURFACTANT TYPE	PROCESS ENERGY (GJ/1000 kg)	TRANSPORTATION ENERGY (GJ/1000 kg)	EMR (GJ/1000 kg)	TOTAL (GJ/1000 kg)
LAS (Pc)	22.7 (37%)	1.3 (2%)	36.9 (61%)	60.9
AS (Pc)	30.3 (41%)	1.19 (2%)	41.7 (57%)	73.2
AS (PKO)	21.5 (39%)	1.68 (3%)	32.6 (58%)	55.8
AS (CNO)	18 (29%)	1.93 (3%)	42.5 (68%)	62.4
AS (PO)	16.9 (33%)	1.73 (3%)	33.4 (64%)	52
APG (PKO)	26.6 (44%)	1.99 (3%)	32.1 (53%)	60.7
APG (CNO)	24.3 (37%)	2.15 (3%)	38.6 (59%)	65.1

Energy requirements vary depending on the life cycle stage and feedstock requirements. Process energy is the energy used in all production steps for primary fuel (gas, oil, coal, etc.). Transportation energy is the energy required per tonne-kilometer for each transport mode to move raw materials, intermediates, and finished product. Energy of Material Resource (EMR) is basically the calorific value of the feedstocks, whether they be fossil fuels used for purposes other than energy production or biobased materials. Feedstocks can include petrochemicals (Pc), or oleochemicals [Oc, which can include palm kernel oil (PKO), palm oil (PO), or coconut oil (CNO)].

Average process energy is 22.9 GJ/1000 kg, ranging from 16.9 (-26%) to 30.3 (+32%). The ratio to the total amount of energy averages about 37%. Average transportation energy is 1.71 GJ/1000 kg, ranging from 1.19 (-30%) to 2.15 (+26%). The ratio to the total amount of energy averages about 2.7%. Average Energy of Material Resource (EMR),is 36.8 GJ/1000 kg, ranging from 32.1 (-13%) to 42.5 (+15%). The ratio to the total amount of energy averages about 60%. Average total energy is 61.4 GJ/1000 kg, ranging from 52 (-15%) to 73.2 (+19%).

Figure 4: Surfactant Production – Energy Usage (GJ/1000kg)



Environmental Emissions include atmospheric emissions, water-borne emissions, and solid waste.

Atmospheric emissions from surfactant production are shown in Table 6, Figure 5 (non-greenhouse emissions) and Figure 6 (greenhouse emissions). Water-borne emissions are shown in Table 7 and Figure 7. Solid waste generation is shown in Table 8 and Figure 8.

Table 6: Atmospheric Emissions from Surfactant Production (kg/1000 kg)

SURFACTANT TYPE	LAS-Pc	AS-Pc	AS-PKO	AS-CNO	AS-PO	APG-PKO	APG-CNO
Particulates	3.6	5.91	5.87	4.09	5.54	13	11.9
Nitrogen Oxides	12.4	20.4	11.6	8.7	9.98	15.1	13.2
Hydrocarbons	13.5	29.1	12.4	11.4	10.8	16.4	15.7
Sulfur Oxides	16.8	22.9	11.7	9.63	9.57	15.5	14.1
Carbon Monoxide	0.76	1.63	1.43	0.75	1.2	2.22	1.78
Methane	0	0	16.7	0.01	17.1	10.9	0.01
Carbon Dioxide (fossil)	1613	2524	1410	1150	1045	1788	1618
Carbon Dioxide (non-fossil)	0	0	477	182	489	343	151
Carbon Dioxide (total)	1613	2524	1887	1332	1534	2131	1769

Figure 5: Atmospheric Emissions (non-greenhouse) (kg/1000 kg)

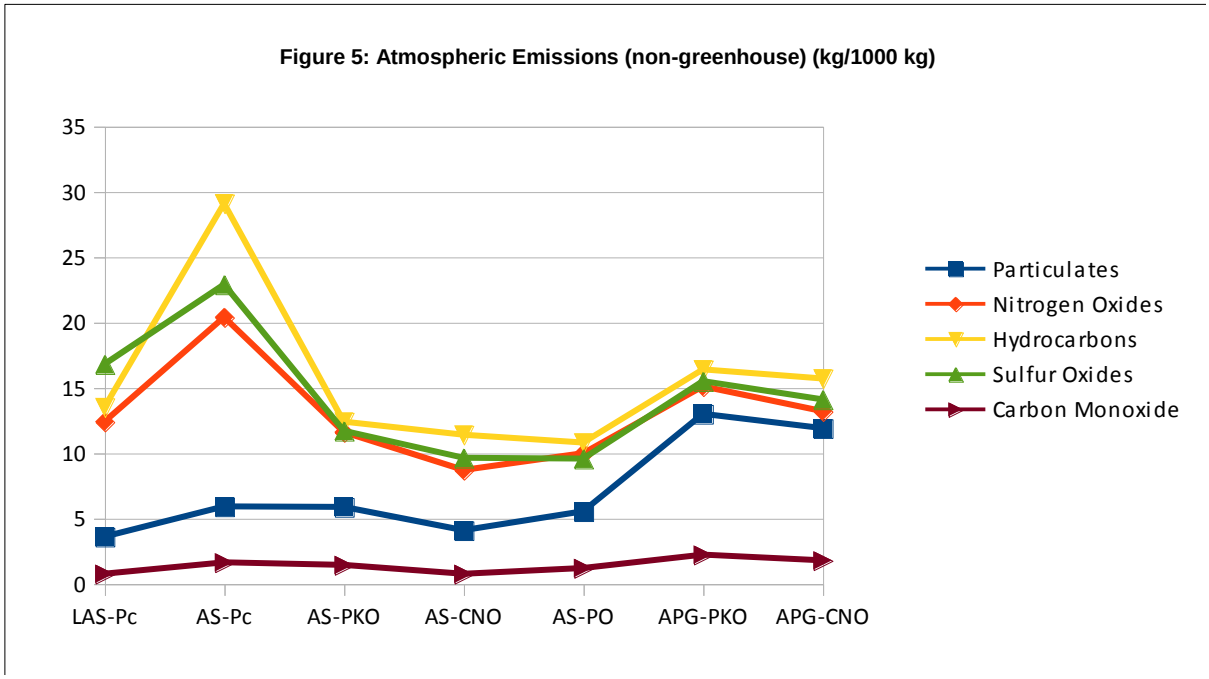


Figure 6: Atmospheric Emissions (greenhouse) (kg/1000 kg)

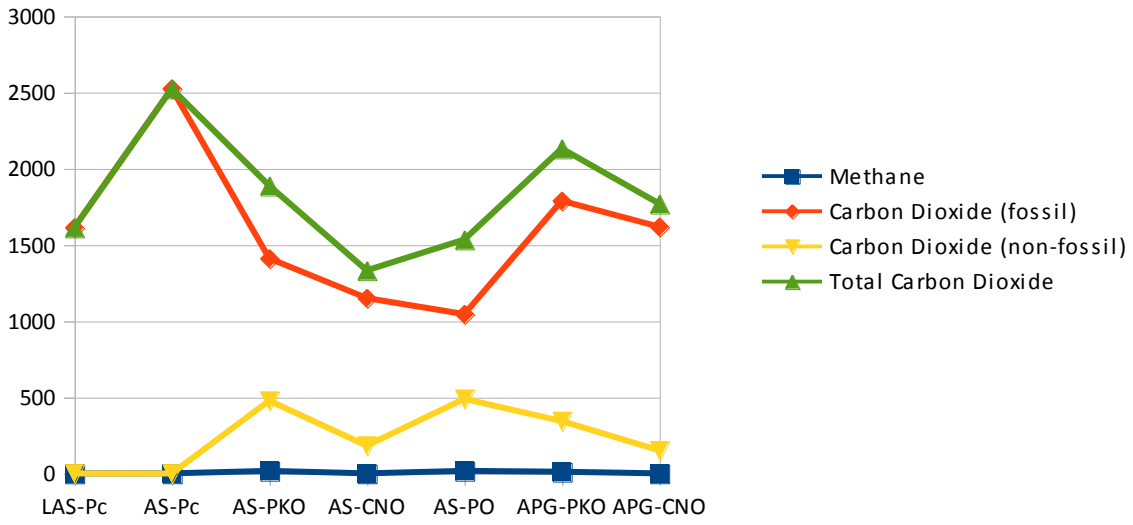


Table 7: Waterborne Emissions from Surfactant Production (kg/1000 kg)

SURFACTANT TYPE	LAS-Pc	AS-Pc	AS-PKO	AS-CNO	AS-PO	APG-PKO	APG-CNO
BOD	0.48	0.14	0.33	9.52	0.34	1.02	7.02
COD	1.33	1.62	2.89	11	2.97	2.81	8.08
Dissolved Solids	3.15	5.33	7.71	32.1	7.61	5.37	21.3
Suspended Solids	0.35	0.2	0.9	0.1	0.69	12.8	12.2

Figure 7: Waterborne Emissions (kg/1000 kg)

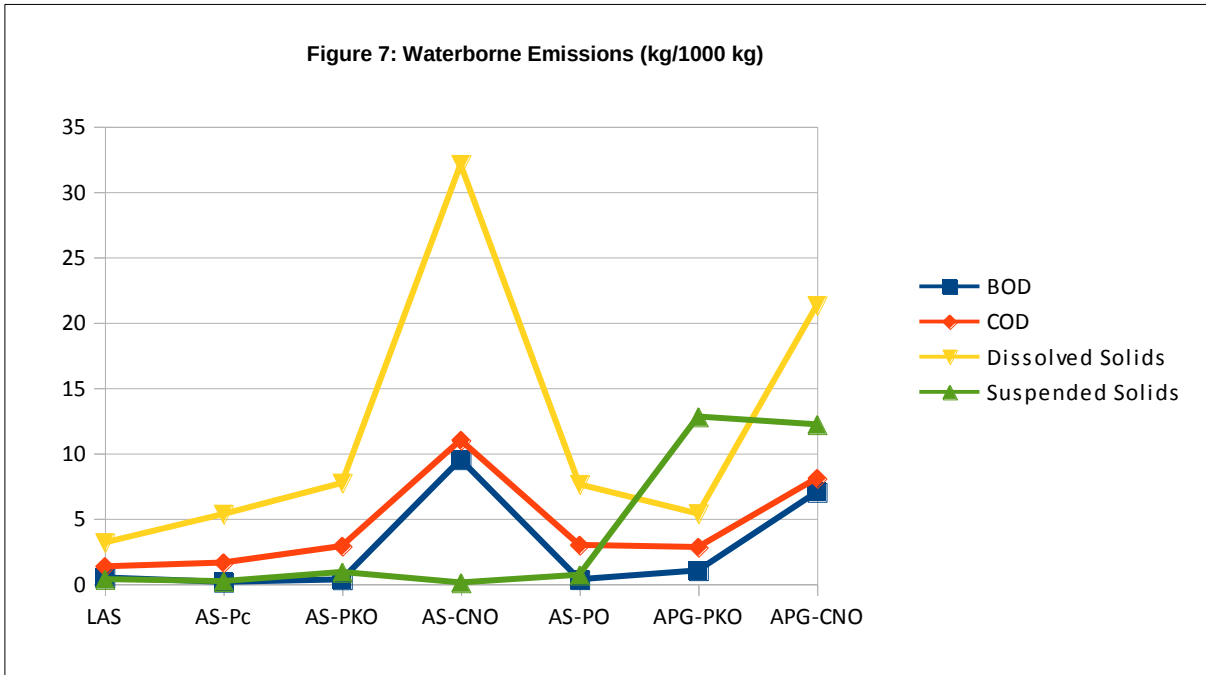
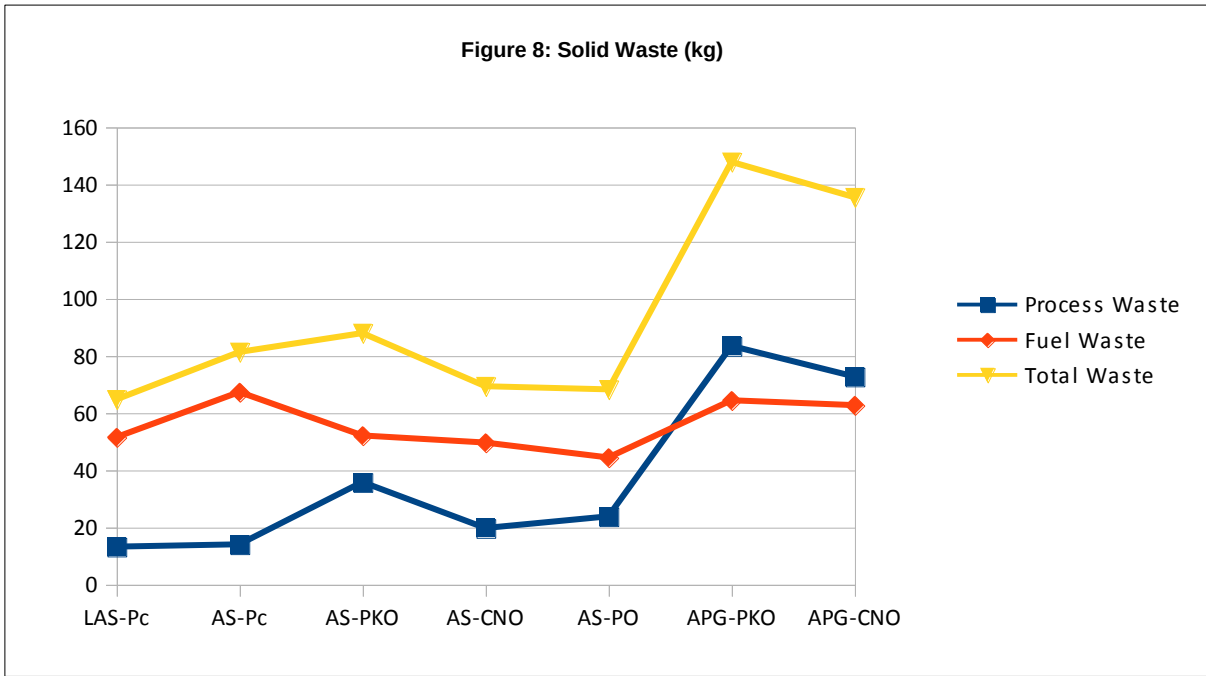


Table 8: Solid Waste from Surfactant Production (kg)

SURFACTANT TYPE	LAS-Pc	AS-Pc	AS-PKO	AS-CNO	AS-PO	APG-PKO	APG-CNO
Process Waste	13.2	14	35.8	19.7	23.8	83.4	72.7
Fuel-related Waste	51.5	67.3	52.1	49.6	44.4	64.4	62.7
Total Waste	64.7	81.3	87.9	69.3	68.2	147.8	135.4

Figure 8: Solid Waste (kg)



Material Extraction

As was seen previously, surfactants can generally be produced from either petrochemical (Pc - crude oil, natural gas) and/or oleochemical [Oc - agricultural materials such as palm oil (PO), palm kernel oil (PKO), coconut oil (CNO), and tallow] feedstocks. Surfactant types that are based on oleochemicals include are LAE, AES, AS, and APG. Surfactants derived from petrochemical feedstock are LAS, AE, AES, and AS (APEs such as NPE. although not included in the subject study, are also based on petroleum feedstock). Note that several of the classes of surfactant can be based on either type of feedstock.

The most significant raw materials extraction issues identified in the subject study are those associated with the extraction of petroleum and natural gas, on the one hand, versus those associated with the growing and harvesting of natural materials on the other (however, the study did not appear to evaluate land use and biodiversity impacts, which are a major issue for production of palm-related products in terms of destruction of rainforests). In general, the biobased surfactants appear to have larger raw material resource requirements, and while the materials required for energy production are also generally higher, the differences are not as great.

Since even those surfactants that are based on natural materials have petrochemical portions, and all of the natural materials also utilize petroleum as fuels in transportation or as raw materials for fertilizers and pesticides, the differences tend to blur and be insignificant.[11] It is not apparent from the available data that raw material resource requirements are significant to the choice of alternative surfactants.

Manufacturing Production

Environmental impacts are qualitatively different for surfactants made exclusively from vegetable oils versus those with petrochemical components. Although very few surfactants used in all-purpose cleaners do not have a petrochemical component, even if their main raw material is palm or coconut oil, there is a distinct difference between surfactants made totally from petrochemicals and those made at least partially with oleochemicals. The petroleum extraction, refining, and petrochemical proction processes have qualitatively more serious environmental impacts than the processes of extracting, refining, and processing of oleochemicals into surfactants, because petrochemical processes release benzene and other toxic chemicals into the environment and the workplace.[15] This type of data is not included in the 1995 study data tabulations, and thus was not quantitatively evaluated.

For example, LAS is based upon benzene, a confirmed human carcinogen. During the process of producing benzene from crude oil, benzene is released into the air from process emissions and from equipment leaks. In addition to benzene, petroleum refineries also release several other hazardous air pollutants, including aldehydes, ammonia, benzo(a)pyrene, biphenyl, carbon monoxide, ethyl benzene, formaldehyde, naphthalene, xylene, and toluene. They also add tremendously to the volatile organic compound loading in the lower atmosphere contributing to photochemical smog. Petroleum refineries are sources of significant water pollution, including oil, phenols, biological oxygen demand, chemical oxygen demand, ammonia, and chromium. They also produce significant quantities of solid waste.[15] However, since the study is twenty years old, much has changed in the pollution control field and emissions have most likely been drastically reduced.

[11] Davis, Gary et al. Household Cleaners: Environmental Evaluation and Proposed Standards for General Purpose Household Cleaners. University of Tennessee Center for Clean Products and Clean Technologies. July 1992. http://isse.utk.edu/ccp/pubs/pdfs/HouseholdCleaners-wofigsandapps.pdf

Other surfactants rely upon the petroleum refining process for paraffin compounds, aromatics, methanol, and in part, for ethylene oxide. In the United States, most ethylene oxide is produced with natural gas. For instance, nonylphenol ethoxylates rely upon phenol, produced from toluene and benzene, and propylene and ethylene, produced from straight-chain cuts from the distillation of crude oil or natural gas.[15]

Surfactants that rely upon palm/palm kernel oils also create environmental releases during production. However, releases related to oleochemical-based surfactants would not include most of the toxic compounds released during petroleum refining.[15] Some surfactants that rely upon oleochemicals as raw materials are made into alcohols by reaction with methanol and ethoxylated using ethylene oxide, which is produced from ethylene. Ethylene is derived from oil and results in the release of benzene and ethylene to the air. Ethoxylation of the different alcohol compounds, whether natural or petrochemical also releases hydrocarbons and ethylene oxide to the air.[15] Many of the surfactants used are sulfated or sulfonated, which releases sulfur dioxides (precursors to acid rain) to the air, although this source is relatively small compared to burning coal for energy production.[15]

All of the surfactants for all-purpose cleaners require energy for processing from raw materials. Davis et al judged the most energy-intensive options to be those based upon the use of sodium hydroxide and chlorine, and any based upon petrochemicals, and stated that this phase of the product life cycle was one of the most significant. Several of the surfactants are based upon intermediates, such as benzene and ethylene oxide, that are highly toxic and hazardous to human health and the environment.[15]

Manufacturing processes that follow raw material processing consist primarily of blending the raw materials into specific formulations, followed by packaging for distribution and sale. Compared to other life cycle stages, the health and environmental issues associated with product formulation are probably relatively insignificant.

The cited studies did not look at human or environmental toxicity in any phase of the life cycle. Human health hazards from the surfactants would exist during the production phase as workers are exposed to the chemicals during the surfactant manufacturing and product formulation process, and have been previously assessed. Engineering and administrative controls such as personal protective equipment (gloves and respiratory equipment) and proper ventilation generally serve to mitigate the exposure side of the risk equation during production.

Other than the previously-assessed health and safety impacts, it is not apparent from the available data that raw material resource requirements are significant to the choice of alternative surfactants.

Transportation

Transportation uses an insignificant amount of energy compared to other uses. The biggest impact category is the energy usage associated with the water (often up to 90%) that is shipped with the active ingredients, which adds greatly to the use of energy in product distribution and the volume of packaging. Use of petroleum fuels for transportation results in depletion of a nonrenewable resource, in releases of hazardous pollutants during the refining process, and in emissions of volatile organic compounds, carbon dioxide, carbon monoxide, and nitrogen oxides during combustion in vehicle engines.[15]

Transportation of cleaning product containers does not present any relevant hazard or exposure, except

for the possibility of emergency situations, when the primary hazard would be human and environmental toxicity.

Transportation should not be a life-cycle phase with significant impact.

Use

During the use phase, the primary impact would the health and safety hazards presented by exposure of users to the chemical; these have been previously assessed. Potential users in this phase could include sensitive populations, including the elderly, children, and sick people who may be users of the cleaning products or may be nearby when they are used by others either in a home, business, or institutional setting. Direct exposures that might affect human health may be through direct skin exposure to liquids or powders, accidental ingestion, or by inhalation of aerosols generated by spray-type products. Indirectly, exposures may be through surfactants present in the environment following discharge; for example, from wastewater treatment plants. However, as the alternatives being considered are significantly more biodegradable than NPE and NP, this exposure pathway is likely to generate little risk to human health or the environment.

End-of-Life

The end-of-life phase consists of disposal of cleaning solutions to the sanitary sewer system or the storm sewer system (the latter in the case of outdoor use), direct discharge to aquatic environments, discharge to soil (potentially, when cleaners are used outdoors or through land application of sewage sludge), or simple evaporation to the air. They could also constitute a component of the municipal solid waste stream if absorbed on wiping materials such as sponges, paper towels, or cloths. The pertinent life cycle impacts of concern during the end-of-life phase are likely to include global warming potential, aquatic toxicity (acute and chronic), and terrestrial toxicity. Information is not available regarding the potential global warming impact of the biodegradation of surfactants. Aquatic toxicity (of both the surfactant itself, as well as its degradates) appears to be generally regarded as a more significant problem than terrestrial toxicity. If the surfactants are not biodegradable or non-toxic, they may accumulate in sewage treatment systems and surface and ground waters to levels that can impact fish and aquatic life. Surfactants may also interfere with sewage treatment plant processes and create objectionable foaming in streams. Most commonly used surfactants are relatively non-toxic and relatively biodegradable under aerobic conditions. Some that are still in wide use, however, such as nonylphenol ethoxylate, are not readily biodegradable in standard tests. Under anaerobic conditions, other widely used surfactants, such as LAS, fail to biodegrade significantly. Since anaerobic conditions exist in sewage treatment plants (sludge digesters), in surface streams and their sediments, and in ground waters, the failure of these ingredients to biodegrade can allow their accumulation.[15] However, these hazards have been previously assessed.

General Conclusions

Although the study did not proceed to quantify and examine the environmental impacts of the raw material usage, energy consumption, and environmental emissions, the following conclusive statement was made:

> "Based on the findings of this study, no technical or scientific basis exists to support a general environmental superiority claim, either for an individual surfactant or for the

various options for sourcing from petrochemical, oleochemical or agricultural feedstocks and minerals."

The study also pointed out that the production processes associated with the petrochemical-based surfactants are generally produced with well-developed technologies that have been fairly-well optimized, implying that the oleochemical processes are not as far advanced. It is likely that much has changed in the twenty years since the study was prepared, and the differences may be even less today than they were then.

In addition, as the amount of surfactant present in a formulation may vary, possibly in the range of 2-5% of the total mass of ingredients, any significant variation in the resource usage or environmental emissions for different surfactants may either magnified or minimized. Until a specific formulation is known, no conclusions may be drawn from the available existing data. Even then, the previously-discussed concerns with comparison of surfactant systems on a mass basis still must be considered.

Therefore, the only factors known to present a demonstrable difference between surfactant alternatives are the human health and environmental hazards previously assessed, based on an analysis of available, existing data.

4.2 Product Function and Performance Impacts

All-purpose cleaners are designed to clean many different types of washable surfaces, although reading the directions will reveal types of surfaces that specific cleaners should not be used on. The benefit of an all-purpose cleaner is that it provides consumers with one cleaner that can be used in most areas of their home. All-purpose cleaners can frequently be used to mop, clean countertops, clean bathroom surfaces, and more. All-purpose cleaners may use many different types of ingredients, such as detergents, grease-cutting agents, solvents, surfactants, and disinfectants – and the function of the cleaning product is a result of a complex combination of functions of the individual ingredients. The surface to be cleaned and the soil to be removed must initially be wet and the soils suspended, solubilized, dissolved or separated in some way so that the soil will not just re-deposit on the surface in question.

Performance of all-purpose cleaners can be measured by tests established by manufacturers, consumer organizations, or governmental organizations. The primary purpose of the testing is to ensure that the cleaner is capable of removing the type of contaminant that it is intended to remove. Testing standards were previously detailed in the first stage of this alternatives assessment. There are no legal requirements regarding the performance of all-purpose cleaners. Although performance may vary between individual all-purpose cleaner products, the difference in performance between an all-purpose cleaner with NPE and one containing an alternative surfactant (or mixture of surfactants) should be negligible since formulators will create and adjust formulations containing the new ingredients until performance is equivalent or better to the original formulation.

Useful life of all-purpose cleaners is on the order of years, and often more than is needed for common consumer applications, and is not particularly relevant since there is no significant difference among the alternatives in this aspect.

Technical and economically-feasible alternatives do exist, as is evidenced by the plethora of products

already in commerce that do not contain NPE as a surfactant, such as Nature's Source® Scrubbing Bubbles from S.C. Johnson[12], fantastik® all-purpose cleaner (also S.C. Johnson)[13], Seventh Generation Free and Clear Natural All-Purpose Cleaner[14], and Method All-Purpose Natural Surface Cleaner[15], among many others by many manufacturers.

4.3 Economic Impacts

No quantitative data was found upon which to base an assessment and monetization of the public health and environmental costs, as well as the costs to government agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife. However, it is believed to be safe to assume that since the alternatives that are (so far) preferable to NPE have significantly better human health and environmental hazard profiles, that any public health and environmental costs should likewise be significantly lower. Due to a lack of persistence, the preferred alternatives should not generate any potential environmental remediation needs due to contamination from surfactant discharges, whereas NPE does have that potential due to the persistence of its NP degradate.

Based on information from surfactant and cleaning product manufacturers who have partnered with DfE, EPA concluded that the NPE alternatives are comparable in cost, especially when viewed as part of a detergent system.[6]

[12] As described on product webpage at http://www.whatsinsidescjohnson.com/en-us/products-by-brand/natures-source/scrubbing-bubbles-natures-source-all-purpose-cleaner.aspx

[13] As described on product webpage at http://www.whatsinsidescjohnson.com/en-us/products-by-brand/fantastik/orange-action-trigger.aspx

[14] As described on product webpage at http://www.seventhgeneration.com/All-Purpose-Cleaner?vx24scG34=1390686&variation=free-clear

[15] As described on product webpage at http://methodhome.com/shop/all-purpose-cleaner-with-powergreen-technology/

5. Consideration of Additional Information

GreenBlue, in conjunction with US EPA, maintains a database, CleanGredients, of cleaning product ingredients that have been shown to satisfy the US EPA DfE program criteria.[16] This database was reviewed to determine whether any or all of the alternatives were included. Table 4 contains the results of this evaluation. It must be noted that the absence of a chemical from the CleanGredients database does not necessarily mean that the chemical failed to pass the pertinent criteria; it may mean that it has not been evaluated as of yet. Review of the hazard data contained within the database did not reveal any additional information (as it was probably used as a primary source for the data included by US EPA in its NPE alternatives assessment).

Table 9: CleanGredients Data

Chemical Class	Chemical Name	CASRN	Listed?	Listed Names
Alkylphenol ethoxylate (APE)	Nonylphenol ethoxylate	127087-87-0	No	None
Sorbitan ester	Sorbitan monostearate	1338-41-6	No	None
Alkyl sulfate ester (AS)	Sodium lauryl sulfate	151-21-3	Yes	Stepanol Me-Dry
Ethoxylated/ propoxylated alcohols	Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether)	64366-70-7	No	None
Linear alcohol ethoxylate (LAE)	C12-15 alcohols, ethoxylated (9EO)	68131-39-5	Yes	Neodol 25-9 EF FAE LOA 25-9
Linear alkylbenzene sulfonate (LAS)	Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt	68411-30-3	No	None
Linear alcohol ethoxylate (LAE)	C9-11 alcohols, ethoxylated (6EO)	68439-46-3	Yes	Bio-soft N91-6 EF FAE NUA 91-6 Empilan KR-6 Masodol 91-6 Neodol 91-6 Rhodasurf 91-6 Tomadol 91-6
Alkyl polyglucose (APG)	D-glucopyranose, oligomeric, decyloctyl glycosides	68515-73-1	Yes	Elotant Milcoside 100 Elotant Milcoside 101 Elotant Milcoside 102 Elotant Milcoside 102H Elotant Milcoside 102NB Elotant Milcoside 102ND Elotant Milcoside 110 Glucopon 215 UP Glucopon 225 DK Masopon 215 Masopon 225 DK
Alkyl ether sulfate (AES)	Polyoxy (1,2-ethanediyl), alpha-sulfo-omega-dodecyloxy-, sodium salt	9004-82-4	No	None

The US EPA Alternatives Assessment indicated that all of the alternatives, except for NPE, met their DfE surfactant criteria, thus not allowing any of the remaining alternatives to be distinguished from one another on that basis.

[16] As detailed in the DfE Surfactant criteria https://www.epa.gov/saferchoice/safer-choice-criteria-surfactants

The US EPA also maintains a Safer Chemical Ingredient List[17], which contains chemicals that meet the criteria of the Design for the Environment (DfE) Safer Product Labeling Program. This list includes many of the chemicals evaluated through the DfE Safer Product Labeling Program. The only two alternatives that are not included on this list (although included in the US EPA AA) are nonylphenol ethoxylates (CASRN 127087-87-0) and benzenesulfonic acid, C10-13 alkyl derivs., sodium salt (CASRN 68411-30-3). However, this non-listing is inconclusive as US EPA states specifically that there may be chemicals not included in this list that are also safer, and the latter chemical may be among these.

[17] US EPA. Safer Chemical Ingredients for Use in DfE-Labeled Products. 2013. http://www.epa.gov/dfe/saferingredients.htm#more

6. Final Comparison of Priority Product and Alternatives

The alternatives under consideration are all-purpose cleaning products containing NPE and similar products containing alternative surfactants. As the only difference is the surfactant, this discussion focuses on alternative surfactants, and which one(s) are the most preferable substitute(s). The relevant factors that were considered are as follows:

- Adverse environmental impacts;
- Adverse public health impacts;
- Environmental fate;
- Physical chemical hazards;
- Physicochemical properties;
- Multimedia life cycle impacts (including materials and resource consumption impacts);
- Product function and performance impacts; and
- Economic impacts.

The hazard assessment and benchmarking process, which addressed the first five factors, leads to the following conclusions:

- NPE is a chemical of very high concern whose use should be avoided, due its ranking as a Draft Benchmark 1 chemical. Therefore, it will be eliminated from the formulation and replaced with an alternative with a better hazard profile.
- Sorbitan monostearate (CASRN 1338-41-6); C12-15 alcohols, ethoxylated (9EO)(CASRN 68131-39-5); Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether)(CASRN 64366-70-7); C9-11 alcohols, ethoxylated (6EO)(CASRN 68439-46-3); and Polyoxy (1,2-ethanediyl), alpha-sulfo-omega-dodecyloxy-, sodium salt (CASRN 9004-82-4) do not meet the minimum data requirements and should not be considered further until new data is available to fill in the gaps.
- Sodium lauryl sulfate (CASRN 151-21-3) is assessed as a chemical which may be used, but for which safer substitutes should be identified (Draft Benchmark 2).
- Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt (CASRN 68411-30-3) and D-glucopyranose, oligomeric, decyloctyl glycosides (CASRN 68515-73-1) are assessed as chemicals which may be used, but for which safer substitutes should be identified (Draft Benchmark 2_{DG}). However, as this assessment is based upon data gaps, it may be that additional data may allow these chemicals to be classified as Draft Benchmark 3 chemicals.

Review of the CleanGredients data and the US EPA Safer Ingredients List are inconclusive. Although the benzenesulfonic acid compound is not listed, it is not known whether it is not listed due to not meeting criteria or because no candidates have been assessed. Qualitative metrics (very high, high, moderate, low, and very low hazard) are shown in the hazard matrix (Table 2); these are, in turn, based on quantitative metrics such as lethal dose concentrations and other toxicological data.

Multimedia life cycle impacts exist for all of the alternatives, but the available data was insufficient or insufficiently distinguishable for individual alternatives to provide any differentiation between the alternatives. Thus, these impacts **do not affect the conclusions**.

Performance of the Priority Product – all purpose cleaners – is of the utmost importance. If a cleaner does not clean to the standards of the user, then it will not perform well in the marketplace. Formulations are reworked until the desired level of performance is achieved at a viable price point.

Thus, performance is not affected by a choice of alternative surfactants, since that choice is predicated upon achieving cost competitiveness and equivalent performance. Thus, these impacts **do not affect the conclusions**.

Economic impacts are not a known factor in the selection of products containing alternative surfactants, since no data were found to properly evaluate this factor. Thus, these impacts **do not affect the conclusions.**

7. Alternatives Selection Decision

Considering the relative draft benchmark scores, the two Draft Benchmark 2_{DG} alternatives - Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt (CASRN 68411-30-3) and D-glucopyranose, oligomeric, decyloctyl glycosides (CASRN 68515-73-1) - are recommended for further assessment. In particular, it may be valuable to conduct further literature research in an attempt to fill the data gaps that prevent assessment of these chemicals as Draft Benchmark 3 chemicals.

In the event that these are determined to be unsuitable for some reason(s), then the Draft Benchmark 2 alternative - Sodium lauryl sulfate (CASRN 151-21-3) - should be considered.

8. Implementation Plan

ACTION ITEM	DESCRIPTION	SCHEDULED COMPLETION TIME*
Reformulation studies to make final surfactant determination	Bench- and pilot-scale studies will be conducted to determine the appropriate surfactant from the recommended alternatives, provided that the appropriate performance and price point can be achieved.	12 months
Submittal of revised Final Alternatives Assessment report	Upon completion of reformulations and final selection of surfactant	As needed
Manufacturing of new formulation	Any capital plant modifications will be designed and constructed and/or operating modifications will be implemented prior to initiation of manufacturing of the new formulation.	6-12 months

* dependent on DTSC regulatory response

SUMMARY OF RESULTS AND LESSONS LEARNED FROM THIS DEMONSTRATION PROJECT

Summary of Results

This demonstration project sought to pilot test the use of alternatives assessment as required under the CA SCP regulations. Eight alternative surfactants for NPE in all-purpose cleaning products were considered in this assessment and informed by prior alternative assessments conducted by US EPA's Design for Environment's program. While the assessment considered a range of multi-media life cycle impacts, human health and environmental hazards were the main factors that presenting a demonstrable difference between NPE and the 8 surfactant alternatives assessed.

Two alternatives – (1) Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt (CASRN 68411-30-3), and (2) D-glucopyranose, oligomeric, decyloctyl glycosides (CASRN 68515-73-1) were identified as safer compared to NPE using the GreenScreen® hazard assessment method. However, skin and eye irritation as well as ecotoxicity impacts were still notable hazards. Moreover, data gaps for critical human health endpoints – including developmental and reproductive toxicity in the case of Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt and carcinogenicity and endocrine disruption in the case of D-glucopyranose, oligomeric, decyloctyl glycosides – downgraded the final benchmark hazard score for both alternatives. Both alternatives received Benchmark 2_{DG} – "Use, but search for safer substitutes". No alternative in this assessment scored higher than a Benchmark 2. As a consequence, this report calls for more research, and at minimum a deeper review of more recent literature in an attempt to fill the more critical data gaps.

The assessment of economic and technical feasibility was limited in this demonstration project due to data availability as a result of resource and methodological limitations. Yet despite these limitations, the project uncovered important challenges that warrant additional consideration by CA DTSC as it seeks to develop alternatives assessment guidance documents that follow requirements outlined in the CA SCP regulations.

Lessons Learned

Lesson 1: Consideration of data gaps is an important component of the hazard assessment process to ensure a transition to safer chemicals. An important principle that guides the alternatives assessment process is an explicit understanding that *lack of evidence should not be equated with evidence of safety.* It is simply unwise for a business to invest in the adoption of an alternative if no data are available to demonstrate that the alternative does not cause critical human health hazards. The past decades have been riddled with examples of significant costs to businesses (as well as the public and the environment) from chemicals that were introduced as replacements for known toxic chemicals, only to be revealed in later research studies as also toxic.

While data gaps are common in the hazard assessment process, data gaps for some hazard endpoints are more problematic. US and the EU authorities charged with regulating chemicals have prioritized restrictive risk management actions on chemicals demonstrating impacts such as carcinogenicity, mutagenicity or reproductive toxicity (CMRs). The GreenScreen® hazard assessment includes 5 such critical human health endpoints (carcinogenicity, mutagenicity, reproductive toxicity, developmental toxicity, and endocrine disruption) in its benchmarking process. The benchmarking process is used to generate a final hazard score considering the individual hazard across each of the 17 human health and safety and ecotoxicity endpoints assessed. In order to be considered a benchmark 3 chemical, "Use, but Opportunity still for improvement," which confers a general level of comfort regarding the overall

hazard profile of the chemical, the GreenScreen method permits data gaps in only 1 of these critical endpoints. If more data gaps are present as was the case for two of the safer alternatives identified in this assessment – (1) Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt (CASRN 68411-30-3), and (2) D-glucopyranose, oligomeric, decyloctyl glycosides (CASRN 68515-73-1), the final benchmark score is downgraded (i.e. determined to be less safe).[18]

The conclusions of this project based on the GreenScreen® hazard assessment method reflect the importance of considering data gaps in decisions about which alternative to consider as a viable replacement for a chemical of concern. No alternative in this assessment was deemed "safe" either because of evidence of harm or because there was no clear evidence of safety. Data gaps in this assessment helped to prioritize where additional research is needed in order to avoid regrettable substitutions.

Lesson 2: Economic and technical feasibility assessments conducted by 3rd party entities not directly involved in business operations using the chemical of concern – priority product are extremely difficult. Such was the case in this demonstration project. This project was designed to use publicly available data. However, there were no publicly available economic data related to the production process for all-purpose cleaners and without direct knowledge of specific production operations, it is impossible to derive such economic estimates. If a "drop-in" substitute could be identified, it is anticipated that there would be minimal changes in the cost of production. Yet if the product requires reformulation, it is impossible to project the associated cost implications without direct knowledge of process changes or new equipment that may be needed. Surveys of impacted businesses to collect such information would be required, which was beyond the scope of this project.

For 3rd party entities, the assessment of technical feasibility was similarly limited by publicly available data. Unless such data is available from prior published performance evaluations, testing of alternatives will be needed to ensure the final product meets necessary performance criteria. Such testing was beyond the scope of this demonstration project. However, performance testing may also be beyond the realm of possibility for some entities needing to comply with the CA SCP regulations. Performance testing is very resource intensive (including time, staffing expertise and equipment). Collaborative mechanisms/structures to leverage resources where they exist among those impacted by the CA SCP regulations will be needed given the resource demands that will likely be involved.

Lesson 3: Socioeconomic feasibility assessments will be a challenge. Although challenges confronting 3rd party direct cost economic assessments will not be a barrier for businesses seeking to comply with CA SCP regulations, the broader socio-economic assessment aspect of the assessment will be a challenge. Within the economic assessment, businesses are also expected to evaluate the public health and environmental costs, as well as the costs to government agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife. There was simply no publicly available economic data to address these measures for the chemical alternatives reviewed in this assessment. Moreover, without additional guidance, there are limited available methods in the literature for many of these measures, such as an assessment of costs to government agencies.

The SCP regulations are an important driver to better understand the external costs associated with

[18] For more details on the GreenScreen® data gap analysis method in the benchmark scoring process, please see the GreenScreen method documents: http://www.greenscreenchemicals.org/method.

production, use and disposal of toxic chemicals in our economy. Lack of available methods and data will be a challenge, yet will also force the development of such methods and assessment tools.

Additional Recommended Actions Not Undertaken in this Demonstration Project

Consider additional alternative surfactants in future alternative assessments. There are hundreds of chemicals that could perform the function as a surfactant in an all-purpose cleaning product. This alternatives assessment limited the evaluation to 8 surfactants that were originally considered by US EPA in their Design for Environment assessment of NPE alternatives. However, future alternatives assessments for NPE may benefit from a broader screening of alternative surfactants for inclusion in the evaluation.

A challenge confronting the practice of alternatives assessment is determining the number of alternatives to consider in the evaluation. As the number of alternatives that are considered increases, so does the resource-level required to complete the analysis (evaluation of hazard, life cycle impacts, economics and performance). However, if not enough alternatives are considered, most if not all could be screened out of the assessment due to hazard, life cycle impacts, or technical/economic feasibility. Resource limitations that constrained the number of alternatives that were assessed in this project will be similar for Small and Medium-sized Enterprises (SMEs) that are required to comply with the CA SCP regulations. Thus it is important for alternatives assessments to make use of and to build upon prior analyses. Alternatives identified as problematic in this assessment could be quickly screened-out in order to spend more time evaluating alternatives that have not been evaluated to date. Given that the alternatives identified were not free of hazards, it is important to broaden the search for safer options in future assessments.

Consider additional chemical hazards in the product formulation. All-purpose cleaners are formulated chemical products. In general, there are five types of ingredients found in household cleaners: surfactants, builders, solvents, antimicrobials, and miscellaneous (e.g., fragrances, dyes, thickeners). While “drop-in” substitute surfactants for NPE may be possible, replacing NPE with another surfactant will likely require reformulating the product to meet performance metrics. To ensure that compliance with the CA SCP regulations results in a transition towards safer consumer product, additional assessment of hazards (or at minimum, a screen against authoritative hazard lists) should be performed on other chemicals above a threshold percent concentration in the formulation. Models exist for what this threshold should be. For example, the US Environmental Protection Agency’s Safer Choice program uses a cut-off of 0.01% (i.e., if a chemical is less than 100 ppm in a product, a hazard assessment does not need to be conducted in order for the product to qualify for the Safer Choice label).

Conclusion

Alternatives assessment as envisioned under the CA SCP regulations is one of the most important developments in recent years to advance the supply of safer chemicals and products. This demonstration project was not intended to present new information on alternatives to NPE, but rather to use existing information to illustrate how the requirements for an alternatives assessment under the regulations could be met in order identify needs and opportunities that could form the basis of public comments to CA DTSC as it develops its CSP compliance guidance documents. The BizNGO Alternatives Assessment Work Group looks forward to working with multiple sectors as they begin the process of assessing their options for safer, feasible substitutes.

Appendices

Appendix 1: Basic Information on Surfactants

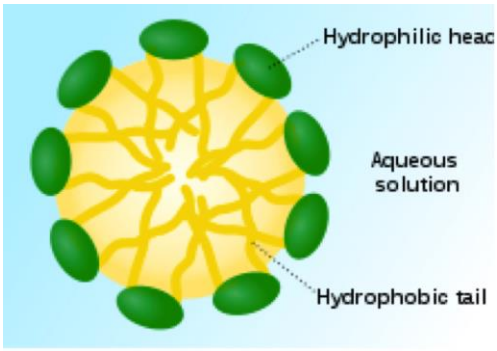
Appendix 2: GreenScreen®

Appendix 3: GreenScreen® Assessment Reports

Appendix 4: Administrative Compliance

Appendix 1: Basic Information on Surfactants

What is a surfactant?

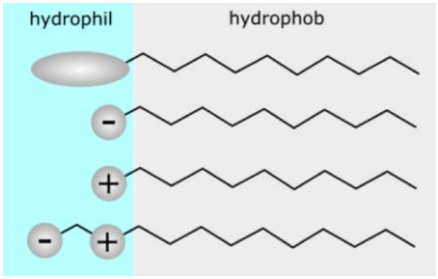


Surfactants (a blend of the words “surface active agents”) are compounds that lower the surface tension of a liquid, the interfacial tension between two liquids, or that between a liquid and a solid. Surfactants may act as detergents, wetting agents, emulsifiers, foaming agents, and dispersants.

Surfactants are usually organic compounds that are amphiphilic, meaning they contain both hydrophobic groups (their *tails*) and hydrophilic groups (their *heads*). Therefore, a surfactant contains both a water-insoluble (or oil-soluble) component and a water-soluble (oil-insoluble) component. Surfactants will diffuse in water and adsorb at interfaces between air and water or at the interface between oil and water, in the case where water is mixed with oil. The insoluble hydrophobic group may extend out of the bulk water phase, into the air or into the oil phase, while the water-soluble head group remains in the water phase. This alignment of surfactants at the surface modifies the surface properties of water at the water/air or water/oil interface. In the bulk aqueous phase, surfactants form aggregates, such as micelles, where the hydrophobic tails form the core of the aggregate and the hydrophilic heads are in contact with the surrounding liquid. The polar "heads" of the micelle, due to favorable interactions with water, form a hydrophilic outer layer that in effect protects the hydrophobic core of the micelle. The compounds that make up a micelle are typically amphiphilic in nature, meaning that micelles are soluble not only in protic solvents such as water but also in aprotic solvents as a reverse micelle.

The "tails" of most surfactants are fairly similar, consisting of a hydrocarbon chain, which can be branched, linear, or aromatic. Many important surfactants include a polyether that are terminated with a highly polar anionic group. The polyethers often feature ethoxylated (polyethylene oxide-like) sequences inserted to increase the hydrophilic character of a surfactant. Polypropylene oxides are inserted to increase the lipophilic character of a surfactant.

How are surfactants classified?

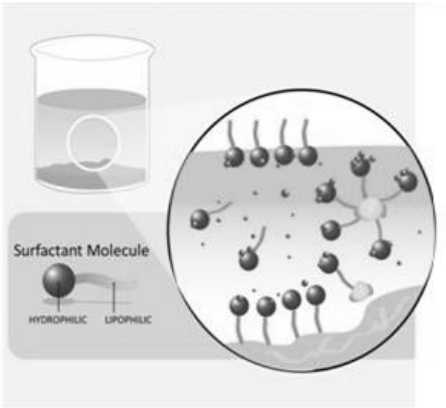


Surfactant classification according to the composition of their head: nonionic, anionic, cationic, amphoteric. Most commonly, surfactants are classified according to the polar head group (on the left in the adjacent diagram). A non-ionic surfactant has no charge groups in its head. The head of an ionic surfactant carries a net charge. If the charge is negative, the surfactant is more specifically called anionic; if the charge is positive, it is called cationic. If a surfactant contains a head with two oppositely charged groups, it is termed amphoteric.

Nonionic and anionic surfactants are the most common, and are both used in hard surface cleaning, laundry, dish care, and personal care. Cationic surfactants (typically quaternary amines) are used primarily in fabric softeners, hair care, and disinfection. Amphoteric surfactants are used primarily in dish care and personal care.

How does a surfactant work?

A surfactant, usually dissolved in water, does the primary work in the cleaning process as it helps to remove dirt, oil, and grease from a surface by enabling the cleaning solution to fully wet the soiled surface so the contaminant can be more easily removed, and then emulsifying or dispersing the contaminant in such a way that it is not re-deposited on the surface. This is done by lowering the interfacial surface tension between the cleaning solution and the soil, and between the soil and the surface, making it easier to remove the soil and keep it removed. The hydrophilic head of the surfactant molecule remains in the water and it pulls the stains towards the water, away from the surface. The surfactant molecules surround the soil particles, break them up, force them away from the surface, and then suspend them so they can be removed.



How are surfactants manufactured?

Alkylphenol ethoxylates (such as NPE) are manufactured by reacting NP with ethylene oxide (EO) under basic conditions. NP is prepared from phenol and tripropylene, yielding a highly-branched, predominantly para-substituted alkylphenol.[6]

Sorbitan esters (such as sorbitan monostearate) are produced by the reaction of fatty acid methyl esters with sorbitan in the presence of a basic catalyst.[6]

Alkyl sulfate esters (such as sodium lauryl sulfate) are produced by sulfation of fatty alcohols followed by neutralization to yield alkyl sulfate ester salts (typically sodium).[6]

Ethoxylated/propoxylated alcohols (such as oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether)) are manufactured by reacting 2-ethylhexanol with ethylene oxide and propylene oxide.[6]

Linear alcohol ethoxylates (such as C9-11 ethoxylated alcohols and C12-15 ethoxylated alcohols) are produced by reacting linear alcohols (derived from fatty acids or alpha-olefins) with ethylene oxide.[6]

Linear alkylbenzene sulfonates (such as benzenesulfonic acid, C10-13 alkyl derivs., sodium salt) are produced by sulfonation of linear alkylbenzene and neutralization. Linear alkylbenzene is manufactured by alkylating benzene with a linear olefin in the presence of an acid catalyst.[6]

Alkyl polyglucoses (such as D-glucopyranose, oligomeric, decyloctyl glycosides) are manufactured by reacting fatty alcohols with glucose in the presence of an acid catalyst.[6]

Alkyl ether sulfates (such as polyoxy (1,2-ethanediyl), alpha-sulfo-omega-dodecyloxy-, sodium salt) are produced by sulfation of linear alcohol ethoxylates, followed by neutralization to produce the salt.[6]

Appendix 2: GreenScreen®

The GreenScreen for Safer Chemicals (GreenScreen®) is a method for comparative Chemical Hazard Assessment (CHA) that can be used for identifying chemicals of high concern and safer alternatives. It is being used by industry, government and NGOs to support product design and development, materials procurement, and as part of alternatives assessment to meet regulatory requirements.[19]

There are 18 hazard endpoints addressed by GreenScreen Hazard Criteria as shown below. The detailed criteria can be found at: http://www.cleanproduction.org/library/GreenScreen_v1_2-2e_CriteriaDetailed_2012_10_10w_all_Lists_vf.pdf.

Environmental Fate	Environmental Health*	Human Health Group I	Human Health Group II	Physical Hazards
Persistence (P)	Acute Aquatic Toxicity (AA)	Carcinogenicity (C)	Acute Mammalian Toxicity (AT)	Reactivity (Rx)
Bioaccumulation (B)	Chronic Aquatic Toxicity(CA)	Mutagenicity & Genotoxicity (M)	Systemic Toxicity & Organ Effects (incl. Immunotoxicity) (ST)	Flammability (F)
		Reproductive Toxicity (R)	Neurotoxicity (N)	
		Developmental Toxicity (incl. Developmental Neurotoxicity) (D)	Sensitization (SnS)	
		Endocrine Activity (E)	Respiratory Sensitization (SnR)	
			Skin Irritation (IrS)	
			Eye Irritation (IrE)	

*Other Ecotoxicity Studies when available

GreenScreen® v1.2 includes four Benchmarks. Each Benchmark includes a set of criteria that a chemical, along with its known and predicted transformation products, must pass. To progress from Benchmark 1 to Benchmark 2, a chemical (including transformation products) must pass all the criteria specified under Benchmark 1. Likewise, to advance from Benchmark 2 to Benchmark 3, the chemical (and its transformation products) must pass all of the criteria in Benchmark 2, etc. These benchmarks and their associated criteria and assignment algorithms are shown on the following page.

[19] Clean Production Action website. http://www.cleanproduction.org/Greenscreen.php. Accessed May 2013.

OCTOBER 2011 (v2)

GreenScreen™ for Safer Chemicals v 1.2 Benchmarks

Start at Benchmark 1 (red) and progress to Benchmark 4 (green)

ABBREVIATIONS

- P Persistence
- B Bioaccumulation
- T Human Toxicity and Ecotoxicity

This chemical passes all of the criteria.

BENCHMARK 4

Low P* + Low B + Low T (Ecotoxicity, Group I, II and II* Human) + Low Physical Hazards (Flammability and Reactivity) + Low (additional ecotoxicity endpoints when available)

Prefer—Safer Chemical

BENCHMARK 3

a. Moderate P or Moderate B
b. Moderate Ecotoxicity
c. Moderate T (Group II or II* Human)
d. Moderate Flammability or Moderate Reactivity

Use but Still Opportunity for Improvement

If this chemical and its breakdown products pass all of these criteria, then move on to Benchmark 4.

BENCHMARK 2

a. Moderate P + Moderate B + Moderate T (Ecotoxicity or Group I, II, or II* Human)
b. High P + High B
c. High P + Moderate T (Ecotoxicity or Group I, II, or II* Human)
d. High B + Moderate T (Ecotoxicity or Group I, II, or II* Human)
e. Moderate T (Group I Human)
f. Very High T (Ecotoxicity or Group II Human) or High T (Group II* Human)
g. High Flammability or High Reactivity

Use but Search for Safer Substitutes

If this chemical and its breakdown products pass all of these criteria, then move on to Benchmark 3.

BENCHMARK 1

a. PBT = High P + High B + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
b. vPvB = very High P + very High B
c. vPT = very High P + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
d. vBT = very High B + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
e. High T (Group I Human)

Avoid—Chemical of High Concern

If this chemical and its breakdown products pass all of these criteria, then move on to Benchmark 2.

BENCHMARK U

- Unspecified Due to Insufficient Data

Group I Human includes Carcinogenicity, Mutagenicity/Genotoxicity, Reproductive Toxicity, Developmental Toxicity (incl. Developmental Neurotoxicity), and Endocrine Activity. **Group II Human** includes Acute Mammalian Toxicity, Systemic Toxicity/Organ Effects-Single Exposure, Neurotoxicity-Single Exposure, Eye Irritation and Skin Irritation. **Group II* Human** includes Systemic Toxicity/Organ Effects-Repeated Exposure, Neurotoxicity-Repeated Exposure, Respiratory Sensitization, and Skin Sensitization. Immune System Effects are included in Systemic Toxicity/Organ Effects. **Ecotoxicity** includes Acute Aquatic Toxicity and Chronic Aquatic Toxicity.

Note: The level of hazard indicated is the lowest hazard level at which a chemical would fail that criterion. However, if the chemical has a higher hazard level than what is listed (e.g. chemical is very High and the criterion is High), it would also fail that criterion.

* For inorganic chemicals with Low B, Low T (Ecotoxicity, Group I, II and II* Human) and Low Physical Hazards (Flammability and Reactivity), persistence alone will not be deemed problematic. Inorganic chemicals that are only persistent may achieve Benchmark 4.

Clean Production Action • www.cleanproduction.org

Used by permission from Clean Production Action

Appendix 3: GreenScreen® Assessment Reports

GreenScreen® Assessment for Nonylphenol Ethoxylates (127087-87-0)

GreenScreen® Version 1.2 Draft Assessment
Note: Validation Has Not Been Performed on this GreenScreen® Assessment

Chemical Name: Nonylphenol ethoxylates

GreenScreen® Assessment Prepared By:
Name: Eric Harrington
Title: Principal
Organization: Green Advantage Consultants
Date: 5/29/2013

Quality Control Performed By:
Name: NA
Title: NA
Organization: NA
Date: NA

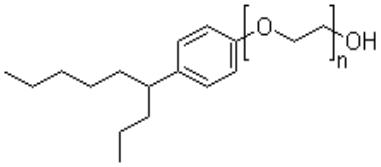
Confirm application of the *de minimus* rule: NA

Chemical Name (CAS #): Nonylphenol ethoxylates (127087-87-0)

Also Called: NA

Chemical Surrogates, analogs or moieties used in this assessment (CAS #): None

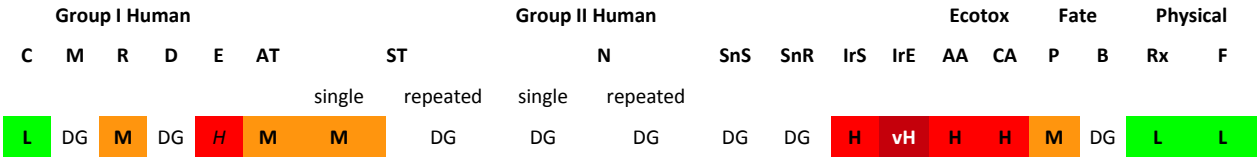
Chemical Structure(s):



Notes related to production specific attributes:
Nonylphenol (NP) is generally a mixture of various isomers, predominantly para-substituted nonylphenol (CASRN 84852-15-3), 4-nonylphenol (CASRN 104-40-5), and nonylphenol (CASRN 25154-52-3), with small amounts of ortho-substituted nonylphenol (CASRN 136-83-4), and traces of 2,4-dinonylphenol (CASRN 84962-08-3). There may be additional isomers representing the numerous branched structures within the nonyl group. Therefore, nonylphenol ethoxylates generally represent a similar distribution of isomers. As the US EPA alternatives assessment[5] evaluated the branched isomer of NPE, this assessment does likewise.

Identify Applications/Functional Uses:
1. Surfactant in cleaning products

Green Screen Rating: Nonylphenol ethoxylates was assigned a Draft Benchmark Score of 1_{TP} based on the classification of its primary transformation product - NP - as a Draft Benchmark 1.



Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance).

Transformation Products and Ratings:

NPEs degrade to more toxic chemicals, including NP, which often partitions to sediment and accumulates, potentially exposing aquatic life to these compounds. NPE degrades via successive removal of the ethylene oxide groups until the nonylphenol (or other intermediates) remains. The NP itself then degrades, albeit at a relatively slow rate. Common degradates of NPE include nonylphenol (NP), nonylphenol (EO1), nonylphenol (EO2), and their carboxylic acid derivatives (nonylphenoxyacetic acid and nonyphenoxyethoxyacetic acid).*20* NP is lethal to fish and other aquatic organisms at low concentrations (lower than for the parent NPE) in both acute and chronic fish studies. In addition, effects on growth and reproduction have been documented. The US EPA recommended Aquatic Life Ambient Water Quality Criteria (AWQC) concentrations for NP are in the low parts per billion, based on this aquatic toxicity information. The US EPA AWQC and its scientific basis are consistent with similar findings and regulatory actions taken by governments in Europe, Canada and Japan. US EPA has rated the toxicity of NP as "very high," based on experimental LC_{50} values in the range of 0.13-1.4 ppm in fish, EC_{50} values in the range of 0.14-0.47 ppm in daphnia and EC_{50} values in the range of 0.027-0.41 ppm in green algae. In addition, a 33-day NOEC (survival) of 0.0074 ppm has been reported in fish and 21-day NOECs (growth, survival and sublethal effects) < 0.1 ppm have been reported in mysid shrimp for nonylphenol.[21]

Functional Use	Life Cycle Stage	Transformation Pathway	Transformation Products	CAS #	On CPA Red List?	Green Screen Rating
NA	End	Biodegradation	nonylphenol	84852-15-3	N	1
NA	End	Biodegradation	nonylphenol (EO1)	104-358 27986-36-3	N	*
NA	End	Biodegradation	nonylphenol (EO2)	20427-84-3 27176-93-8	N	*
NA	End	Biodegradation	nonylphenoxyacetic acid	3115-49-9	N	*
NA	End	Biodegradation	nonylphenoxyethoxyacetic acid	106807-78-7	N	*

*Not evaluated, since evaluation of nonylphenol resulted in a rating of Benchmark 1.

Hazard Classification Summary Section:

[20] ToxEcology Environmental Consulting Ltd. 2002. Alternatives to Nonylphenol Ethoxylates: Review of Toxicity, Biodegradation, and Technical-Economic Aspects. Prepared for Environment Canada.

a) [21] US Environmental Protection Agency. 2012. DfE Alternatives Assessment for Nonylphenol Ethoxylates. Washington, D.C. http://www.epa.gov/dfe/pubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M or L): L
Nonylphenol ethoxylates was assigned a score of **LOW** for carcinogenicity based on being Not Classified per GHS.

- CERI -
  - All test data was negative for carcinogenicity.

Mutagenicity/Genotoxicity (M) Score (H, M or L): DG
No data were found for mutagenicity/genotoxicity.

Reproductive Toxicity (R) Score (H, M, or L): M
Nonylphenol ethoxylates was assigned a score of **MODERATE** for reproductive toxicity based on being on the "GHS Japan Category 2 Suspected Reproductive Toxicity" list per the GreenScreen® List Translator. It is also listed with EU H-phrase H361fd (from an authoritative list), which places it in the **MODERATE** category. No other data were found.

- ECHA C&L Inventory -
  - EU H-phrase H361fd

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M or L): DG
No data were found for developmental toxicity.

Endocrine Activity (E) Score (H, M or L): *H*
Nonylphenol ethoxylates was assigned a score of **HIGH** for endocrine activity based on being on the "EU ED Category 1," "EU ED Category 2," "OSPAR Endocrine Disruptor," and "SIN Endocrine Disruptors" lists per the GreenScreen® List Translator (all are screening lists). No other overriding data were found.

Group II and II* Human Health Effects (Group II and II* Human)
Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M or L): M
Nonylphenol ethoxylates was assigned a score of **MODERATE** for acute mammalian toxicity based on oral LD50 values in the >300-2000 mg/kg range.

- US EPA 2006 -
  - Based on experimental oral LD_{50} values for NPE in the range of 1680 mg/kg (EO=6) to 1890 mg/kg (EO=10). EO9 is the most common degree of ethoxylation, and toxicity tends to increase with lower degrees of ethoxylation.

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)
Group II Score (single dose: vH, H, M or L); DG
No data were found for systemic toxicity/organ effects - single dose.

Group II* Score (repeated dose: H, M, L): DG
No data were found for systemic toxicity/organ effects - repeated dose.

Neurotoxicity (N)
Group II Score (single dose: vH, H, M or L): DG
No data were found for neurotoxicity - single dose.

Group II* Score (repeated dose: H, M, L): DG
No data were found for neurotoxicity - repeated dose.

Skin Sensitization (SnS) Group II* Score (H, M or L): DG
No data were found for skin sensitization.

Respiratory Sensitization (SnR) Group II* Score (H, M or L): DG
No data were found for respiratory sensitization.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M or L): H
Nonylphenol ethoxylates was assigned a score of **HIGH** for skin irritation/corrosivity based on the assignment of EU Risk Phrase R38.

- Chemical Book -
  - EU Risk Phrase R38

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M or L): vH
Nonylphenol ethoxylates was assigned a score of **VERY HIGH** for eye irritation/corrosivity based on the assignment of EU Risk Phrase R41.

- Chemical Book -
  - EU Risk Phrase R41

Ecotoxicity (Ecotox)

Acute Aquatic Toxicity (AA) Score (vH, H, M or L): H
Nonylphenol ethoxylates was assigned a score of **HIGH** for acute aquatic toxicity based on LC/EC_{50} values in the >1-10 range.

- US EPA 2012 -
  - Based on experimental LC_{50} values for NPE9 in the range of 1.0-14 ppm in fish, EC_{50} values for NPE9 in the range of 2.9-14.0 ppm in daphnia and an EC_{50} value for NPE9 of 12 ppm in green algae.

Chronic Aquatic Toxicity (CA) Score (vH, H, M or L): H
Nonylphenol ethoxylates was assigned a score of **HIGH** for chronic aquatic toxicity based on NOEC values in the >0.1-1.0 range.

- US EPA 2012 -
  - Based on an experimental NOEC of 1.0 ppm in fish and a NOEC of 10 ppm in daphnia in 7-day growth assays with NPE9.

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): M
Nonylphenol ethoxylates was assigned a score of **MODERATE** for persistence based on lack of ready biodegradability.

- US EPA 2012 -
  - Based on experimental data indicating that NPE9 does not pass standard ready biodegradability assays, reaching 31% in an OECD 30-day BOD test and 14-34% in an OECD modified Sturm test. Typical metabolites formed in aerobic biodegradation include nonylphenol and its lower-molecular weight ethoxylates (NPE1, NPE2) and ether-carboxylates (NPEC1, NPEC2). These have been found in STP effluents, sewage sludge and sediments, and can persist in the environment, especially under anaerobic conditions.

Bioaccumulation (B) Score (vH, H, M, L, or vL): DG
No data were found for bioaccumulation.

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M or L): L
Nonylphenol ethoxylates were assigned a score of **LOW** for reactivity based on a Chemwatch database classification of 1 and lack of classification as reactive in any regulatory codes.

Flammability (F) Score (vH, H, M or L): L
Nonylphenol ethoxylates was assigned a score of **LOW** for flammability based on being Not Classified per GHS.

- US EPA 2011 -
  - Flashpoint is 282°C, which places it in the Not Classified category per GHS.

References

Carolina International Sales Co., Inc. Material Safety Data Sheet: Nonylphenol Ethoxylate. http://www.ciscochem.com/msds/files/Nonylphenol_9.pdf

Chemical Book. http://www.chemicalbook.com/ChemicalProductProperty_EN_CB2719447.htm

Chemicals Evaluation and Research Institute. 2007. Hazard Assessment Report Poly (Oxyethylene) Nonylphenol Ether. Japan. http://www.cerij.or.jp/ceri_en/hazard_assessment_report/pdf/en_9016_45_9.pdf

Chemwatch. 2010. Chemical Database and Management Systems.

Clean Production Action. 2011. GreenScreen List Translator. http://www.cleanproduction.org/library/greenscreen-translator-benchmark1-possible%20benchmark1.pdf

European Chemicals Agency. Classification and Labelling Inventory: Nonylphenol Ethoxylates. http://clp-inventory.echa.europa.eu/SummaryOfClassAndLabelling.aspx?SubstanceID=123856&HarmOnly=no

US Environmental Protection Agency. 2006. Inert Reassessments: Four Exemptions from the Requirements for a Tolerance for Nonylphenol Ethoxylates. Washington D.C. http://www.epa.gov/opprd001/inerts/nonylpheny.pdf

US Environmental Protection Agency. 2012. DfE Alternatives Assessment for Nonylphenol Ethoxylates. Washington, D.C. http://www.epa.gov/dfe/pubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf

GreenScreen® Assessment for Nonylphenol *(CASRN 84852-15-3)*

GreenScreen® Version 1.2 Draft Assessment
Note: Validation Has Not Been Performed on this GreenScreen® Assessment

Chemical Name: 4-nonylphenol

GreenScreen® Assessment Prepared By:
Name: Eric Harrington
Title: Principal
Organization: Green Advantage Consultants
Date: 5/24/2013

Quality Control Performed By:
Name: NA
Title: NA
Organization: NA
Date: NA

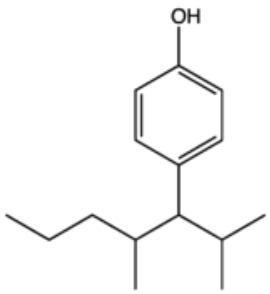
Confirm application of the *de minimus* rule: N/A

Chemical Name (CAS #): phenol, 4-nonyl-, branched (84852-15-3)

Also Called: nonylphenol

Chemical Surrogates, analogs or moieties used in this assessment (CAS #): None

Chemical Structure(s):

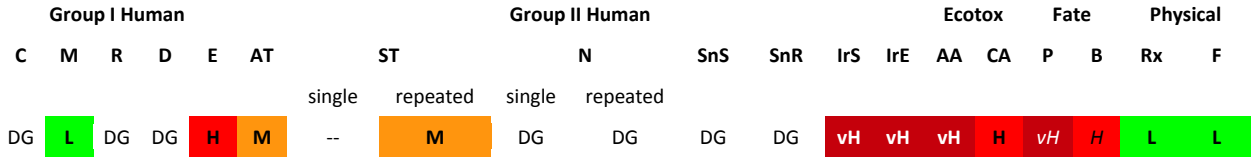


Notes related to production-specific attributes:
Nonylphenol (NP) is generally a mixture of various isomers, predominantly para-substituted nonylphenol (CASRN 84852-15-3), 4-nonylphenol (CASRN 104-40-5), and nonylphenol (CASRN 25154-52-3), with small amounts of ortho-substituted nonylphenol (CASRN 136-83-4), and traces of 2,4-dinonylphenol (CASRN 84962-08-3). There may be additional isomers representing the numerous branched structures within the nonyl group. As the US EPA alternatives assessment[5] evaluated the branched isomer of NPE, this assessment will evaluate the branched form (CASRN 84852-15-3) of NP (the degradation product of concern for that form of NPE).

Identify Applications/Functional Uses:
1. Reactant in surfactant manufacturing for cleaning products

Green Screen Rating: Nonylphenol was assigned a Draft Benchmark Score of **1** based on GreenScreen® benchmark classifications 1a, 1c, and 1e. Classification 1a - PBT - is met by the Very High value for Persistence combined with the High value for Endocrine Disruption. Classification 1c - vPT - is met by a

combination of Very High Persistence, Very High Aquatic Toxicity, and High Endocrine Disruption. Classification 1e - High T - is met by the High Endocrine Disruption score. Despite some data gaps, a Draft Benchmark Score of 1 may be assigned based on as few as one endpoint, as is the case with nonylphenol. As NP is being evaluated as a transformation product of NPE, NPE is also assigned a Draft Benchmark Score of 1.



Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance).
Note: See Appendix 2 for the hazard acronyms

Transformation Products and Ratings:

No data are available on transformation products of nonylphenol.

Hazard Classification Summary:

<u>Group I Human Health Effects (Group I Human)</u>

Carcinogenicity (C) Score (H, M or L): DG
No relevant data were available for nonylphenol for carcinogenicity.

Mutagenicity/Genotoxicity (M) Score (H, M or L): L
Nonylphenol was assigned a score of **LOW** for mutagenicity based on negative results in the Ames assay, in vitro chromosomal aberration assay, or in vivo micronucleus assay.

- US EPA 2009 -
  - The mutagenicity potential of p-nonylphenol was evaluated in vitro in S. typhimurium (TA 100, TA1535, TA98, TA 1538 and TA1537) and a mammalian cell line (V79 Chinese hamster cells) in the presence and absence of metabolic activation up to 500 µg/plate of test substance. No increases in mutation frequency were reported at any concentration tested with or without metabolic activation.
  - p-Nonylphenol was evaluated in an in vivo micronucleus test conducted with NMRI mice (5/sex/dose). A single dose of 500 mg/kg (maximum tolerated dose) was used. The test substance did not demonstrate any mutagenic potential in this in vivo system.

Reproductive Toxicity (R) Score (H, M, or L): DG
Existing data could not be evaluated to the extent that a conclusion (which requires a weight-of-evidence approach) could be reached.

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M or L): DG
Existing data could not be evaluated to the extent that a conclusion (which requires a weight-of-evidence approach) could be reached.

Endocrine Activity (E) Score (H, M or L): H

Nonylphenol was assigned a score of **High** for endocrine activity based on inclusion on the EU list of Substances of Very High Concern.

- ECHA 2012 -
  - 4-Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB and well-defined substances which include any of the individual isomers or a combination thereof] are identified as substances of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) because they are substances with endocrine-disrupting properties for which there is scientific evidence of probable serious effects to the environment which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH. This conclusion is based on the fact that there is strong evidence from high-quality studies of endocrine-mediated adverse effects in fish species. Results for amphibians provide indication that effects in other taxa may be endocrine-mediated, i.e. caused by an estrogen-like mode of action, too. According to the OECD (Organisation for Economic Cooperation and Development) guidance document for endocrine disruptors (OECD, 2012), 4-nonylphenols need to be considered as endocrine disruptors based on these results. Moreover, based on the widely-accepted IPCS definition for endocrine disruptors (WHO/IPCS, 2002; WHO: World Health Organization/IPCS: INSTITUTE OF PEACE & CONFLICT STUDIES), 4-nonylphenols are considered to be endocrine disruptors.

Group II and II* Human Health Effects (Group II and II* Human)

Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M or L): M

Nonylphenol was assigned a score of **Moderate** for acute mammalian toxicity based on test data indicating an oral LD_{50} value of 1880 mg/kg-bw.

- US EPA 2009 -
  - Acute oral toxicity LD_{50} is indicated as being 1880 mg/kg-bw, but the species and test protocol are not specified.

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)

Group II Score (single dose: vH, H, M or L); DG

No data were found for systemic toxicity/organ effects for single-dose studies.

Group II* Score (repeated dose: H, M, L): M

Nonylphenol was assigned a score of **Moderate** for systemic toxicity/organ effects based on repeated exposure in sub-chronic toxicity studies with rats. NOAEL was determined to be 50 mg/kg-bw/d, with the GreenScreen® criteria for Moderate classification being >10-100 mg/kg-bw/d.

- ECHA 2012 -
  - The NOAEL was determined to be 50 mg/kg-bw/d, based on a small decrease in body weight and food consumption in the 150 mg/kg-bw/d group.

Neurotoxicity (N)

Group II Score (single dose: vH, H, M or L): DG
No data were found for single-dose neurotoxicity.

Group II* Score (repeated dose: H, M, L): DG
No data were found for repeated dose neurotoxicity.

Skin Sensitization (SnS) Group II* Score (H, M or L): DG
Inconclusive data were found for skin sensitization.

- US EPA 2009 -
  - The results of several guinea pig maximization tests suggest that nonylphenol does not have significant skin sensitizing potential.
- Nordic Council of Ministers -
  - Three investigations using guinea pigs and different test protocols, two tests showed no skin sensitization, while the third concluded that the moderate degree of observed irritation indicated a sensitization potential. The source indicated that these conflicting data could not lead to a classification as a skin sensitizer or not.

Respiratory Sensitization (SnR) Group II* Score (H, M or L): DG
No relevant data were available for nonylphenol for respiratory sensitization.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M or L): vH
Nonylphenol was assigned a score of **Very High** for skin irritation/corrosivity based on classification as GHS Category 1B (per the SIN List), which places it in the Very High category per GreenScreen[?].

- US EPA 2009 -
  - Nonylphenol is listed as "highly irritating or corrosive".
- ChemSec -
  - Nonylphenol is listed as Skin Corrosion Category 1B.

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M or L): vH
Nonylphenol was assigned a score of **Very High** for eye irritation/corrosivity based on classification as GHS Category 1, which places it in the Very High category per GreenScreen®.

- US EPA 2009 -
  - Nonylphenol is listed as "highly irritating or corrosive".

Ecotoxicity (Ecotox)

Acute Aquatic Toxicity (AA) Score (vH, H, M or L): vH
Nonylphenol was assigned a score of **Very High** for acute aquatic toxicity based on GHS Classification of Acute 1.

- US EPA 2005 -
  - In freshwater studies, observed EC_{50} values for Daphnia magna ranged from 104-190 µg/l. Observed LC_{50} values for 3 trout species and two trout subspecies ranged from140-270 µg/l. Observed LC_{50} values for 9 threatened/endangered species or surrogates thereof ranged from 110-289 µg/l. Observed LC_{50} values for fathead minnow ranged from 128-360 µg/l, and for bluegill the value was 209 µg/l.
  - In saltwater studies, observed LC_{50} values for sheepshead minnows ranged from 142-310 µg/l, were 70 µg/l for inland silversides, and 17 µg/l for winter flounder.

Chronic Aquatic Toxicity (CA) Score (vH, H, M or L): H
Nonylphenol was assigned a score of **High** for chronic aquatic toxicity based on observed LC_{50} values (see Acute Aquatic Toxicity data summary above).

- US EPA 2005 -
  - See data summary above

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): *vH*
Nonylphenol was assigned a score of *Very High* for persistence based on estimates produced using the US EPA PBT Profiler tool. This was the most conservative score based on various sources of data and estimates.

- US EPA 2005 -
  - Observed half-lives in freshwater environments ranged from 16-20 days, which would place NP in the Moderate category.
- PBT Profiler -
  - The estimated half-life is 38 days in water, 75 days in soil, 340 days in sediment, and 0.31 days in air, resulting in classifications of Moderate, High, Very High, and Low, respectively. The most conservative classification would be Very High.

Bioaccumulation (B) Score (vH, H, M, L, or vL): *H*
Nonylphenol was assigned a score of *HIGH* for bioaccumulation based on a BCF of up to 2168, depending on the medium (fresh or salt water) and the species.

- US EPA 2005 -
  - In saltwater animals, BCF data ranged from 78.75 for caridean shrimp to 2168 for the common mussel. The latter value was estimated because steady-state tissue concentration was not reached during 16 days of exposure.

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M or L): L
Nonylphenol was assigned a score of **LOW** for reactivity based on a lack of reactivity alerts and DOT and UN transportation classifications.

- NOAA -
  - NP has no reactivity alerts and has a DOT Classification of Corrosive (UN Class 8), rather than a reactivity classification.

Flammability (F) Score (vH, H, M or L): L
Nonylphenol was assigned a score of **LOW** for flammability based on being unclassifiable per GHS. Materials that are unclassifiable per GHS are assigned a score of Low following GreenScreen® criteria (CPA 2011).

- NOAA -
  - NP has a flashpoint of 285° F (141° C), which makes it unclassifiable per GHS.

References

Clean Production Action. 2011. The GreenScreen® Guidance for Safer Chemicals v 1.2: Guidance for Hazard

Assessment and Benchmarking Chemicals. http://www.cleanproduction.org/library/greenScreenv1-2/DRAFT_GreenScreen_v1-2_Guidance_2011_1018_v2.pdf

European Chemicals Agency. 2012. Support document of Identification of 4-Nonylphenol, Branched and Linear. http://echa.europa.eu/documents/10162/16559221-1576-43d6-8306-228357265f34

International Chemical Secretariat ChemSec). 2013. SIN List Database. http://www.chemsec.org/what-we-do/sin-list/sin-database

Nordic Council of Ministers. 1993. Health Effects of Selected Chemicals, Volume 4. http://books.google.com/books?id=GC4fm8RPqdkC&pg=PA99&lpg=PA99&dq=nonylphenol+sensitization&source=bl&ots=Xnsab4v8ME&sig=Mowt73CUynezLiJLtswPZ8PGgWY&hl=en&sa=X&ei=A6efUdSmF6S3ygGk44DQBw&ved=0CDAQ6AEwAQ#v=onepage&q=nonylphenol%20sensitization&f=false

U.S. Environmental Protection Agency. 2005. Aquatic Life Ambient Water Quality Criteria - Nonylphenol FINAL. EPA-822-R-05-005. http://water.epa.gov/scitech/swguidance/standards/criteria/aqlife/nonylphenol/upload/2006_5_18_criteria_nonylphenol_final-doc.pdf

US Environmental Protection Agency. 2009. Screening-Level Hazard Characterization: Alkylphenols Category. http://www.epa.gov/chemrtk/hpvis/hazchar/Category_Alkylphenols_Sept2009.pdf

US Environmental Protection Agency. 2010. Nonylphenol (NP) and Nonylphenol Ethoxylates (NPE) Action Plan. http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/RIN2070-ZA09_NP-NPEs%20Action%20Plan_Final_2010-08-09.pdf.

U.S. Environmental Protection Agency. 2012. PBT Profiler. Version 2.000. http://www.pbtprofiler.net/

U.S. National Oceanic and Atmospheric Administration, Office of Response and Restoration. CAMEO Chemicals Database version 2.4. http://cameochemicals.noaa.gov/chemical/8914

GreenScreen® Assessment for Sorbitan Monostearate (1338-41-6)

GreenScreen® Version 1.2 Draft Assessment
Note: Validation Has Not Been Performed on this GreenScreen® Assessment

Chemical Name: Sorbitan Monostearate

GreenScreen® Assessment Prepared By:
Name: Eric Harrington
Title: Principal
Organization: Green Advantage Consultants
Date: 5/29/2013

Quality Control Performed By:
Name: NA
Title: NA
Organization: NA
Date: NA

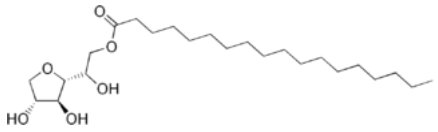
Confirm application of the *de minimus* rule: NA

Chemical Name (CAS #): Sorbitan Monostearate (1338-41-6)

Also Called: NA

Chemical Surrogates, analogs or moieties used in this assessment (CAS #): None

Chemical Structure(s):



Notes related to production specific attributes:

Identify Applications/Functional Uses:
1. Surfactant in cleaning products

Green Screen Rating: Sorbitan monostearate was assigned a Draft Benchmark Score of U based on not meeting the minimum data set requirements for or Group 1 Human Health or Group II Human Health endpoints.

Group I Human						Group II Human								Ecotox		Fate		Physical	
C	M	R	D	E	AT		ST		N		SnS	SnR	IrS	IrE	AA	CA	P	B	Rx	F
						single	repeated	single	repeated											
L	L	DG	DG	DG	L	DG	L	DG	DG		DG	DG	H	DG	H	H	L	*vL*	L	L

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance).

Transformation Products and Ratings:
US EPA found that no persistent degradates were formed, and thus did not evaluate ecotoxicity of degradates.[6] No additional data have been found.

Hazard Classification Summary Section:

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M or L): L
Sorbitan monostearate was assigned a score of **LOW** for carcinogenicity based on a lack of evidence for carcinogenicity potential.

- US NLM -
  - No evidence of carcinogenicity potential in rats and mice given sorbitan monostearate orally.

Mutagenicity/Genotoxicity (M) Score (H, M or L): L
Sorbitan monostearate was assigned a score of **LOW** for mutagenicity based on a lack of confirmed evidence.

- ACC -
  - Bacterial or mammalian gene mutation assays or *in vitro* chromosomal aberration assays showed any evidence of mutagenic or clastogenic activity, with or without metabolic activation.
- US EPA 2010 -
  - However, chromosomal aberrations were induced with the *in vitro* Chinese hamster lung cell assay. Without evidence of mutations in germ cells, the substance is classified as non-classifiable and thus of low hazard.

Reproductive Toxicity (R) Score (H, M, or L): DG
No data were found on reproductive toxicity.

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M or L): DG
No data were found on developmental toxicity.

Endocrine Activity (E) Score (H, M or L): DG
No data were found on endocrine activity.

Group II and II* Human Health Effects (Group II and II* Human)
Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M or L): L
Sorbitan monostearate was assigned a score of **LOW** for acute mammalian toxicity based on LD_{50} values in the >2000 mg/kg range.

- US EPA 2010 -
  - Wistar rats (10/sex) were administered a single dose of CASRN 1338-41-6 (purity not specified) via gavage at 15,900 mg/kg and observed for 14 days. No mortalities were observed. LD_{50} > 15,900 mg/kg. Dermal and inhalation toxicity data were not found.

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)

Group II Score (single dose: vH, H, M or L): DG
No data were found on system toxicity/organ effects - single dose.

Group II* Score (repeated dose: H, M, L): L
Sorbitan monostearate was assigned a score of **LOW** for systemic toxicity/organ effects based on repeated oral exposure with an NOAEL greater than 100 mg/kg-bw/d.

- US EPA 2010 -
  - An 80-week repeated-dose toxicity study with CASRN 1338-41-6 in mice showed enlarged kidneys and nephrosis following dietary exposure at 5200 mg/kg-bw/day; the NOAEL for systemic toxicity is 2600 mg/kg-bw/day. No effects on reproductive organs (testes, ovaries, uterus) were noted in these studies.

Neurotoxicity (N)
Group II Score (single dose: vH, H, M or L): DG
No data were found for neurotoxicity - single dose.

Group II* Score (repeated dose: H, M, L): DG
No data were found for neurotoxicity - repeated dose.

Skin Sensitization (SnS) Group II* Score (H, M or L): DG
No data were found for skin sensitization.

Respiratory Sensitization (SnR) Group II* Score (H, M or L): DG
No data were found for respiratory sensitization.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M or L): H
Sorbitan monostearate was assigned a score of **HIGH** for skin irritation/corrosivity based on the assignment of EU Risk Phrase R38.

- ChemicalBook -
  - EU Risk Phrase R38

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M or L): DG
No data were found for eye irritation/corrosivity.

<u>Ecotoxicity (Ecotox)</u>

Acute Aquatic Toxicity (AA) Score (vH, H, M or L): H
Sorbitan monostearate was assigned a score of **HIGH** for acute aquatic toxicity based on LC/EC_{50} values in the >1-10 range.

- US EPA 2012 -
  - Based on an experimental LC_{50} value of > 6.3 ppm in fish, an EC50 value of >13 ppm in daphnia and an EC_{50} value of >56 ppm in green algae.

Chronic Aquatic Toxicity (CA) Score (vH, H, M or L): H
Sorbitan monostearate was assigned a score of **HIGH** for chronic aquatic toxicity based on NOEC values in the >0.1-1.0 range.

- US EPA 2012 -

- Based on an experimental NOEC of 0.66 ppm in a 21-day reproduction study in daphnia.

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): L
Sorbitan monostearate was assigned a score of **LOW** for persistence based on significant biodegradation.

- US EPA 2012 -
  - Based on experimental data indicating that sorbitan monostearate achieves ≥ 75% biodegradation in 4 weeks as measured by BOD in the MITI test (OECD 301C). Information on the 10-day window was not available.

Bioaccumulation (B) Score (vH, H, M, L, or vL): *vL*
Sorbitan monostearate was assigned a score of **VERY LOW** for bioaccumulation based on BAF values in the <= 100 range, and log K_{ow} values estimated to be in the <= 4 range.

- US EPA 2010 -
  - BAF estimated at 27.5; log Kow estimated at 3.4

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M or L): L
Sorbitan monostearate was assigned a score of **LOW** for reactivity based on Chemwatch database classification of 1 and lack of classification as reactive in any regulatory codes.

Flammability (F) Score (vH, H, M or L): L
Sorbitan monostearate was assigned a score of **LOW** for flammability based on Chemwatch database classification of 1 and lack of classification as flammability in any regulatory codes.

References

American Chemistry Council; Aliphatic Esters Panel. 2003. High Production Volume (HPV) Chemical Challenge Program Test Plan for the Sorbitan Esters Category of the Aliphatic Esters Chemicals. http://www.epa.gov/hpv/pubs/summaries/alipestr/c13466rt2.pdf)

ChemicalBook. http://www.chemicalbook.com/ProductChemicalPropertiesCB2783774_EN.htm

Chemwatch. 2010. Chemical Database and Management Systems.

US Environmental Protection Agency. 2010. Screening Level Hazard Characterization: Sorbitan Esters Category. Washington D.C. http://www.epa.gov/chemrtk/hpvis/hazchar/Category_Sorbitan%20Esters_June%202010.pdf

US Environmental Protection Agency. 2012. DfE Alternatives Assessment for Nonylphenol Ethoxylates. Washington, D.C. http://www.epa.gov/dfe/pubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf

US National Library of Medicine. Hazardous Substances Data Bank. "Sorbitan Monostearate." http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~vmYDNw:1

GreenScreen® Assessment for Sodium Lauryl Sulfate (151-21-3)

GreenScreen® Version 1.2 Draft Assessment
Note: Validation Has Not Been Performed on this GreenScreen® Assessment

Chemical Name: Sodium lauryl sulfate

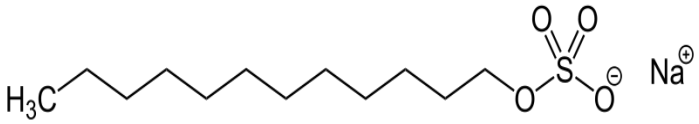
GreenScreen® Assessment Prepared By:
Name: Eric Harrington
Title: Principal
Organization: Green Advantage Consultants
Date: 5/29/2013

Quality Control Performed By:
Name: NA
Title: NA
Organization: NA
Date: NA

Confirm application of the *de minimus* rule: NA

Chemical Name (CAS #): Sodium lauryl sulfate (151-21-3)
Also Called: Sodium dodecyl sulfate

Chemical Surrogates, analogs or moieties used in this assessment (CASs #): None
Chemical Structure(s):



Notes related to production specific attributes: NA

Identify Applications/Functional Uses:
1. Surfactant in cleaning products

Green Screen Rating: Sodium lauryl sulfate was assigned a Draft Benchmark Score of 2 based on GreenScreen® Criterion 2f: Very High Eye Irritation.

Group I Human									Group II Human						Ecotox				Fate		Physical	
C	M	R	D	E	AT	ST			N		SnS	SnR	IrS	IrE	AA	CA	P	B	Rx		F	
						single	repeated		single	repeated												
L	L	L	L	DG	H	*M*	M		DG	DG	L	DG	H	vH	vH	H	vL	vL	L		H	

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance).

Transformation Products and Ratings:
AS compounds degrade via enzymatic cleavage of the ester, followed by oxidation of the resulting alcohol into the corresponding fatty acid, which is then ultimately biodegraded by β-oxidation. There is no indication of recalcitrant metabolites.[22]

a) [22] Human and Environmental Risk Assessment on Ingredients of European Household Cleaning Products. Alkyl Sulphates Environmental Risk Assessment. March 2002. http://www.heraproject.com/files/3-E-04-HERA%20AS%20Env%20web%20wd.pdf

Hazard Classification Summary Section:

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M or L): L
Sodium lauryl sulfate was assigned a score of **LOW** for carcinogenicity based on having adequate data available, negative studies, no structural alerts, and being Not Classified per GHS.

- US EPA 2009 -
  - There is no evidence that sodium lauryl sulfate is carcinogenic. While the full study reports are not available, summary data on two carcinogenicity studies with sodium (C12-C15) alkyl sulfate show no increase in tumor incidence, nor any impact on tumor type at levels up to up to 1.5% (highest dose tested) in the diet.

Mutagenicity/Genotoxicity (M) Score (H, M or L): L
Sodium lauryl sulfate was assigned a score of **LOW** for mutagenicity based on adequate data, negative studies, no structural alerts, and being Not Classified per GHS.

- Inchem -
  - Negative in Ames test (with and without metabolic activation), lymphoma cell forward mutation assay in mice (with and without metabolic activation), sister chromatid exchange in Chinese hamsters (with and without metabolic activation), and rat micronucleus assay.

Reproductive Toxicity (R) Score (H, M, or L): L
Sodium lauryl sulfate was assigned a score of **LOW** for reproductive toxicity based on adequate data, negative studies, no structural alerts, and being Not Classified per GHS.

- HERA -
  - The 2-generation reproductive study on the AOS (alpha olefin sulfonate – a structurally similar class of compounds) mixture showed a complete absence of treatment-related effects on reproductive capacity or systemic organ pathology at systemic doses ranging from 100-252 mg/kg/day based on food intake, similar to the NOELs in repeated dose studies on AS. The lack of reproductive organ toxicity in dietary, repeated dose studies on various AS surfactants, even at doses in excess of the NOELs, provides further corroboration for the absence of specific, surfactant-mediated effects on the reproductive organs. The comparable toxicokinetic and metabolic profiles of category surfactants, as well as their the toxicological similarities for this and other toxicological endpoints, support the conclusion that insights from the reproductive toxicity study on AOS are applicable to AS.

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M or L): L
Sodium lauryl sulfate was assigned a score of **LOW** for developmental toxicity based on adequate data, negative studies, no structural alerts, and being Not Classified per GHS.

- HERA -
  - Developmental toxicity studies have consistently shown that AS is without major skeletal or visceral effects on the developing foetus. In some studies there was evidence of slightly delayed foetal development, however this effect was observed only at dose levels inducing toxicity in the maternal animals. In the rat the lowest LOEL for maternal effects, based on depression of body weight and/or local irritation was *ca*. 300 mg/kg/day; for developmental effects NOELs were *ca*. 300 mg/kg/day.

Endocrine Activity (E) Score (H, M or L): DG
No data were found for endocrine activity.

Group II and II* Human Health Effects (Group II and II* Human)
Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M or L): H
Sodium lauryl sulfate was assigned a score of **HIGH** for acute mammalian toxicity based on being on the "GHS Japan Category 3 Acute Mammalian Toxicity" and "GHS New Zealand Category 3 Acute Mammalian Toxicity" lists per the GreenScreen® List Translator. In addition, LD_{50} data are found in the range of >50-300 mg/kg, placing them in the **HIGH** category.

- ESIS -
  - IUCLID data for oral LD_{50} range from 200-2800 mg/kg (HIGH). Dermal LD_{50} values range from 580-2000 mg/kg (MODERATE).

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)
Group II Score (single dose: vH, H, M or L): *M*
Sodium lauryl sulfate was assigned a score of *MODERATE* for systemic toxicity/organ effects based on single exposure based on being on the "GHS Japan Category 3 Systemic Toxicity Single Exposure" list per the GreenScreen® List Translator. No overriding data was found.

Group II* Score (repeated dose: H, M, L): M
Sodium lauryl sulfate was assigned as score of **MODERATE** for systemic toxicity/organ effects based on repeated doses based on NOAEL values in the range of >10-100 mg/kg-bw and higher.

- ESIS -
  - IUCLID data for oral NOAEL range from 100-2000 mg/kg.

Neurotoxicity (N)
Group II Score (single dose: vH, H, M or L): DG
No data were found for neurotoxicity - single dose.

Group II* Score (repeated dose: H, M, L): DG
No data were found for neurotoxicity - repeated dose.

Skin Sensitization (SnS) Group II* Score (H, M or L): L
Sodium lauryl sulfate was assigned a score of **LOW** for skin sensitization based on an exemption determination for tolerances.

- Federal Register -
  - Sodium lauryl sulfate is not a skin sensitizer.

Respiratory Sensitization (SnR) Group II* Score (H, M or L): DG
No data were found for respiratory sensitization.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M or L): H
Sodium lauryl sulfate was assigned a score of **HIGH** for skin irritation/corrosivity based on assignment of EU Risk Phrase R38.

- Chemtrade -
  - EU Risk Phrase R38

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M or L): vH
Sodium lauryl sulfate was assigned a score of **VERY HIGH** for eye irritation/corrosivity based on assignment of EU Risk Phrase R41.

- Chemtrade -
  - EU Risk Phrase R41

Ecotoxicity (Ecotox)

Acute Aquatic Toxicity (AA) Score (vH, H, M or L): vH
Sodium lauryl sulfate was assigned a score of **HIGH** for acute aquatic toxicity based on LC/EC_{50} values in the <=1 range.

- US EPA 2012 -
  - Based on experimental LC_{50} values ranging from 1.0-34.9 ppm in fish, EC_{50} values ranging from 1.8-49 ppm in daphnia and EC_{50} values ranging from 30-150 ppm in green algae.

Chronic Aquatic Toxicity (CA) Score (vH, H, M or L): H
Sodium lauryl sulfate was assigned a score of **HIGH** for chronic aquatic toxicity based on NOEC values in the >0.1-1.0 range.

- US EPA 2012 -
  - Based on an experimental NOEC of 0.75 ppm for blood effects in a 60-day chronic assay in fish, an experimental NOEC of 0.22 ppm in a 56-day chronic assay in invertebrates, and experimental NOEC values in the range of ≤ 0.1 – 50 ppm in 14-15-day chronic assays in green algae measuring cell count, growth rate and/or biomass. Note that in the two assays reporting a NOEC of 0.1 or ≤ 0.1 ppm, the lowest dose tested was 0.1 ppm, and the effect (increase in cell count) was reported at 0.5 ppm. Madsen, et al report a measured chronic NOEC of > 0.55 ppm for algae and HERA reports a lowest chronic value for algae of 12 ppm.

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): vL
Sodium lauryl sulfate was assigned a score of **VERY LOW** for persistence based on meeting the 10-day window criterion.

- US EPA 2012 -
  - Based upon experimental data indicating that this material achieves 60% or greater biodegradation as measured by oxygen uptake in assays similar to OECD 301C (MITI test) and meets the 10-day window criterion.

Bioaccumulation (B) Score (vH, H, M, L, or vL): vL
Sodium lauryl sulfate was assigned a score of **VERY LOW** for bioaccumulation based on log K_{ow} values less than or equal to 4.

- ECHA -
  - Measured log K_{ow} is <= -2.03. The available data indicates thatC12 alkyl sulfates have a very low potential for bioconcentration and the substance will not accumulate to significant levels in the aquatic environment.

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M or L): L
Sodium lauryl sulfate was assigned a score of **LOW** for reactivity due to a Chemwatch database classification of 1 for reactivity and lack of classification as reactive in any regulatory codes.

Flammability (F) Score (vH, H, M or L): H
Sodium lauryl sulfate was assigned a score of **HIGH** for flammability based on being Not Classified per GHS.

- Chemwatch
  - Classified as DOT Div 4.1 Flammable Solid, and as a readily-combustible solid which corresponds to GHS Category 1 or 2 (H or M).

References

Chemtrade International. 2007. Material Safety Data Sheet: Sodium Lauryl Sulfate. http://www.trade-chem.com/products/MSDS/SLS.pdf

Chemwatch. 2010. Chemical Database and Management Systems.

Clean Production Action. 2011. GreenScreen List Translator. http://www.cleanproduction.org/library/greenscreen-translator-benchmark1-possible%20benchmark1.pdf

European Chemicals Agency. Dossier: Sodium Dodecyl Sulfate. http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d80a3c6-17a5-3287-e044-00144f67d249/AGGR-3813feb3-6d8a-4909-9348-745b21d45580_DISS-9d80a3c6-17a5-3287-e044-00144f67d249.html#AGGR-3813feb3-6d8a-4909-9348-745b21d45580

European Chemical Substances Information System. IUCLID Data Set. http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/151213.pdf

HERA. 2002. Human and Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Alcohol Sulphates. Draft. http://www.heraproject.com/files/3-HH-04-%20HERA%20AS%20HH%20web%20wd.pdf

Inchem. SIDS Initial Assessment Profile, Sodium Dodecyl Sulfate. http://www.inchem.org/documents/sids/sids/151213.html

US Federal Register 74 FR 40503. 2009. Sodium Lauryl Sulfate: Exemption from the Requirement for a Tolerance. https://federalregister.gov/a/E9-19314

US Environmental Protection Agency. 2009. Sodium Lauryl Sulfate Human Health Risk Assessment. Washington, D.C. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0041-0004

US Environmental Protection Agency. 2012. DfE Alternatives Assessment for Nonylphenol Ethoxylates.

Washington, D.C. http://www.epa.gov/dfe/pubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf

GreenScreen® Assessment for Oxirane, Methyl-, Polymer with Oxirane, Mono(2-Ethylhexyl Ether) (64366-70-7)

GreenScreen® Version 1.2 Draft Assessment
Note: Validation Has Not Been Performed on this GreenScreen® Assessment

Chemical Name: Oxirane, Methyl-, Polymer with Oxirane, Mono(2-Ethylhexyl Ether)

GreenScreen® Assessment Prepared By:
Name: Eric Harrington
Title: Principal
Organization: Green Advantage Consultants
Date: 5/29/2013

Quality Control Performed By:
Name: NA
Title: NA
Organization: NA
Date: NA

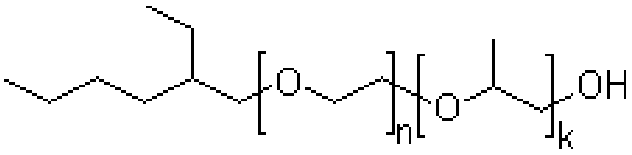
Confirm application of the *de minimus* rule: NA

Chemical Name (CAS #): Oxirane, Methyl-, Polymer with Oxirane, Mono(2-Ethylhexyl Ether) (64366-70-7)

Also Called: NA

Chemical Surrogates, analogs or moieties used in this assessment (CAS #): None

Chemical Structure(s):



Notes related to production specific attributes: NA

Identify Applications/Functional Uses:
1. Surfactant for cleaning products

Green Screen Rating: Oxirane, Methyl-, Polymer with Oxirane, Mono(2-Ethylhexyl Ether) was assigned a Draft Benchmark Score of U based on not meeting the minimum data set requirements for Group I Human Health, Group II Human Health, or Environmental Fate endpoints.

Group I Human								Group II Human							Ecotox			Fate		Physical	
C	M	R	D	E	AT	ST			N		SnS	SnR	IrS	IrE	AA	CA	P	B	Rx	F	
						single	repeated	single	repeated												
DG	DG	*DG*	*DG*	DG	DG	--	DG	*DG*	*DG*		*DG*	*DG*	DG	**vH**	**M**	*M*	**L**	**DG**	**L**	**L**	

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance).

Transformation Products and Ratings:
US EPA found that no persistent degradates were formed, and thus did not evaluate ecotoxicity of degradates.[5] No additional data have been found.

Hazard Classification Summary Section:

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M or L): DG
No data were found for carcinogenicity.

Mutagenicity/Genotoxicity (M) Score (H, M or L): DG
No data were found for mutagenicity/toxicity.

Reproductive Toxicity (R) Score (H, M, or L): DG
No data were found for reproductive toxicity.

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M or L): DG
No data were found for developmental toxicity.

Endocrine Activity (E) Score (H, M or L): DG
No data were found for endocrine activity.

Group II and II* Human Health Effects (Group II and II* Human)
Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M or L): DG
No data were found for acute mammalian toxicity.

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)
Group II Score (single dose: vH, H, M or L): DG
No data were found for systemic toxicity/organ effects - single dose.

Group II* Score (repeated dose: H, M, L): DG
No data were found for systemic toxicity/organ effects - repeated dose.

Neurotoxicity (N)
Group II Score (single dose: vH, H, M or L): DG
No data were found for neurotoxicity - single dose.

Group II* Score (repeated dose: H, M, L):
No data were found for neurotoxicity - repeated dose.

Skin Sensitization (SnS) Group II* Score (H, M or L): DG
No data were found for skin sensitization.

Respiratory Sensitization (SnR) Group II* Score (H, M or L): DG
No data were found for respiratory sensitization.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M or L): DG
No data were found for skin irritation/corrosivity.

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M or L): vH
Oxirane, Methyl-, Polymer with Oxirane, Mono(2-Ethylhexyl Ether) was assigned a score of **VERY HIGH** for eye irritation/corrosivity based on assignment of EU H-Phrase H318.

- ECHA -
  - EU H-Phrase H318

Ecotoxicity (Ecotox)

Acute Aquatic Toxicity (AA) Score (vH, H, M or L): M
Oxirane, Methyl-, Polymer with Oxirane, Mono(2-Ethylhexyl Ether) was assigned a score of **MODERATE** for acute aquatic toxicity based on EC_{50} values in the >10-100 range.

- US EPA -
  - Based upon an experimental 48-hr EC_{50} data of > 100 ppm in daphnia and a 72-hr EC_{50} in the range of 54-98 ppm in algae.

Chronic Aquatic Toxicity (CA) Score (vH, H, M or L): *M*
Oxirane, Methyl-, Polymer with Oxirane, Mono(2-Ethylhexyl Ether) was assigned a score of *MODERATE* for chronic aquatic toxicity based on estimated toxicity values 10% of acute values.

- US EPA -
  - Based upon the experimental acute toxicity data and expert judgment. In the absence of data, chronic toxicity values for nonionic surfactants are estimated to be 10% of the measured acute toxicity data (LC/EC_{50} values).

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): L
Oxirane, Methyl-, Polymer with Oxirane, Mono(2-Ethylhexyl Ether) was assigned a score of **LOW** for persistence based on significant biodegradability.

- US EPA -
  - Based upon experimental data indicating that this material achieves 60% or greater ThOD,/ThCO2 (> 70% DOC) biodegradation in an OECD 301F series assay, but without meeting the 10-day window criterion.

Bioaccumulation (B) Score (vH, H, M, L, or vL): DG
No data were found for bioaccumulation.

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M or L): L
Oxirane, Methyl-, Polymer with Oxirane, Mono(2-Ethylhexyl Ether) was assigned a score of **LOW** for reactivity due to a Chemwatch database classification of 1 for reactivity and lack of classification as

reactive in any regulatory codes.

Flammability (F) Score (vH, H, M or L): L

Oxirane, Methyl-, Polymer with Oxirane, Mono(2-Ethylhexyl Ether) was assigned a score of **LOW** for flammability due to a Chemwatch database classification of 1 for flammability and lack of classification as flammable in any regulatory codes.

References

Chemwatch. 2010. Chemical Database and Management Systems.

European Chemicals Agency. Classification and Labelling Inventory: Oxirane, Methyl-, Polymer with Oxirane, Mono(2-Ethylhexyl Ether). http://clp-inventory.echa.europa.eu/SummaryOfClassAndLabelling.aspx?SubstanceID=80723&HarmOnly=no?DisclaimerAgr=Agree&Index=68515-73-1&ExecuteSearch=true&fc=true&lang=en

US Environmental Protection Agency. 2012. DfE Alternatives Assessment for Nonylphenol Ethoxylates. Washington, D.C. http://www.epa.gov/dfe/pubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf

GreenScreen® Assessment for C12-15 Alcohols, Ethoxylated (9EO) (68131-39-5)

GreenScreen® Version 1.2 Draft Assessment
Note: Validation Has Not Been Performed on this GreenScreen® Assessment

Chemical Name: C12-15 Alcohols, Ethoxylated (9EO)

GreenScreen® Assessment Prepared By:
Name: Eric Harrington
Title: Principal
Organization: Green Advantage Consultants
Date: 5/29/2013

Quality Control Performed By:
Name: NA
Title: NA
Organization: NA
Date: NA

Confirm application of the *de minimus* rule: NA

Chemical Name (CAS #):C12-15 Alcohols, Ethoxylated (9EO) (68131-39-5)
Also Called: NA

Chemical Surrogates, analogs or moieties used in this assessment (CASs #): None

Chemical Structure(s):

$$CH_3\text{-}(CH2)_{n=12\text{-}15}\text{-}CH_2\text{-}(O\text{-}CH_2\text{-}CH_2)_9\text{-}OH$$

Notes related to production specific attributes: NA

Identify Applications/Functional Uses:
1. Surfactant in cleaning products

Green Screen Rating: C12-15 Alcohols, Ethoxylated (9EO) was assigned a Draft Benchmark Score of U based on not meeting the minimum data set requirements for Group I and Group II Human Health.

Group I Human									Group II Human						Ecotox				Fate		Physical	
C	M	R	D	E	AT	ST			N		SnS	SnR	IrS	IrE	AA	CA	P	B	Rx	F		
						single	repeated		single	repeated													
L	**L**	DG	DG	DG	**M**	DG	DG		DG	DG	**L**	DG	**H**	**vH**	**vH**	**H**	***vL***	**L**	**L**	**L**		

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance).

Transformation Products and Ratings:
A degradation mechanism similar to that for NPE is applicable to LAE; that is, stepwise removal of the ethylene oxide groups. However, unlike in the case of NPE and NP, with LAE, the alkyl portion of the parent alcohol can be simultaneously and completed degraded. Linear alcohol ethoxylates are hypothesized to initially degrade by central cleavage into either linear fatty alcohols, carboxylic fatty acids, polyethylene glycol (PEG), monocarboxylated PEG, or dicarboxylated PEG, or degrade by ω, β-oxidation of the alkyl chain into carboxylated alcohol ethoxylates with a carboxylic group on the alkyl chain, monocarboxylated PEG, or dicarboxylated PEG. PEG, the primary biodegradation intermediate, exhibits much lower toxicity than the parent surfactants (e.g. no toxicity in a sea urchin sperm cell toxicity test were observed at PEG concentrations of <200,000µg/L; Ghiradini et al., 2000).[5]

Hazard Classification Summary Section:

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M or L): L
C12-15 Alcohols, Ethoxylated (9EO) was assigned a score of **LOW** for carcinogenicity based on adequate data, negative studies, no structural alerts, and being Not Classified per GHS.

- HERA -
  - The available oral and dermal long term toxicity/carcinogenicity studies, even if not performed according to the accepted guidelines for carcinogenicity bioassays, appear to be scientifically well conducted and documented. On the basis of the information presented it can be concluded that alcohol ethoxylates are not carcinogenic. This assessment is further supported by the absence of any mutagenic or genotoxic activity of this compound class.

Mutagenicity/Genotoxicity (M) Score (H, M or L): L
C12-15 Alcohols, Ethoxylated (9EO) was assigned a score of **LOW** for mutagenicity based on adequate data, negative studies, no structural alerts, and being Not Classified per GHS.

- HERA -
  - In all available *in vitro* and *in vivo* genotoxicity assays, there was no indication of genetic toxicity of broad range of structurally different alcohol ethoxylates. Most of the studies were performed in accordance with GLP and following OECD guideline methodologies. The remaining *in vitro* and *in vivo* studies were well documented and conducted. The structure of alcohol ethoxylates are not of concern for potential genotoxicity. Based on the presented data, it is therefore concluded that there is no evidence that AEs are either mutagenic or genotoxic.

Reproductive Toxicity (R) Score (H, M, or L): L
No usable data were found for reproductive toxicity.

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M or L): DG
No usable data were found for developmental toxicity.

Endocrine Activity (E) Score (H, M or L): DG
No data were found for endocrine activity.

Group II and II* Human Health Effects (Group II and II* Human)
Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M or L): M
C12-15 Alcohols, Ethoxylated (9EO) was assigned a score of **MODERATE** for acute mammalian toxicity based on having LD_{50} values in the >100-2000 mg/kg range.

- HERA -
  - Acute oral toxicity of alcohol ethoxylates has been extensively evaluated in numerous studies with rats, but also with dogs and monkeys. The oral LD_{50} values for rats were found

to range from 600 mg/kg to more than 10,000 mg/kg. Values for other animals were in the same range. Alcohol ethoxylates were shown to have a low order of acute dermal toxicity in the rat and rabbit with LD_{50} values typically greater than the maximum applied dose, ranging from greater than 0.8 to greater than 5 g/kg in rats. LD_{50} values in rabbits were greater than 2 g/kg but less than 5 g/kg.

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)
Group II Score (single dose: vH, H, M or L): DG
No data were found for systemic toxicity/organ effects - single dose

Group II* Score (repeated dose: H, M, L): DG
No data were found for systemic toxicity/organ effects - repeated dose.

Neurotoxicity (N)
Group II Score (single dose: vH, H, M or L): DG
No data were found for neurotoxicity - single dose.

Group II* Score (repeated dose: H, M, L): DG
No data were found for neurotoxicity - repeated dose.

Skin Sensitization (SnS) Group II* Score (H, M or L): L
C12-15 Alcohols, Ethoxylated (9EO) was assigned a score of **LOW** for skin sensitization based on adequate data with negative results, no structural alerts, and being Not Classified per GHS.

- HERA -
  - Based on a weight of evidence approach and considering quality criteria in evaluating the studies, alcohol ethoxylates are not considered to be skin sensitizers.

Respiratory Sensitization (SnR) Group II* Score (H, M or L): DG
No data were found for respiratory sensitization.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M or L): H
C12-15 Alcohols, Ethoxylated (9EO) was assigned a score of **HIGH** for skin irritation/corrosivity based on being classified as GHS Category 2.

- BASF -
  - GHS Category 2

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M or L): vH
C12-15 Alcohols, Ethoxylated (9EO) was assigned a score of **VERY HIGH** for eye irritation/corrosivity based on being classified as GHS Category 1.

- BASF -
  - GHS Category 1

<u>Ecotoxicity (Ecotox)</u>

Acute Aquatic Toxicity (AA) Score (vH, H, M or L): vH
C12-15 Alcohols, Ethoxylated (9EO) was assigned a score of **VERY HIGH** for acute aquatic toxicity based on LC/EC_{50} values in the <=1 ppm range.

- US EPA 2012 -
    - Based on experimental LC_{50} values ranging from 1.2-11.0 ppm in fish, EC_{50} values ranging from 1.3-1.6 ppm in daphnia and an EC_{50} value of 0.70 ppm in green algae.

Chronic Aquatic Toxicity (CA) Score (vH, H, M or L): H
C12-15 Alcohols, Ethoxylated (9EO) was assigned a score of **HIGH** for chronic aquatic toxicity based on NOEC values in the >0.1-1.0 ppm range.

- US EPA 2012 -
    - Based on an experimental NOEC of 0.4 ppm in fish and an experimental NOEC of 1.0 ppm in daphnia, measured in 7-day growth assays with C12-15 alcohols, ethoxylated (EO9).

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): vL
C12-15 Alcohols, Ethoxylated (9EO) was assigned a score of **VERY LOW** for persistence based on meeting the 10-day window criterion.

- US EPA 2012 -
    - Based on experimental data indicating that this compound passes standard ready biodegradation tests. In addition, biodegradation information for C12-15 alcohols, ethoxylated (7EO and 9EO) are reported in the CleanGredients® Database indicating that these materials meet the 10-day window criterion in OECD 301-series tests. Persistent biodegradation products are not formed.

Bioaccumulation (B) Score (vH, H, M, L, or vL): L
C12-15 Alcohols, Ethoxylated (9EO) was assigned a score of **LOW** for bioaccumulation based on BCF values in the >100-500 range.

- HERA -
    - Maximum BCF estimated to be less than 387.5; minimum BCF estimated to be less than 12.7, which would be in the very low-low range. Log K_{ow} is estimated to be 4.43-6.05, which would result in a score of Moderate. However, log K_{ow} is difficult to measure for surfactants, as surfactants will be located preferentially at the interface(s) in an oil/water system. This must be remembered whenever log K_{ow} data are used for surfactants. BCF data should carry a higher weight-of-evidence rating.

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M or L): L
C12-15 Alcohols, Ethoxylated (9EO) was assigned a score of **LOW** for reactivity due to a Chemwatch database classification of 1 for reactivity and lack of classification as reactive in any regulatory codes.

Flammability (F) Score (vH, H, M or L): L
C12-15 Alcohols, Ethoxylated (9EO) was assigned a score of **LOW** for flammability based on being Not Classified per GHS.

- Air Products -
    - Flashpoint = 188°C; not classifiable per GHS

References

Air Products. 2011. Material Safety Data Sheet: Tomadol 25-9 Surfactant. https://apdirect.airproducts.com/msds/DisplayPDF.aspx?docid=73338.

BASF. 2011. Safety Data Sheet: Masai. (http://www.agricentre.basf.co.uk/agroportal/uk/media/product_files_uk/safety_data_sheets/Masai_MSDS.pdf)

Chemwatch. 2010. Chemical Database and Management Systems.

HERA. 2007. HERA Human and Environmental Risk Assessment on Ingredients of European Household Cleaning Products, Alcohol Ethoxylates, Version 1.0. http://www.heraproject.com/files/34-F-09%20HERA%20AE%20Report%20Version%202%20-%203%20Sept%2009.pdf

US Environmental Protection Agency. 2012. DfE Alternatives Assessment for Nonylphenol Ethoxylates. Washington, D.C. http://www.epa.gov/dfe/pubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf

GreenScreen® Assessment for Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt (68411-30-3)

GreenScreen® Version 1.2 Draft Assessment
Note: Validation Has Not Been Performed on this GreenScreen® Assessment

Chemical Name: Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt

GreenScreen® Assessment Prepared By:
Name: Eric Harrington
Title: Principal
Organization: Green Advantage Consultants
Date: 5/29/2013

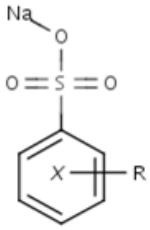
Quality Control Performed By:
Name: NA
Title: NA
Organization: NA
Date: NA

Confirm application of the *de minimus* rule: NA

Chemical Name (CAS #): Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt (68411-30-3)

Also Called: NA

Chemical Surrogates, analogs or moieties used in this assessment (CASs #): None
Chemical Structure(s):



Notes related to production specific attributes: NA

Identify Applications/Functional Uses:
1. Surfactant in cleaning products

Green Screen Rating: Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt was assigned a Draft Benchmark Score of 2_{DG} based on GreenScreen® Criterion 3b: Moderate (or High) Ecotoxicity (Acute and Chronic Aquatic Toxicity); Criterion 3c: Moderate (or High) Group II Human Toxicity (Eye and Skin Irritation), but not meeting the minimum data requirements for Group I or II Human Health.

Group I Human										Group II Human						Ecotox		Fate		Physical	
C	M	R	D	E	AT	ST				N		SnS	SnR	IrS	IrE	AA	CA	P	B	Rx	F
						single	repeated	single	repeated												
L	L	DG	DG	L	M	DG	DG	DG	DG	L	DG	H	H	H	H	vL	L	L	L		

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance).

Transformation Products and Ratings:
Primary biodegradation of LAS results in the formation of sulfophenyl carboxylates (SPCs) as intermediates, with a corresponding loss of aquatic toxicity. Further biodegradation involves cleavage of the aromatic ring and the complete conversion of LAS and SPCs into inorganic substances. SPCs are not persistent and have toxicities lower than that of the LAS by several orders of magnitude.[23]

Hazard Classification Summary Section:

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M or L): L
Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt was assigned a score of **LOW** for carcinogenicity based on adequate studies with negative evidence, no structural alerts, and being Not Classified per GHS.

- HERA -
  - Even though the studies are old and were not performed and/or evaluated according to GLP and current requirements (number of animals, doses, scope of investigations) the information that they provide is still useful. All the studies were well conducted according to common practice at the time and toxicity was observed at the higher dose tested in some of the studies. All of the studies consistently showed lack of evidence of carcinogenicity in all species tested (rats and mice). There is no reason to believe that LAS has a carcinogenic potential.

Mutagenicity/Genotoxicity (M) Score (H, M or L): L
Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt was assigned a score of **LOW** for mutagenicity based on adequate studies with negative evidence, no structural alerts, and being Not Classified per GHS.

- HERA -
  - There is no indication of genetic toxicity for LAS in any of the in vitro assays. The results of the in vivo test systems were consistent with the results of the in vitro assays. LAS was tested in cytogenetic assays in rat and mouse, in a dominant lethal assay in rat, and in two micronucleus tests in mice. None of these tests indicated any genetic toxicity of the test compound in vivo. Substance is thus not classified per GHS.

Reproductive Toxicity (R) Score (H, M, or L): DG
No data was found for reproductive toxicity.

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M or L): DG
No data was found for developmental toxicity.

Endocrine Activity (E) Score (H, M or L): L
Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt was assigned a score of **LOW** for endocrine activity based on adequate studies with negative results and no structural alerts.

- CleanGredients -
  - Neither LAS nor its sulfophenylcarboxylate biodegradation intermediates displayed

estrogenic activity in two in vitro assays.

Group II and II* Human Health Effects (Group II and II* Human)

Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M or L): M

Benzenesulfonic Acid, C10-13 Alkyl Derivs, Sodium Salt was assigned a score of **MODERATE** for acute mammalian toxicity based on being on the "GHS New Zealand Category 4 Acute Mammalian Toxicity" list per the GreenScreen® List Translator. In addition, IUCLID data also place this compound in the >300-2000 mg/kg range (**MODERATE**).

- ESIS -
  - IUCLID data for oral LD_{50} range from 650-4700 mg/kg (**MODERATE**).

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)

Group II Score (single dose: vH, H, M or L): DG

No data were found for systemic toxicity/organ effects - single dose.

Group II* Score (repeated dose: H, M, L): DG

No data were found for systemic toxicity/organ effects - repeated dose.

Neurotoxicity (N)

Group II Score (single dose: vH, H, M or L): DG

No data were found for neurotoxicity - single dose.

Group II* Score (repeated dose: H, M, L): DG

No data were found for neurotoxicity - repeated dose.

Skin Sensitization (SnS) Group II* Score (H, M or L): L

Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt was assigned a score of **LOW** for skin sensitization based on HPV data indicating that it is not a sensitizer.

- Soap and Detergent Association -
  - Not sensitizer per US EPA HPV data

Respiratory Sensitization (SnR) Group II* Score (H, M or L): DG

No data were found for respiratory sensitization.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M or L): H

Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt was assigned a score of **HIGH** for skin irritation/corrosivity based on HPV data indicating that it is irritating to the skin, corresponding to EU GHS Category 2.

- Soap and Detergent Association -
  - Irritating to skin per US EPA HPV data; corresponds to EU GHS Category 2

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M or L): H

Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt was assigned a score of **HIGH** for eye irritation/corrosivity based on HPV data indicating that it is irritating to the eyes, corresponding to EU GHS Category 2A.

- Soap and Detergent Association -
  - irritating to eyes per US EPA HPV data; corresponds to EU GHS Category 2A

Ecotoxicity (Ecotox)

Acute Aquatic Toxicity (AA) Score (vH, H, M or L): H
Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt was assigned a score of **HIGH** for acute aquatic toxicity based on LC/EC_{50} values in the >1-10 ppm range.

- US EPA 2012 -
  - Based on experimental 96-hr LC_{50} values in the range of 1.7-7.8 ppm in fish, 48-hr EC_{50} values in the range of 1.62-9.3 ppm in daphnia, and 72-hr and 96-hr EC_{50} values in the range of 4.2-127 ppm for algae.

Chronic Aquatic Toxicity (CA) Score (vH, H, M or L): H
Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt was assigned a score of **HIGH** for chronic aquatic toxicity based on NOEC values in the >0.1-1.0 ppm range.

- US EPA 2012 -
  - Based on experimental NOECs in the of 0.15-2.0 mg/L for 14-196-day chronic toxicity tests in fish, experimental NOECs in the range of 0.3-3.25 mg/L in 21-day reproduction tests in daphnia, and experimental NOECs of 0.1-3.1 mg/L for 72-hr and 15-day chronic toxicity tests in algae.

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): vL
Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt was assigned a score of **VERY LOW** for persistence based on meeting the 10-day window criterion.

- US EPA 2012 -
  - Based upon experimental data indicating that the C10-13 alkyl derivative achieves 94% biodegradation in a DOC-Die away test, that the dodecyl alkyl derivative achieves 69% in an OECD 301-B test and that this compound (C10-13 sodium salt) achieves 93-95% after 28 days in a DOC-Die away test that meets the 10-day window criterion.

Bioaccumulation (B) Score (vH, H, M, L, or vL): L
Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt was assigned a score of **LOW** for bioaccumulation based on a BCF value in the >100-500 range.

- Soap and Detergent Association -
  - BCF = 104

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M or L): L
Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt was assigned a score of **LOW** for reactivity due to a Chemwatch database classification of 1 for reactivity and lack of classification as reactive in any

regulatory codes.

Flammability (F) Score (vH, H, M or L): L
Benzenesulfonic Acid, C10-13 Alkyl Derivs., Sodium Salt was assigned a score of **LOW** for flammability due to a Chemwatch database classification of 1 for flammability and lack of classification as flammable in any regulatory codes.

References

HERA. 2009. Human and Environmental Risk Assessment on Ingredients of European Household Cleaning Products, LAS, Linear Alkylbenzene Sulphonate, Version 4.0. http://www.heraproject.com/files/48-F-HERA_LAS_Report_(Version_4_-_June_09).pdf

Chemwatch. 2010. Chemical Database and Management Systems.

CleanGredients. "General Ingredient Information: LAS." http://www.cler.com/news/20070129LASCleanGredientlisting.pdf

Clean Production Action. 2011. GreenScreen List Translator. http://www.cleanproduction.org/library/greenscreen-translator-benchmark1-possible%20benchmark1.pdf

European Chemical Substances Information System. IUCLID Data Set. http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/68411303.pdf

The Soap and Detergent Association; Linear Alkylbenzene Sulfonate (LAS)/Alkylbenzene Sulfonate Consortium. 2008. High Production Volume (HPV) Chemical Challenge Program: Final Revised Test Plan and Assessment with Robust Study Summaries for Linear and Branched Alkylbenzene Sulfonic Acids and Derivatives, Part II: Robust Study Summaries for LAS/ABS Category. http://www.epa.gov/hpv/pubs/summaries/alkybenz/c14187rr.pdf

US Environmental Protection Agency. 2012. DfE Alternatives Assessment for Nonylphenol Ethoxylates. Washington, D.C. http://www.epa.gov/dfe/pubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf

GreenScreen® Assessment for C9-11 Alcohols, Ethoxylated (6EO) (68439-46-3)

GreenScreen® Version 1.2 Draft Assessment
Note: Validation Has Not Been Performed on this GreenScreen® Assessment

Chemical Name: C9-11 Alcohols, Ethoxylated (6EO)

GreenScreen® Assessment Prepared By:
Name: Eric Harrington
Title: Principal
Organization: Green Advantage Consultants
Date: 5/29/2013

Quality Control Performed By:
Name: NA
Title: NA
Organization: NA
Date: NA

Confirm application of the *de minimus* rule: NA

Chemical Name (CAS #): C9-11 Alcohols, Ethoxylated (6EO) (68439-46-3)
Also Called: NA

Chemical Surrogates, analogs or moieties used in this assessment (CASs #): None

Chemical Structure(s):

$$CH_3\text{-}(CH2)_{n=9\text{-}11}\text{-}CH_2\text{-}(O\text{-}CH_2\text{-}CH_2)_6\text{-}OH$$

Notes related to production specific attributes: NA

Identify Applications/Functional Uses:
1. Surfactant in cleaning products

Green Screen Rating: C9-11 Alcohols, Ethoxylated (6EO) was assigned a Draft Benchmark Score of U based on not meeting the minimum data set requirements for Group II Human Health and Environmental Fate endpoints.

Group I Human						Group II Human										Ecotox		Fate		Physical	
C	M	R	D	E	AT	ST				N		SnS	SnR	IrS	IrE	AA	CA	P	B	Rx	F
						single	repeated	single	repeated												
L	L	L	DG	DG	*M*	DG	DG	DG	DG	L	DG	H	vH	H	H	vL	DG	L	L		

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance).

Transformation Products and Ratings:
A degradation mechanism similar to that for NPE is applicable to LAE; that is, stepwise removal of the ethylene oxide groups. However, unlike in the case of NPE and NP, with LAE, the alkyl portion of the parent alcohol can be simultaneously and completed degraded. Linear alcohol ethoxylates are hypothesized to initially degrade by central cleavage into either linear fatty alcohols, carboxylic fatty acids, polyethylene glycol (PEG), monocarboxylated PEG, or dicarboxylated PEG, or degrade by ω, β-oxidation of the alkyl chain into carboxylated alcohol ethoxylates with a carboxylic group on the alkyl chain, monocarboxylated PEG, or dicarboxylated PEG. PEG, the primary biodegradation intermediate, exhibits much lower toxicity than the parent surfactants (e.g. no toxicity in a sea urchin

sperm cell toxicity test were observed at PEG concentrations of <200,000µg/L; Ghiradini et al., 2000).

Hazard Classification Summary Section:

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M or L): L
C9-11 Alcohols, Ethoxylated (6EO) was assigned a score of **LOW** for carcinogenicity based on adequate studies with negative results, no structural alerts, and being Not Classified per GHS.

- HERA -
  - The available oral and dermal long term toxicity/carcinogenicity studies, even if not performed according to the accepted guidelines for carcinogenicity bioassays, appear to be scientifically well conducted and documented. On the basis of the information presented it can be concluded that alcohol ethoxylates are not carcinogenic. This assessment is further supported by the absence of any mutagenic or genotoxic activity of this compound class.

Mutagenicity/Genotoxicity (M) Score (H, M or L): L
C9-11 Alcohols, Ethoxylated (6EO) was assigned a score of **LOW** for mutagenicity based on adequate studies with negative results, no structural alerts, and being Not Classified per GHS.

- HERA -
  - In all available *in vitro* and *in vivo* genotoxicity assays, there was no indication of genetic toxicity of broad range of structurally different alcohol ethoxylates. Most of the studies were performed in accordance with GLP and following OECD guideline methodologies. The remaining *in vitro* and *in vivo* studies were well documented and conducted. The structure of alcohol ethoxylates are not of concern for potential genotoxicity. Based on the presented data, it is therefore concluded that there is no evidence that AEs are either mutagenic or genotoxic.

Reproductive Toxicity (R) Score (H, M, or L): L
C9-11 Alcohols, Ethoxylated (6EO) was assigned a score of **LOW** for reproductive toxicity based on adequate studies with adequate negative data, no structural alerts, and being Not Classified per GHS.

- HERA -
  - There was only limited information on reproductive toxicity available. Two oral and one dermal study of AEs were identified. The oral studies were not performed in accordance with GLP or OECD protocol. However, the studies were judged to be of good quality and reliable. The presented information indicates that the investigated AEs did not cause reproductive toxicity when applied orally or dermally and the NOAEL for reproductive toxicity is greater than 250 mg/kg bw/d for selected AEs.

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M or L): DG
No data were found for developmental toxicity.

Endocrine Activity (E) Score (H, M or L): DG
No data were found for endocrine activity.

Group II and II* Human Health Effects (Group II and II* Human)
Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic

Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M or L): *M*
C9-11 Alcohols, Ethoxylated (6EO) was assigned a score of *MODERATE* for acute mammalian toxicity based on being on the "GHS New Zealand Category 4 Acute Mammalian Toxicity" list per the GreenScreen® List Translator. No more specific data were found.

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)
Group II Score (single dose: vH, H, M or L): DG
No data were found for systemic toxicity/organ effects - single dose.

Group II* Score (repeated dose: H, M, L): DG
No data were found for systemic toxicity/organ effects - repeated dose.

Neurotoxicity (N)
Group II Score (single dose: vH, H, M or L): DG
No data were found for neurotoxicity - single dose.

Group II* Score (repeated dose: H, M, L): DG
No data were found for neurotoxicity - repeated dose.

Skin Sensitization (SnS) Group II* Score (H, M or L): L
C9-11 Alcohols, Ethoxylated (6EO) was assigned a score of **LOW** for skin sensitization based on adequate data and negative results, no structural alerts, and being Not Classified per GHS.

- HERA -
  - Based on a weight of evidence approach and considering quality criteria in evaluating the studies, alcohol ethoxylates are not considered to be skin sensitizers.

Respiratory Sensitization (SnR) Group II* Score (H, M or L): DG
No data were found for respiratory sensitization.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M or L): H
C9-11 Alcohols, Ethoxylated (6EO) was assigned a score of HIGH for skin irritation/corrosivity based on assignment of EU H-Phrase H315.

- ECHA
  - H-Phrase H315 "Causes skin irritation"

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M or L): vH
C9-11 Alcohols, Ethoxylated (6EO) was assigned a score of VERY HIGH for eye irritation/corrosivity based on assignment of EU H-Phrase H318.

- ECHA -
  - H-Phrase H318 "Causes serious eye damage"

<u>Ecotoxicity (Ecotox)</u>

Acute Aquatic Toxicity (AA) Score (vH, H, M or L): H
C9-11 Alcohols, Ethoxylated (6EO) was assigned a score of **HIGH** for acute aquatic toxicity based on LC/EC_{50} values in the >1-10 ppm range.

- US EPA 2012 -
  - Based on experimental LC_{50} values ranging from 1.6-2 mg/L for C11EO5 to 8-9 mg/L for C9-11EO5 in fish; 5.4-14 mg/L for C9-11EO6 in invertebrates; and 2.9-3.5 mg/L for C11EO5 in algae.

Chronic Aquatic Toxicity (CA) Score (vH, H, M or L): H
C9-11 Alcohols, Ethoxylated (6EO) was assigned a score of **HIGH** for chronic aquatic toxicity based on NOEC values in the >0.1-1.0 ppm range.

- US EPA 2012 -
  - Based on an measured NOECs in juvenile fish of 1.0-4.4 mg/L (survival), 0.73 mg/L (reproduction) and 1.0 mg/L (growth) for C9-11 EO6; and a LOEC of > 2.0 mg/L in algae, measured in a 7-day reproduction study with C9-11EO6.

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): vL
C9-11 Alcohols, Ethoxylated (6EO) was assigned a score of **VERY LOW** for persistence based on meeting the 10-day window criterion.

- US EPA 2012 -
  - Based on experimental data indicating that this compound passes standard ready biodegradation tests. C9-11EO8 consumed 80% ThOD in 28 days in a closed bottle test, and C10-12 EO6 released 83% ThCO2 in the OECD 301B assay. Persistent biodegradation products are not formed. C9-11EO6 is also reported to pass several OECD 301-series tests, consistently meeting the 10-day window criterion.

Bioaccumulation (B) Score (vH, H, M, L, or vL): DG
No data were found for bioaccumulation.

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M or L): L
C9-11 Alcohols, Ethoxylated (6EO) was assigned a score of **LOW** for reactivity due to a Chemwatch database classification of 1 for reactivity and lack of classification as reactive in any regulatory codes.

Flammability (F) Score (vH, H, M or L): L
C9-11 Alcohols, Ethoxylated (6EO) was assigned a score of **LOW** for flammability based on being Not Classifiable per GHS.

- Air Products -
  - Flashpoint = 142.7°C, Not Classifiable per GHS[d]

References

Air Products. 2011. Material Safety Data Sheet: Tomadol 91-6 Surfactant. https://apdirect.airproducts.com/msds/DisplayPDF.aspx?docid=63165.

Chemwatch. 2010. Chemical Database and Management Systems.

Clean Production Action. 2011. GreenScreen List Translator. http://www.cleanproduction.org/library/greenscreen-translator-benchmark1-possible%20benchmark1.pdf

ECHA. Classification and Labelling Inventory. http://clp-inventory.echa.europa.eu/SummaryOfClassAndLabelling.aspx?SubstanceID=29510&HarmOnly=no?DisclaimerAgr=Agree&Index=68515-73-1&ExecuteSearch=true&fc=true&lang=en

HERA. 2007. Human and Environmental Risk Assessment on Ingredients of European Household Cleaning Products, Alcohol Ethoxylates, Version 1.0. http://www.heraproject.com/files/34-F-09%20HERA%20AE%20Report%20Version%202%20-%203%20Sept%2009.pdf

US Environmental Protection Agency. 2012. DfE Alternatives Assessment for Nonylphenol Ethoxylates. Washington, D.C. http://www.epa.gov/dfe/pubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf

GreenScreen® Assessment for D-Glucopyranose, Oligomeric, Decyloctyl Glycosides (68515-73-1)

GreenScreen® Version 1.2 Draft Assessment
Note: Validation Has Not Been Performed on this GreenScreen® Assessment

Chemical Name: D-Glucopyranose, Oligomeric, Decyloctyl Glycosides

GreenScreen® Assessment Prepared By:
Name: Eric Harrington
Title: Principal
Organization: Green Advantage Consultants
Date: 5/29/2013

Quality Control Performed By:
Name: NA
Title: NA
Organization: NA
Date: NA

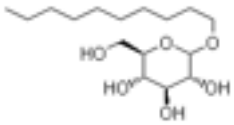
Confirm application of the *de minimus* rule: NA

Chemical Name (CAS #): D-Glucopyranose, Oligomeric, Decyloctyl Glycosides (68515-73-1)

Also Called: NA

Chemical Surrogates, analogs or moieties used in this assessment (CAS #): None

Chemical Structure(s):



Notes related to production specific attributes: NA

Identify Applications/Functional Uses:
1. Surfactant in cleaning product

Green Screen Rating: D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a Draft Benchmark Score of 2_{DG} based on GreenScreen® Criterion 3b: Moderate (or High) Ecotoxicity (Acute and Chronic Aquatic Toxicity); Criterion 3c Moderate (or High) Group II Human Toxicity (Eye Irritation), but not meeting the minimum data requirements for Group I or II Human Health.

Group I Human									Group II Human						Ecotox		Fate		Physical	
C	M	R	D	E	AT	ST			N		SnS	SnR	IrS	IrE	AA	CA	P	B	Rx	F
						single	repeated		single	repeated										
DG	**L**	**L**	**L**	DG	**L**	DG	**L**		DG	DG	**L**	DG	**H**	**vH**	**M**	**M**	**vL**	*L*	**L**	**L**

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance).

Transformation Products and Ratings:
US EPA found that no persistent degradates were formed, and thus did not evaluate ecotoxicity of degradates.[5] No additional data have been found.

Hazard Classification Summary Section:

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M or L): DG
No data were found for carcinogenicity.

Mutagenicity/Genotoxicity (M) Score (H, M or L): L
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **LOW** for mutagenicity based on adequate data with negative results, no structural alerts, and being Not Classified per GHS.

- EAS Consulting Group -
    - C12-16 alkyl polyglycoside was tested on Salmonella typhimurium TA 98, TA 100, TA 1535, TA 1537 and TA 1538 in two independent experiments, both with and without S9 mix metabolic activation according to the OECD guideline 471. Compared with concurrent negative controls, no precipitations or enhanced revertant rates were observed in all strains tested in the presence or absence of metabolic activation. C12-16 Alkyl Polyglycoside did not induce reverse mutations and were not mutagenic in this test system. Cultured Chinese hamster V79 lung fibroblasts were exposed repeatedly to C12-16 alkyl polyglycosides every 4 hours per OECD Guideline No. 473 (EU Guideline B10). No biological effects, with respect to aberration induction, were observed at any time, either with or without S9 activation. It was concluded that C12-16 Alkyl Polyglycosides were not clastogenic under the conditions of the test design. Based on the fact that different alkyl polyglycosides show the same metabolic pathway resulting in the occurrence of sugar and different fatty alcohols (in this case C8 to C16 alcohol), these fatty alcohols can be seen as a category with comparable toxicological properties with regard to chromosome aberration. Therefore, alkyl polyglycosides can be considered as a group with regard to toxicological properties. As a consequence, results from the chromosome aberration study obtained with C12-16 alkyl polyglycosides are representative for the whole group of alkyl polyglycosides (C8-16 alkyl polyglycosides).

Reproductive Toxicity (R) Score (H, M, or L): L
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **LOW** for reproductive toxicity based on adequate data and negative results, no structural alerts, and being Not Classified per GHS.

- EAS Consulting Group -
    - No effects indicative of general toxicity were observed in parental animals. Relative and absolute weights of testes, epididymides and seminal vesicles did not differ between test and control animals. With regard to reproductive parameters, no test substance-related symptoms were observed. Mean litter weights, pup weights, sex ratios, and gestation periods did not differ significantly among all groups. No clinical pre-weaning effects were noted and necropsy or histological examination did not reveal any effects in parental or FI pups. On the basis of these results, a NOAEL of 1000 mg/kg-bw/day was determined. Based on the fact that different Alkyl Polyglycosides discussed in this document show a similar metabolic pathway resulting in the occurrence of sugar and different fatty alcohols (in this case C8 to C16 alcohol), and that fatty alcohols can be seen as a category with comparable toxicological properties with regard to systemic toxicity, alkyl polyglycosides are regarded as a group with similar toxicological properties on repeated dose toxicity. As a consequence, results from repeated application studies obtained with C12-16 alkyl

polyglycosides are representative for the whole group of alkyl polyglycosides (C8-16 alkyl polyglycosides).

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M or L): L
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **LOW** for developmental toxicity based on adequate data with negative results, no structural alerts, and being Not Classified per GHS.

- EAS Consulting Group -
  - All dams tolerated the applied dose levels of up to 1000 mg/kg-bw/day without lethality. Maternal body weight gain was not affected by treatment. For maternal toxicity a NOAEL of 1000 mg/kg-bw was deduced. All females had viable fetuses, and pre- and post-implantation losses as well as mean numbers of resorption were not affected by treatment at any dose. Skeletal and visceral examinations also did not detect any treatment-related malformations. For embryo/fetotoxicity and teratogenicity, the NOAEL was also determined to be 1000 mg/kg bw with no effect observed at any dose level tested. Based on the fact that different alkyl polyglycosides discussed in this document show a similar metabolic pathway resulting in the occurrence of sugar and different fatty alcohols (in this case C8 to C16 alcohol), and that fatty alcohols can be seen as a category with comparable toxicological properties with regard to systemic toxicity, all alkyl polyglycosides are regarded as a group with similar toxicological properties on repeated dose toxicity. As a consequence,results from repeated application studies obtained with C12-16 alkyl polyglycosides are representative for the whole group of alkyl polyglycosides (C8-16 alkyl polyglycosides).

Endocrine Activity (E) Score (H, M or L): DG
No data were found for endocrine activity.

<u>Group II and II* Human Health Effects (Group II and II* Human)</u>
Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M or L): L
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **LOW** for acute mammalian toxicity based on LD 50 values in the >2000 mg/kg range.

- EAS Consulting Group -
  - LD50 established to be greater than 5000 mg/kg bw.

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)
Group II Score (single dose: vH, H, M or L): DG
No data were found for systemic toxicity/organ effects - single dose.

Group II* Score (repeated dose: H, M, L): L
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **LOW** for systemic toxicity/organ effects based on repeated exposure NOAEL values in the >100 mg/kg-bw range.

- EAS Consulting Group -
  - Since only local reversible effects on the forestomach based on irritation were observed,

the No-Observed-Adverse-Effect Level (NOAEL) for systemic oral toxicity was therefore calculated to be 1000 mg/kg bw/day. A dermal study for subacute toxicity with C8-10 alkyl polyglycoside (60% active substance) was conducted in New Zealand white rabbits with doses between 60 mg and 3000 mg /kg bw/day applied to the intact skin for 14 days. Doses at 1500 mg/kg bw/day and above induced severe skin irritation after repeated application as well as several changes in hematological and clinical parameters and testicular atrophy. Minimal to mild skin irritation was seen in dose groups starting from 540 mg/kg bw/day, whereas no clinical, hematological or organ changes were reported at this dose. At and below 180 mg/kg bw/day, none of the described adverse events were observed. A NOAEL for systemic effects was set at 540 mg/kg bw/day. Based on the fact that different alkyl polyglycosides discussed in this document show the same general metabolic pathway resulting in the occurrence of sugar and different fatty alcohols (in this case C8 to C16 alcohol), and that fatty alcohols can be seen as a category with comparable toxicological properties with regard to systemic toxicity, all alkyl polyglycosides is regarded as a group with similar toxicological properties on repeated dose toxicity. As a consequence, results from repeated application studies obtained with C 12- 16 alkyl polyglycosides are representative for the whole group of alkyl polyglycosides (C8-16 alkyl polyglycosides).

Neurotoxicity (N)
Group II Score (single dose: vH, H, M or L): DG
No data were found for neurotoxicity - single dose.

Group II* Score (repeated dose: H, M, L): DG
No data were found for neurotoxicity - repeated dose.

Skin Sensitization (SnS) Group II* Score (H, M or L): L
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **LOW** for skin sensitization based on adequate data with negative results, no structural alerts, and being Not Classified per GHS.

- EAS Consulting Group -
  - Although the test products covered a broad range from C8 to C16 Alkyl Polyglycosides in different ratios and derived from different raw materials (fatty alcohol from natural and synthetic sources), none of the products induced any skin reaction indicative of sensitization in any volunteer supporting the animal study results.

Respiratory Sensitization (SnR) Group II* Score (H, M or L): DG
No data were found for respiratory sensitization.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M or L): H
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **HIGH** for skin irritation/corrosivity based on assignment of EU H-Phrase H 315.

- ECHA -
  - EU H-Phrase H315 "Causes skin irritation"

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M or L): vH
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **VERY HIGH** for eye irritation/corrosivity based on being classified as highly irritating.

- EAS Consulting Group -

- C8/10 alkyl polyglycosides were evaluated as being highly irritating to the eye.
- ECHA -
  - EU H-Phrase H318 "Causes serious eye damage"

Ecotoxicity (Ecotox)

Acute Aquatic Toxicity (AA) Score (vH, H, M or L): M
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **MODERATE** for acute aquatic toxicity based on LC/EC_{50} values in the >10-100 ppm range.

- US EPA 2012 -
  - Based upon an experimental 96-hr LC_{50} of 101 ppm in fish, an experimental 48-hr EC_{50} of 20 ppm in daphnids and an experimental 72-hr EC_{50} of 47 mg/L in algae.

Chronic Aquatic Toxicity (CA) Score (vH, H, M or L): M
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **MODERATE** for chronic aquatic toxicity based on NOEC values in the >1.0-10 ppm range.

- US EPA 2012 -
  - Based upon an experimental 72-hr NOEC of 5.7 mg/L in algae, and experimental data for an analog (C12-14 alkyl glycoside). Data reported for the analog include a 4-week NOEC of 1.8 mg/L in fish, a 21-day NOEC of 1.0 mg/L in daphnia and a 72-hr NOEC of 2.0 mg/L in algae.

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): vL
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **VERY LOW** for persistence based on meeting the 10-day window criterion.

- US EPA 2012 -
  - Based upon experimental data indicating that this material achieves 81-82% after 28-days in an OECD 301- D assay and 94% after 28 days in an OECD 301-E assay. This material met the 10-day window criterion in both tests.

Bioaccumulation (B) Score (vH, H, M, L, or vL): L
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **LOW** for bioaccumulation based on a log Kow value of <=4.

- ECHA -
  - Log Kow < 1.77 (deduced from similar substances.

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M or L): L
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **LOW** for reactivity due to a Chemwatch database classification of 1 for reactivity and lack of classification as reactive in any regulatory codes.

Flammability (F) Score (vH, H, M or L): L
D-Glucopyranose, Oligomeric, Decyloctyl Glycosides was assigned a score of **LOW** for flammability due

to a Chemwatch database classification of 1 for flammability and lack of classification as flammable in any regulatory codes.

References

Chemwatch. 2010. Chemical Database and Management Systems.

EAS Consulting Group. 2007. Letter to FDA, "Submission of GRAS Notification for Alkyl Polyglycoside Surfactants."

ECHA. Classification and Labeling Inventory. http://clp-inventory.echa.europa.eu/SummaryOfClassAndLabelling.aspx?SubstanceID=135996&HarmOnly=no?DisclaimerAgr=Agree&Index=68515-73-1&ExecuteSearch=true&fc=true&lang=en

ECHA. Dossier. http://apps.echa.europa.eu/registered/data/dossiers/DISS-97de31b2-116c-033a-e044-00144f67d031/AGGR-df179356-e60e-4897-82d3-1ef0307e76f7_DISS-97de31b2-116c-033a-e044-00144f67d031.html#AGGR-df179356-e60e-4897-82d3-1ef0307e76f7

US Environmental Protection Agency. 2012. DfE Alternatives Assessment for Nonylphenol Ethoxylates. Washington, D.C. http://www.epa.gov/dfe/pubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf

GreenScreen® Assessment for Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt (9004-82-4)

GreenScreen® Version 1.2 Draft Assessment
Note: Validation Has Not Been Performed on this GreenScreen® Assessment

Chemical Name: Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt

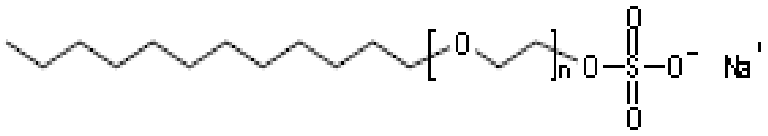
GreenScreen® Assessment Prepared By:
Name: Eric Harrington
Title: Principal
Organization: Green Advantage Consultants
Date: 5/29/2013
Quality Control Performed By:
Name: NA
Title: NA
Organization: NA
Date: NA

Confirm application of the *de minimus* rule: NA

Chemical Name (CAS #): Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt (9004-82-4)
Also Called: sodium lauryl ether sulfate (SLES)

Chemical Surrogates, analogs or moieties used in this assessment (CAS #): None

Chemical Structure(s):



Notes related to production specific attributes: NA

Identify Applications/Functional Uses:
1. Surfactant in cleaning products

Green Screen Rating: Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a Draft Benchmark Score of U based on not meeting the minimum data set requirements for Group II Human Health and Environmental Fate endpoints.

Group I Human								Group II Human								Ecotox		Fate		Physical	
C	M	R	D	E	AT	ST				N		SnS	SnR	IrS	IrE	AA	CA	P	B	Rx	F
						single	repeated	single	repeated												
L	L	L	L	DG	M	DG	DG	DG	DG			L	DG	H	vH	vH	vH	L	DG	L	L

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance).

Transformation Products and Ratings:
AES degradation appears to occur by any of three routes: 1) ω-/β-oxidation of the alkyl chain, 2) enzymatic cleavage of the sulfate substituent leaving an alcohol ethoxylate, or 3) cleavage of an ether bond producing either the alcohol (central cleavage) or an alcohol ethoxylate and an oligo(ethylene glycol) sulfate. The subsequent degradation of the resulting intermediates encompasses oxidation of the alcohol to the corresponding fatty acid (itself then degraded via ß-oxidation) or degradation of the alcohol ethoxylate (via central cleavage or degradation from either end of the molecule) or degradation of the oligo(ethylene glycol) sulfate. The ultimate biodegradability of alcohol ethoxylates is well established. The degradation of AES does not produce any recalcitrant metabolite, and it has also been established that the aquatic toxicity of AES decreases in the course of AES degradation.[24]

24

b) HERA Human and Environmental Risk Assessment on Ingredients of European Household Cleaning Products, Alcohol Ethoxysulfates, AES, Environmental Risk Assessment, 2002. http://www.heraproject.com/files/1-E-04-HERA%20AES%20ENV%20%20web%20wd.pdf

Hazard Classification Summary Section:

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M or L): L
Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **LOW** for carcinogenicity based on adequate data with negative results, no structural alerts, and being Not Classified per GHS.

- HERA -
  - The available oral and dermal long term toxicity/carcinogenicity studies, even if not performed according to accepted guidelines for carcinogenicity bioassays, appear to be conducted and documented in an acceptable manner. It is therefore concluded that there is sufficient evidence that AES is not carcinogenic in the tested species under the conditions described.

Mutagenicity/Genotoxicity (M) Score (H, M or L): L
Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **LOW** for mutagenicity based on adequate data with negative results, no structural alerts, and being Not Classified per GHS.

- HERA -
  - A structure activity analysis did not reveal any functional groups in the chemical structure of AES that were associated with mutagenic or genotoxic properties. In all available in vitro and in vivo genotoxicity assays, there is no indication of genetic toxicity of AES. Only 2 studies, an Ames test and a mouse lymphoma assay were conducted according to OECD guideline methodologies and GLP regulations. However, all the other available in vitro and in vivo studies appear to be well documented and conducted. Some of these studies were published in peer-reviewed journals. Based on the presented data, it is therefore concluded that there is no evidence that AES are either mutagenic or genotoxic.

Reproductive Toxicity (R) Score (H, M, or L): L
Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **LOW** for reproductive toxicity based on adequate data with negative results, no structural alerts, and being Not Classified per GHS.

- HERA -
  - AES did not adversely affect reproduction in the rat and the NOAEL for reproductive effects was > 300 mg/kg.

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M or L): L
Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **LOW** for developmental toxicity based on adequate data with negative results, no structural alerts, and being Not Classified per GHS.

- HERA -
  - A NOAEL greater than 1000 mg/kg bw/day can be estimated for teratogenicity and embryotoxicity on the basis of the segment II embryotoxicity study which is judged to be of highest reliability. The NOAEL for developmental toxicity appears to be greater than 750 mg/kg bw/day. In other assessments, these levels have been deemed to be equivalent to no developmental toxicity.

Endocrine Activity (E) Score (H, M or L): DG
No data were found for endocrine activity.

Group II and II* Human Health Effects (Group II and II* Human)
Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M or L): M
Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **MODERATE** for acute mammalian toxicity based on being on the "GHS New Zealand Category 4 Acute Mammalian Toxicity" list per the GreenScreen® List Translator. LD50 values are reported to be in the >300-2000 mg/kg range, which also classifies SLES as **MODERATE**.

- Stepan Company -
  - Oral LD_{50} is 1600 mg/kg.

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)
Group II Score (single dose: vH, H, M or L): DG
No data were found for systemic toxicity/organ effects - single dose.

Group II* Score (repeated dose: H, M, L): DG
No data were found for systemic toxicity/organ effects - repeated dose.

Neurotoxicity (N)
Group II Score (single dose: vH, H, M or L): DG
No data were found for neurotoxicity - single dose.

Group II* Score (repeated dose: H, M, L): DG
No data were found for neurotoxicity - repeated dose.

Skin Sensitization (SnS) Group II* Score (H, M or L): L
Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **LOW** for skin sensitization based on adequate data with negative results, no structural alerts, and being Not Classified per GHS.

- HERA -
  - Taking a weight of evidence approach and considering quality criteria (i.e., compliance with OECD methods, GLP) in evaluating reliability of individual studies, AES are not considered to be a skin sensitizers. The vast majority of available guinea pig studies in which AES was tested for skin sensitization properties demonstrated the absence of skin sensitizing potential of AES. Only a few studies indicated a weak sensitization potential of AES, but it should be taken into consideration that observed reactions may have been confounded with irritation reactions.

Respiratory Sensitization (SnR) Group II* Score (H, M or L): DG

No data were found for respiratory sensitization.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M or L): H
Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **HIGH** for skin irritation/corrosivity based on being classified as irritating to skin according to EU criteria.

- HERA -
  - The irritation potential of AES is concentration dependent. Materials with concentrations higher than 70% are moderately to severely irritating to rabbit skin under the conditions of the EC irritation test, and therefore classified as irritating to skin according to EU criteria. At concentrations between 10 and 30%, the AES solutions exhibit mild to moderate irritancy under the conditions of an occluded patch test. AES concentrations below 1% are virtually non-irritating under the conditions of the acute skin irritation testing protocol.

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M or L): vH
Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **VERY HIGH** for eye irritation/corrosivity based on being classified as severely irritating according to EU criteria.

- HERA -
  - In two independent OECD and GLP compliant acute eye irritation studies, the triisopropanolammonium salt of C12-14E2S (90% active material) and NaC12-14E2S (28% active material) were shown to be moderately to severely irritating to rabbit eyes. Due to its persistent effects, these materials were to be classified as severely irritating, according to the EU criteria.

Ecotoxicity (Ecotox)

Acute Aquatic Toxicity (AA) Score (vH, H, M or L): vH
Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **VERY HIGH** for acute aquatic toxicity based on LC/EC_{50} values in the <=1 range.

- US EPA 2012 -
  - Based on experimental 96-hr LC_{50} values in the range of 1.0-28 ppm in fish, a 96-hr EC_{50} of 1.17 ppm in daphnia, and an LC_{50} value of 4-65 ppm for C12-15 AE1-3S in algae.

Chronic Aquatic Toxicity (CA) Score (vH, H, M or L): vH
Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **VERY HIGH** for chronic aquatic toxicity based on NOEC values in the <=0.1 ppm range.

- US EPA 2012 -
  - Based on experimental NOECs ranging from 0.1-0.88 ppm in 20-30-day chronic toxicity tests in fish, NOECs ranging from 0.3-6.3 mg/L in 7-day chronic toxicity tests in daphnids, and NOECs ranging from 0.35-0.9 mg/L in 72-96-hour chronic toxicity tests in algae.

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): L
Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **LOW** for persistence based on the likelihood of meeting the 10-day window criterion.

- US EPA 2012 -
  - Based on experimental data indicating that the C12-14AE2S achieves 58-100% ThOD after

28 days in a Closed Bottle Test, that the C12-18AE8.5S achieves 100% ThOD after 28 days in a Closed Bottle Test, and that this mixture corresponding to this CAS number achieves 58.6% degradation after 2 weeks in a MITI OECD 301-C test. Information on the 10-day window was not available, however, the MITI test data suggest that this compound could meet the 10-day window criterion.

Bioaccumulation (B) Score (vH, H, M, L, or vL): DG
No data were found for bioaccumulation.

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M or L): L
Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **LOW** for reactivity due to a Chemwatch database classification of 1 for reactivity and lack of classification as reactive in any regulatory codes.

Flammability (F) Score (vH, H, M or L): L
Polyoxy (1,2-Ethanediyl), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **LOW** for flammability due to a Chemwatch database classification of 1 for flammability and lack of classification as flammable in any regulatory codes.

References

Chemwatch. 2010. Chemical Database and Management Systems.

Clean Production Action. 2011. GreenScreen List Translator. http://www.cleanproduction.org/library/greenscreen-translator-benchmark1-possible%20benchmark1.pdf

HERA. 2002. Human and Environmental Risk Assessment on Ingredients of European Household Cleaning Products, Alcohol Ethoxy Sulfates, AES, Environmental Risk Assessment. http://www.heraproject.com/files/1-E-04-HERA%20AES%20ENV%20%20web%20wd.pdf

Stepan Company. 2009. Sodium 2-(2-dodocyloxyethoxy) ethyl sulphate (sodium laureth sulfate; CAS no. 3088-31-1) Test Plan.

US Environmental Protection Agency. 2012. DfE Alternatives Assessment for Nonylphenol Ethoxylates. Washington, D.C. http://www.epa.gov/dfe/pubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf

Appendix 4: Administrative Compliance

The Safer Consumer Product Regulations are comprised of 11 articles, of which one - Article 5: Alternatives Analysis - is specifically pertinent to this document. The following tables document each requirement of that article and where in the AA that requirement is complied with.

Compliance with Section 69505: Guidance Materials

COMPLIANCE LOCATION	TEXT
NA	(α) Guidance Materials. Before finalizing the initial list of Priority Products, the Department shall make available on its website guidance materials to assist persons in performing AAs under this article. The Department shall periodically revise and update the guidance materials.
NA	(β) Sample Alternatives Analyses. The Department shall also post on its website examples of AAs that are available in the public domain at no cost. The posting must indicate, for each AA, the name of the person or entity that prepared the AA.

Compliance with Section 69505.1: General Provisions

COMPLIANCE LOCATION	TEXT
NA	(α) Applicability. This article does not apply to a product for which the notification requirements of section 69505.2 or section 69505.3 have been fully and timely met.
Entire document	(β) AA Requirements.
Entire document	(1) Except as otherwise provided in subsection (a) above and subsections (b), (c) and (d) of section 69505.4, a responsible entity for a Priority Product shall conduct an AA for the Priority Product and shall comply with all applicable requirements of this article.
Entire document	(2) A responsible entity subject to the requirements of paragraph (1) shall prepare, sign, and submit to the Department AA Reports as follows:
NA	(A) Except as provided in subsection (c), a responsible entity shall submit the Preliminary AA Report to the Department no later than 180 days after the date the product is listed on the final Priority Products list posted on the Department's website, unless the Department specifies a different due date in the Priority Products list.
NA	(B) Except as provided in subsection (c), a responsible entity shall submit the Final AA Report no later than twelve (12) months after the date the Department issues a notice of compliance for the Preliminary AA Report, unless the responsible entity requests and the Department approves an extended due date.
NA	(C) For a product that is first placed into the stream of commerce in California after the date the product is listed on the Priority Products list, the due date for the Preliminary AA Report shall be 180 days after the product is first placed into the stream of commerce in California, unless the Department specifies a different due date in the Priority Products list.
Entire document	(3) The requirements of this article applicable to a responsible entity may be fulfilled entirely or in part by the responsible entity, and/or entirely or in part by a person acting on behalf of or in the stead of the responsible entity. This paragraph does not apply to sections 69505.2 and 69505.3.
NA	(χ) AA Report Due Date Extension.
NA	(1) A responsible entity may request, and the Department may grant, a one-time extension of up to ninety (90) days to the submission deadline for the AA Report or Alternate Process AA Work Plan if the extension request is based on circumstances that could not reasonably be anticipated or controlled by the responsible entity. The extension request must be received at least sixty (60) days before the applicable due date.
NA	(2) The extension request must include:
NA	(A) The name of, and contact information for, the person filing the extension request;
NA	(B) The name of, and contact information for, the responsible entity(ies) on whose behalf the AA Reports will be submitted;
NA	(C) If different from subparagraphs (A) and (B), the name of, and contact information for, the manufacturer(s) and importer(s) of the product;
	(D) Information identifying and describing the responsible entity's Priority Product, and the brand name(s) and product name(s) under which the Priority Product is placed into the

COMPLIANCE LOCATION	TEXT
NA	stream of commerce in California, and, if the Priority Product is a component of one or more assembled products, a description of the known product(s) in which the component is used;
NA	(E) The due date for the AA Report;
NA	(F) The amount of additional time requested; and
NA	(G) The reason the extension is needed, including an explanation as to why the circumstances necessitating the extension could not reasonably be anticipated or controlled by the responsible entity.
NA	(3) The Department shall approve or deny the extension request in whole or in part and provide notice to the person submitting the extension request of the decision within thirty (30) days of receipt of the extension request. Failure by the Department to issue a decision within thirty (30) days does not constitute an approval of the extension request.
NA	(δ) Consideration of Information. A responsible entity conducting an AA shall consider all relevant information made available on the Department's website, and any additional information or technical assistance the Department may provide regarding alternatives analysis. The responsible entity shall summarize these efforts in the Final AA Report or final Abridged AA Report, whichever is applicable.
	(ε) Compliance Status. Notwithstanding any other provision of this chapter, failure of the Department to make a compliance determination for an AA Report or Alternate Process AA Work Plan within the applicable timeframe specified in section 69505.9, or failure of the Director or the Department to respond to an appeal or Request for Review submitted under article 7 within sixty (60) days, shall not cause an AA Report or Alternate Process AA Work Plan to be deemed compliant with this article.

Compliance with Section 69505.2: Removal/Replacement Notifications in Lieu of Alternatives Analysis

COMPLIANCE LOCATION	TEXT
NA	(α) Applicability.
NA	(1)
NA	(A) The requirements of this article do not apply to a responsible entity's Priority Product if the manufacturer of the Priority Product submits one of the following notifications to the Department no later than the due date for submitting the Preliminary AA Report:
NA	1. A Chemical Removal Intent and/or Confirmation Notification that complies with subsections (b) and (c);
NA	2. A Product Removal Intent and/or Confirmation Notification that complies with subsections (b) and (d); or
NA	3. A Product-Chemical Replacement Intent and/or Confirmation Notification that complies with subsections (b) and (e)
NA	(B) If only a Chemical Removal, Product Removal, or Product-Chemical Replacement Intent Notification is submitted to the Department by the date specified in subparagraph (A), within ninety (90) days of the submission date, or by the due date for the Preliminary AA Report, whichever is later, the manufacturer shall submit one of the following to the Department:
NA	1. A removal or replacement Confirmation Notification; or
NA	2. A Preliminary AA Report, Abridged AA Report, or Alternate Process AA Work Plan.
NA	(2)
NA	(A) If a Preliminary AA Report or Alternate Process AA Work Plan has already been submitted to the Department, the requirements of this article pertaining to performance of a second stage AA and submission of a Final AA Report do not apply if one of the notifications specified in paragraph (1)(A) is submitted to the Department prior to the due date for submitting the Final AA Report.
NA	(B) If only a Chemical Removal, Product Removal, or Product-Chemical Replacement Intent Notification is submitted to the Department by the date specified in subparagraph (A), the manufacturer shall submit a removal or replacement Confirmation Notification or a Final AA Report by the later of the following dates:
NA	1. Ninety (90) days after the Intent Notification is submitted; or
NA	2. The due date for the Final AA Report.
NA	(3) A manufacturer is not in compliance with section 69505.1(b), if the manufacturer submits a notification under this section, in lieu of submitting the otherwise required AA Report(s), and that notification is not submitted by the applicable due date or does not fully meet the applicable content requirements specified in subsections (b) through (e).
NA	(β) Content Requirements for Intent and Confirmation Notifications. Chemical Removal, Product Removal, and Product-Chemical Replacement Intent and Confirmation Notifications must include:
NA	(1) The name of, and contact information for, the person submitting the notification.

COMPLIANCE LOCATION	TEXT
NA	
NA	(2) The name of, and contact information for, any known responsible entity(ies).
NA	(3) If different from paragraphs (1) and (2), the name of, and contact information for, the manufacturer(s) and importer(s) of the product.
NA	(4) The name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer directly sold the Priority Product within the prior twelve (12) months.
NA	(5) Identification and location of the manufacturer's retail sales outlets where the manufacturer sold, supplied, or offered for sale the Priority Product in California, if applicable.
NA	(6) Information identifying and describing the Priority Product and the reformulated product, if applicable, and the brand name(s) and labeling information under which the Priority Product and the reformulated product, if applicable, are/were placed into the stream of commerce in California, and, if the product is a component of one or more assembled products, a description of the known product(s) in which the component is used.
NA	(7) The intended uses, and targeted customer base(s), for the Priority Product and the reformulated product, if applicable.
NA	(8) The measures the manufacturer will take, or has taken, to:
NA	(A) If applicable, provide information regarding the reformulated product to persons selling or distributing the Priority Product in California; and
NA	(B) Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California.
NA	(9) For Chemical Removal Notifications and/or Product-Chemical Replacement Notifications, the Chemical(s) of Concern that will be or have been removed from the product and, as applicable, the following information:
NA	(A) Information explaining the rationale and the factors considered in deciding to reformulate the product;
NA	(B) Laboratory analytical testing methodology and quality control and assurance protocols used or that will be used to confirm that the Chemical(s) of Concern has/have been removed, and identification of the testing laboratory;
NA	(C) Information demonstrating that the Chemical(s) of Concern has/have been removed from the product that was a Priority Product;
NA	(D) The name of the replacement chemical(s), the concentration of each replacement chemical in the reformulated product, and the hazard traits and/or environmental or toxicological endpoints known to be associated with the replacement chemical(s);
NA	(E) Laboratory analytical testing methodology and quality control and assurance protocols used or that will be used to measure the concentration of the replacement chemical(s) in the product, and identification of the testing laboratory; and
NA	(F) Information demonstrating that the replacement chemical(s) meet one of the following criteria:

COMPLIANCE LOCATION	TEXT
NA	1. The replacement chemical(s) is/are not on the list of Candidate Chemicals; or
	2. The replacement chemical(s) is/are Candidate Chemical(s) that is/are already in use to manufacture the same product, in lieu of the Chemical(s) of Concern, by the same or a different responsible entity. For purposes of this subsection, "same product" means a product that has the same or similar product description as the Priority Product; has the same intended use(s) and targeted customer base(s) as
NA	the Priority Product; and fulfills the functional, performance, and legal requirements of the Priority Product.
NA	(10) The certification statement specified in subsection (c),(d) or (e), as applicable.
NA	(χ) Chemical Removal Notification Certification Statements. Chemical Removal Intent and Confirmation Notifications must include whichever of the following certification statements is applicable:
NA	(1) Chemical Removal Intent Notifications must include a statement certifying that the manufacturer intends to do all of the following within ninety (90) days of the date the notification is submitted to the Department:
NA	(A) Remove the Chemical(s) of Concern from the Priority Product without the use of one or more replacement chemicals or otherwise adding other chemicals to the product;
NA	(B) Provide information regarding the reformulated product to persons selling or distributing the Priority Product in California;
NA	(C) Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California; and
NA	(D) Submit a Chemical Removal Confirmation Notification to the Department for the Priority Product.
NA	(2) Chemical Removal Confirmation Notifications must include a statement certifying that:
NA	(A) The Chemical(s) of Concern has/have been removed from the product that was a Priority Product without the use of one or more replacement chemicals or otherwise adding other chemicals to the product;
NA	(B) Information regarding the reformulated product has been provided to persons selling or distributing the Priority Product in California; and
NA	(C) The manufacturer has ceased, and will not resume, fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California.
NA	(δ) Product Removal Notification Certification Statements. Product Removal Intent and Confirmation Notifications must include whichever of the following certification statements is applicable:
NA	(1) Product Removal Intent Notifications must include a statement certifying that the manufacturer intends to do both of the following within ninety (90) days of the date the notification is submitted to the Department:
NA	(A) Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California; and

COMPLIANCE LOCATION	TEXT
	(B) Submit a Product Removal Confirmation Notification to the Department for the product.
NA	
	(2) Product Removal Confirmation Notifications must include a statement certifying that the manufacturer has ceased, and will not resume, fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California.
NA	
	(ε) Product-Chemical Replacement Notification Certification Statements. Product-Chemical Replacement Intent and Confirmation Notifications must include whichever of the following certification statements is applicable:
NA	
NA	(1) Product-Chemical Replacement Intent Notifications must include a statement certifying that the manufacturer intends to do all of the following within ninety (90) days of the date the notification is submitted to the Department:
NA	(A) Remove the Chemical(s) of Concern from the Priority Product;
NA	(B) Provide information regarding the reformulated product to persons selling or distributing the Priority Product in California;
NA	(C) Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California; and
NA	(D) Submit a Product-Chemical Replacement Confirmation Notification to the Department for the Priority Product.
NA	(2) Product-Chemical Replacement Confirmation Notifications must include a statement certifying that:
NA	(A) The Chemical(s) of Concern has/have been removed from the product that was a Priority Product;
NA	(B) The replacement chemical(s) meet the criteria specified in subparagraph 1. or subparagraph 2. of subsection (b)(9)(F);
	(C) Information regarding the reformulated product has been provided to persons selling or distributing the Priority Product in California; and
	(D) The manufacturer has ceased, and will not resume, fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California.

Compliance with Section 69505.3: Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis

COMPLIANCE LOCATION	TEXT
NA	(α) Notification Requirements. This article does not apply to a responsible entity's Priority Product for which the manufacturer submits an Alternatives Analysis Threshold Notification to the Department concurrently with the Priority Product Notification, or by the due date for the Preliminary AA Report for the Priority Product. Each notification must include:
NA	(1) The name of, and contact information for, the person submitting the notification;
NA	(2) The name of, and contact information for, any known responsible entity(ies);
NA	(3) If different from paragraphs (1) and (2), the name of, and contact information for, the manufacturer(s) and importer(s) of the Priority Product;
NA	
NA	(4)
	(A) A statement certifying that the Chemical(s) of Concern is/are present in the manufacturer's Priority Product only as contaminants and the concentration of each Chemical of Concern does not exceed the PQL for that chemical; or
NA	
	(B) A statement certifying that the Chemical(s) of Concern does/do not exceed the Alternatives Analysis Threshold(s) specified by the Department under section 69503.5(c) for the Chemical(s) of Concern.
NA	
	(5) If applicable, identification of the PQL for each Chemical of Concern in the Priority Product, and the information and method used to determine the PQL;
NA	
NA	(6) The source of the Chemical(s) of Concern in the Priority Product;
	(7) Information identifying and describing the Priority Product, the brand name(s) and labeling information under which the Priority Product is placed into the stream of commerce in California, and, if the Priority Product is a component of one or more assembled products, a description of the known product(s) in which the component is used;
NA	
	(8) Laboratory analytical testing methodology and quality control and assurance protocols used to measure each Chemical of Concern in the Priority Product, and identification of the testing laboratory; and
NA	
NA	(9) A demonstration and certification that the manufacturer meets and will continue to meet the criteria and conditions that are the basis for the exemption in this section.
NA	(β) Burden of Proof. The manufacturer bears the burden of proof to demonstrate that the concentration of the Chemical(s) of Concern in its Priority Product does not exceed the applicable Alternatives Analysis Threshold.
NA	(χ) Notification Revisions. If any of the information listed in subsection (a) changes significantly, the manufacturer shall submit to the Department a revised Alternatives Analysis Threshold Notification within thirty (30) days of the change.
NA	(δ) Change in Product's Exemption Status. If the Priority Product no longer meets the criteria for an Alternatives Analysis Threshold exemption, the manufacturer shall notify the Department of this change within thirty (30) days of the change, and shall submit to the Department a Preliminary AA Report or an applicable Intent and/or Confirmation Notification under section 69505.2 within 180 days of the change.

COMPLIANCE LOCATION	TEXT
	(ε) Determination of Exemption Eligibility. The exemption in subsection (a) does not apply if the Department notifies the person who submitted the Alternatives Analysis Threshold Notification that the information contained in the notification is inaccurate or inadequate to support an Alternatives Analysis Threshold exemption.

Compliance with Section 69505.4: Alternatives Analysis Process and Options

COMPLIANCE LOCATION	TEXT
Entire Report	(α) AA Stages.
Entire Report	(1) An AA must be conducted in two stages.
NA	(2) The responsible entity shall initially complete the first stage of the AA, and submit a Preliminary AA Report that complies with sections 69505.1(b)(2)(A) and 69505.7.
Entire Report	(3) The responsible entity shall next complete the second stage of the AA, and submit a Final AA Report that complies with sections 69505.1(b)(2)(B) and 69505.7.
NA	(β) Abridged AA Reports. After completing the first five (5) steps of the first stage of the AA under subsections (a) through (e) of section 69505.5, a responsible entity that determines a functionally acceptable and technically feasible alternative is not available may prepare and submit an Abridged AA Report, in lieu of the Preliminary and Final AA Reports, if:
NA	(1) The responsible entity summarizes in the Abridged AA Report the first stage AA findings in compliance with the applicable requirements of section 69505.7;
NA	(2) The responsible entity summarizes in the Abridged AA Report its findings with respect to section 69505.6(a) in compliance with the applicable requirements of section 69505.7;
NA	(3) The responsible entity submits an Abridged AA Report to the Department by the due date specified in section 69505.1(b)(2)(A); and
NA	(4) The responsible entity includes an implementation plan in the Abridged AA Report that specifies the milestones and dates for implementation of proposed regulatory responses, which shall, at a minimum, include the regulatory responses required under sections 69506.3 and 69506.8.
NA	(χ) Alternate Process AA.
NA	(1) A responsible entity may use an AA process that differs from the process specified in sections 69505.5 and 69505.6, if:
NA	(A) The responsible entity's alternate process provides the information needed to prepare a Final AA Report that substantially complies with section 69505.7.
NA	(B) The responsible entity's alternate process compares the Priority Product and the alternatives under consideration using, at a minimum, the same relevant factors and, when applicable, associated exposure pathways and life cycle segments specified in sections 69505.5 and 69505.6.
	(C) The responsible entity submits an Alternate Process AA Work Plan to the Department

COMPLIANCE LOCATION	TEXT
NA	with sufficient information to demonstrate that the alternate process complies with subparagraphs (A) and (B), and sufficient information for the Department to specify an appropriate due date for submittal of the Final AA Report.
NA	1. The Alternate Process AA Work Plan shall include the information specified in subsections (c), (d), and (e) of section 69505.7.
NA	2. If the Alternate Process AA Work Plan includes information for which trade secret protection is claimed, the responsible entity shall also submit a redacted copy of the work plan that excludes that information.
NA	3. The Alternate Process AA Work Plan shall be accompanied by an executive summary organized in conformance with the organization of the work plan that is sufficient to convey to the public a general understanding of the work plan, and that excludes any information for which trade secret protection is claimed. If the Department subsequently rejects a trade secret claim, the responsible entity shall, at the Department's request, submit a revised executive summary within thirty (30) days of the request to add any information for which a trade secret claim is rejected and which the Department specifies must be included in the executive summary.
NA	
NA	(D) The Alternate Process AA Work Plan is submitted to the Department no later than the due date for the Priority Product Notification for the product.
NA	(E)
	1. The responsible entity timely submits a Final AA Report to the Department that substantially complies with section 69505.7.
NA	2. The due date for the Final AA Report is eighteen (18) months after the date the Department issues a notice of compliance for the Alternate Process AA Work Plan, unless the responsible entity requests and receives Department approval of an extended due date using the procedures specified for Preliminary AA Reports in section 69505.7(k)(1)(B), or the Department otherwise approves an extended due date under section 69505.9(b)(4)(A). If the Department approves an extended due date, the responsible entity shall provide a yearly progress report until the Final AA Report is submitted. Each progress report must provide all of the information specified in subparagraphs 1. through 6. of section 69505.7(k)(1)(A).
NA	(2) If the Alternate Process AA Work Plan is disapproved by the Department under section 69505.9(b)(3), the responsible entity shall submit a Preliminary AA Report to the Department within 180 days after the Department issues the notice of disapproval.
NA	(δ) Previously Completed AAs. A responsible entity may comply with section 69505.1(b) by submitting to the Department a report for a previously completed AA for the Priority Product, if the Department determines that the report is substantially equivalent to the Final AA Report requirements of section 69505.7 and contains sufficient information for the Department to determine any necessary regulatory response(s) under article 6. The previously completed AA may be either an AA conducted or obtained by the responsible entity or a publicly available AA.
NA	(1) A responsible entity submitting a report under this subsection shall submit the report no later than the deadline for submitting a Preliminary AA Report, except that a one-time extension may be requested under section 69505.1(c).
NA	(2) A responsible entity submitting an existing report under this subsection may supplement the report with additional information to render the report substantially equivalent to the Final

COMPLIANCE LOCATION	TEXT
	AA Report requirements of section 69505.7.
	(ε) Revised Alternative Selection Decision.
NA	(1) If after submitting the Final AA Report, the responsible entity selects one or more alternatives that differ from the alternative(s) identified as the selected alternative(s) in the Final AA Report, the responsible entity shall submit a revised Final AA Report to the Department at least sixty (60) days prior to placing the newly selected alternative product(s) into the stream of commerce in California. The revised Final AA Report must explain the differences from the original Final AA Report, identify the information used to support the revisions to the Final AA Report, and describe the rationale for selecting the different alternative(s). The Department shall review and make a compliance determination with respect to the revised Final AA Report in accordance with the procedures and criteria set forth in section 69505.9.
NA	(2) Paragraph (1) also applies if:
NA	(A) The selection decision in the original Final AA Report was to retain the Priority Product, and the responsible entity later decides to select an alternative to replace the Priority Product; or
NA	(B) The responsible entity later decides to retain the Priority Product in lieu of a previously selected alternative product.
	(3) The requirements of this subsection only apply for three (3) years after the date the original Final AA Report is approved by the Department.
	(ϕ) Reformulation. Except as provided in section 69505.2, if prior to submitting the Final AA Report for a Priority Product the responsible entity removes, or reduces the concentration of, the Chemical of Concern(s) and uses one or more replacement Candidate Chemical(s), the Alternatives Analysis evaluation and comparison shall include consideration of both the Priority Product and the reformulated product.

Compliance with Section 69505.5: Alternatives Analysis: First Stage

COMPLIANCE LOCATION	TEXT
	The first stage of the AA shall include the six (6) steps described below:
NA	(α) Step 1, Identification of Product Requirements and Function(s) of Chemical(s) of Concern.
NA	(1) The responsible entity shall identify the functional, performance, and legal requirements of the Priority Product that must also be met by the alternatives under consideration.
NA	(2) The responsible entity shall identify the role(s), if any, of the Chemical(s) of Concern in meeting the Priority Product's requirements identified under paragraph (1).
NA	(3)
	(A) The responsible entity shall determine if the Chemical(s) of Concern or alternative replacement chemical(s) is/are necessary to meet the Priority Product's requirements identified under paragraph (1).
NA	(B) If the responsible entity determines that neither the Chemical(s) of Concern nor alternative replacement chemical(s) is/are necessary to meet the Priority Product's requirements identified under paragraph (1), the responsible entity shall evaluate removal of the Chemical(s) of Concern from the Priority Product without the use of any replacement chemical(s) as one of the alternatives to the Priority Product. Alternatively, the responsible entity may submit Chemical Removal Intent and/or Confirmation Notifications to the Department in lieu of completing the Alternatives Analysis and submitting the required AA Reports.
NA	(β) Step 2, Identification of Alternatives.
NA	(1)
	(A) In addition to any alternative identified under subsection (a)(3)(B), the responsible entity shall identify and consider alternatives that meet the definition of "alternative" under section 69501.1 and meet the Priority Product's requirements identified under subsection (a)(1).
NA	(B) The responsible entity shall research and evaluate available information that identifies existing possibly viable alternatives for consideration in the AA. This research and evaluation shall include, but is not limited to, information posted on the Department's website. The responsible entity shall consider any identified alternative in the AA, or explain in the AA Report why such an alternative is not viable for consideration.
NA	(2) Alternatives that do not involve the use of one or more replacement chemicals, or otherwise adding chemicals to the product, do not require compliance with subsection (c).
NA	(χ) Step 3, Identification of Factors Relevant for Comparison of Alternatives.
NA	(1) A factor listed in paragraph (2), in conjunction with an associated exposure pathway and life cycle segment, if applicable, is relevant if:
	(A) The factor makes a material contribution to one or more adverse public health impacts, adverse environmental impacts, adverse waste and end-of-life effects, and/or materials and resource consumption impacts associated with the Priority Product and/or one or more alternatives under consideration; and
NA	(B) There is a material difference in the factor's contribution to such impact(s) between the Priority Product and one or more alternatives under consideration and/or between two

COMPLIANCE LOCATION	TEXT
NA	or more alternatives.
	(2) The responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to identify the factors listed below and the associated exposure pathways and life cycle segments, if applicable, that are relevant for the comparison of the Priority Product and the alternatives under consideration:
NA	(A) Adverse environmental impacts;
NA	(B) Adverse public health impacts;
NA	(C) Adverse waste and end-of-life effects;
NA	(D) Environmental fate;
NA	(E) Materials and resource consumption impacts;
NA	(F) Physical chemical hazards; and
NA	(G) Physicochemical properties.
NA	(3) The responsible entity's identification of relevant exposure pathways shall consider both of the following:
NA	(A) Chemical quantity information:
NA	1. Quantities of the Chemical(s) of Concern or alternative replacement chemical(s) necessary to manufacture the Priority Product and each alternative under consideration; and
NA	2. Estimated volume and/or mass of the Chemical(s) of Concern or alternative replacement chemical(s) that is/are or would be placed into the stream of commerce in California as a result of the Priority Product and each alternative under consideration.
NA	(B) Exposure factors specified in section 69503.3(b).
NA	(δ) Step 4, Initial Evaluation and Screening of Alternative Replacement Chemicals.
	(1) For those alternatives under consideration that involve removing or reducing the concentration of the Chemical(s) of Concern and using one or more alternative replacement chemicals, or otherwise adding chemicals to the product, the responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to evaluate and compare each of the alternative replacement chemicals under consideration with the Chemical(s) of Concern in the Priority Product with respect to each of the following factors to the extent relevant:
NA	(A) Adverse environmental impacts;
NA	(B) Adverse public health impacts;
NA	(C) Environmental fate;
NA	(D) Physical chemical hazards; and

COMPLIANCE LOCATION	TEXT
NA	(E) Physicochemical properties.
NA	(2) The responsible entity may eliminate from further consideration in the AA any alternative replacement chemical(s) that it determines has/have the potential to pose adverse impacts equal to or greater than those posed by the Chemical(s) of Concern.
NA	(ε) Step 5, Consideration of Additional Information. In the first stage of the AA, the responsible entity may consider pertinent factors and information not specifically identified in this section. This may include, but is not limited to, consideration of the factors and information specified in section 69505.6. A responsible entity may eliminate an alternative from further consideration based on the additional factors and information as long as the reason for its elimination is explained in the Preliminary AA Report and there are alternatives remaining to be evaluated in the second AA stage.
NA	(ϕ) Step 6, Preliminary AA Report Preparation.
NA	(1) The responsible entity shall prepare, for inclusion in the Preliminary AA Report, a work plan and proposed implementation schedule for completion of the second AA stage and preparation and submittal of the Final AA Report.
	(2) The responsible entity shall prepare and submit to the Department a Preliminary AA Report as specified in section 69505.7.

Compliance with Section 69505.6: Alternatives Analysis: Second Stage

COMPLIANCE LOCATION	TEXT
Entire Report	After receiving approval of the Preliminary AA Report from the Department, the responsible entity shall compare the Priority Product with the alternatives still under consideration. The second stage of the AA shall include the five (5) steps described below:
Section 2.2	(α) Step 1, Identification of Factors Relevant for Comparison of Alternatives.
Section 2.2.1-2.2.7, 2.2.8	(1) Adverse Impacts and Multimedia Life Cycle Impacts. The responsible entity may use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to re-evaluate the identification of factors and the associated exposure pathways and life cycle segments, if applicable, determined to be relevant under section 69505.5(c) for the comparison of the Priority Product and the alternatives still under consideration after completion of the first AA stage. In addition to the factors determined to be relevant under this paragraph and/or section 69505.5(c), the factors specified in paragraphs (2) and (3) are relevant for all comparisons of the Priority Product and the alternatives.
Section 2.2.9	(2) Product function and performance. The responsible entity shall identify the principal manufacturer-intended use(s) or application(s), the functional and performance attributes, and the applicable legal requirements for the Priority Product. The responsible entity shall, at a minimum, evaluate: 1. The useful life of the Priority Product, and that of the alternatives under consideration; 2. The function and performance of each alternative relative to the Priority Product and other alternatives under consideration; and 3. Whether an alternative exists that is functionally acceptable, technically feasible, and economically feasible.
Section 2.2.10	(3) Economic impacts. 1. The responsible entity shall evaluate, monetize, and compare for the relevant exposure pathways and life cycle segments the following impacts of the Priority Product and the alternatives: a. Public health and environmental costs; and b. Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife. 2. If the responsible entity's alternative selection decision is to retain the Priority Product based in whole or in part on internal cost impacts, this decision must be explained in the Final AA Report. The Final AA Report must include a quantified comparison of the internal cost impacts of the Priority Product and the alternatives, including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs.
Sections 2.3, 2.5	(β) Step 2, Comparison of the Priority Product and Alternatives. The responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to evaluate and compare the Priority Product and each of the alternatives under consideration with respect to each relevant factor and associated exposure pathways and life cycle segments, if applicable, identified under subsection (a) above and section

COMPLIANCE LOCATION	TEXT
Section 2.4	69505.5(c). The responsible entity shall compare each alternative with the Priority Product and with each of the other alternatives under consideration.
Section 3	(χ) Step 3, Consideration of Additional Information. As part of the second stage of the AA, the responsible entity may also consider other pertinent information not specifically identified in this section. This may include, but is not limited to, reconsideration of the factors and information identified in section 69505.5.
Entire Report	(δ) Step 4, Alternative Selection Decision. The responsible entity shall select the alternative(s) that will replace the Priority Product, unless the decision is to retain the existing Priority Product. The selection of an alternative or the decision to retain the Priority Product shall be based on and supported by the comparative analysis conducted under subsections (b) and (c).
	(ε) Step 5, Final AA Report Preparation. The responsible entity shall prepare and submit to the Department a Final AA Report as specified under section 69505.7.

Compliance with Section 69505.7: Alternatives Analysis Reports

COMPLIANCE LOCATION	TEXT
Entire Report	(α) General Requirements.
Entire Report	(1) Preliminary and Final AA Reports and Abridged AA Reports must each include all of the applicable information specified in subsections (b) through (k).
Appendix 4	(2) The responsible entity shall include in the AA Reports sufficient information for the Department to determine:
	(A) Compliance with the substantive and administrative requirements of this article; and
	(B) The appropriate due date for submission of the Final AA Report, and the appropriate due date for any regulatory response (s) required under article 6.
Change Log	(3) The responsible entity shall identify and explain in the Final AA Report all differences in the information and analyses presented in the Preliminary AA Report and the Final AA Report. The responsible entity must identify in the Final AA Report the information sources used to support changes from the Preliminary AA Report to the Final AA Report.
NA	(4) The responsible entity shall maximize the scope of information in the AA Report that can be made available to the public, while maintaining protection of legitimate trade secrets.
NA	(A) If the AA Report contains information claimed by the responsible entity to be a trade secret, a separate publicly available AA Report shall be submitted to the Department that excludes claimed trade secret information only to the extent necessary to protect its confidential nature.
NA	(B) If the Department subsequently rejects a trade secret claim and/or the nature and/or extent of redaction, the responsible entity shall, at the Department's request, submit a revised publicly available AA Report and executive summary within thirty (30) days of the request to add any information for which a trade secret claim or redaction is rejected.
Page 1	(β) Executive Summary. AA Reports must include a publicly available executive summary sufficient to convey a general understanding of the scope and results of the AA and the rationale for the AA selection decision. The executive summary must be organized in conformance with the organization of the AA Report and must include for each section of the AA Report a detailed summary of the information presented. Information for which trade secret protection is claimed must not be included in the executive summary.
Page 9	(χ) Preparer Information. This section of the AA Report must include:
	(1) The name of, and contact information for, the person submitting the AA Report;
	(2) If applicable, the name of, and contact information for, all responsible entities on whose behalf the AA Report is being submitted; and
Page 10	(3) The names of the parties that were involved in funding, directing, overseeing, preparing, and/or reviewing the AA.
	(δ) Responsible Entity and Supply Chain Information. This section of the AA Report must include:
	(1) The name of, contact information for, and headquarters location of the manufacturer(s) and

COMPLIANCE LOCATION	TEXT
	importer(s), if applicable, and, if the AA Report is prepared on behalf of a consortium of manufacturers or other persons in the Priority Product's supply chain, a list of the participants along with their contact information;
	(2) The name of, and contact information for, any person(s) identified on the Priority Product label as the manufacturer, importer, or distributor;
	(3) The name of, and contact information for, all persons in California other than the final purchaser or lessee to whom the manufacturer or importer directly sold the Priority Product within the prior twelve (12) months; and
Section 1	(4) Identification and location of the manufacturer's and/or importer's retail sales outlets where the manufacturer and/or importer sold, supplied, or offered for sale the Priority Product in California, if applicable.
	(ε) Priority Product Information. This section of the AA Report must include:
	(1) The brand name(s) and product name(s) under which the Priority Product is placed into the stream of commerce in California;
	(2) If the Priority Product is a component of one or more assembled products, a description of the known product(s) in which the component is used;
	(3) Identification of the Chemical(s) of Concern for the Priority Product;
Section 2.2	(4) Any Material Safety Data Sheets and/or Safety Data Sheets related to the Priority Product; and
	(5) The information specified in paragraphs (1) and (2) of section 69505.5(a).
Sections 2.3, 2.5	(ϕ) Scope of Relevant Comparison Factors. Each AA Report must identify which factors and, when applicable, associated exposure pathways and life cycle segments were determined to be relevant, under sections 69505.5(c) and 69505.6(a), for evaluation and comparison of the Priority Product and its alternatives. For each factor, and exposure pathway and life cycle segment, if applicable, determined not to be relevant, the AA Report must explain the rationale and identify, and explain the pertinent findings of, the supporting information for this determination.
Executive Summary, Section 2.3	(γ) Scope and Comparison of Alternatives. The AA Reports must identify and describe the alternatives chosen to be evaluated and compared, and explain the rationale for selecting and screening out specific alternatives at each stage of the alternatives comparison process. For any alternative that is screened out because it is determined that its adverse impacts are equal to or greater than those of the Priority Product, the responsible entity shall describe in the AA Report the method used to determine equal or greater adverse impacts, including the method used to compare the multiple factors associated with the impacts, and the rationale for any trade-offs made among the factors.
Executive Summary, Section 2.3	(1) Each Preliminary AA Report and Abridged AA Report must include the information collected and the comparison conducted under section 69505.5 for the Chemical(s) of Concern and the alternative replacement chemical(s). This must include a matrix, or other summary format, that provides a clear visual comparison that summarizes the information collected regarding the relevant adverse impacts, and their associated relevant exposure pathways and life cycle segments, for the Chemical(s) of Concern and each alternative replacement chemical being considered, and the comparative results of evaluating this information.

COMPLIANCE LOCATION	TEXT
	(2) The Final AA Report must include the information collected and the comparison conducted under sections 69505.5 and 69505.6 for the Priority Product and its alternatives, including:
NA	(A) A matrix, or other summary format, that provides a clear visual comparison that summarizes the information collected regarding the relevant comparison factors, and their associated relevant exposure pathways and life cycle segments, for the Priority Product and each alternative considered, and the comparative results of evaluating this information; and
Appendix 4	
Section 2.3, Appendix 2	(B) Identification and description of how any relevant safeguards provided by other federal and California State regulatory programs were considered in the AA.
	(3) The responsible entity shall demonstrate in the Final AA Report that all of the requirements of section 69505.6 have been met.
Entire Report	(η) Methodology. The AA Report shall identify and describe the analytical tools, models, and software used to conduct the AA, and discuss any of their limitations. The AA Report shall also identify any published methodologies and/or guidelines used, and any deviations from those methodologies and/or guidelines.
	(ι) Supporting Information.
	(1) All information used as supporting information in performance of the AA and preparation of the AA Reports must be cited in the AA Reports and made available to the Department upon request. The AA Reports must include a brief summary of the information reviewed and considered under section 69505.1(d).
	(2) The Final AA Report must identify information that is not currently available but, if it were available, could be used to:
Section 3	(A) Validate information used for purposes of sections 69505.5 and 69505.6; and/or
NA	
	(B) Address any uncertainties in the analyses conducted under sections 69505.5 and 69505.6.
Section 3	
	(φ) Selected Alternative(s).
	(1) The Preliminary AA Report must identify and describe the alternatives selected for further evaluation in the second stage of the AA, and explain the rationale for the selection decision.
Section 3	
	(2) The Final AA Report must identify and describe the alternative(s), if any, selected to replace the Priority Product. The description of the selection decision must include an analysis that evaluates and compares the selected alternative(s) against the Priority Product and a detailed list and explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product. The Final AA Report must also include:
NA	
	(A) The product function and performance information specified in section 69505.6(a)(2) for the selected alternative(s). If no alternative is selected, this information must be provided in the Final AA Report or Abridged AA Report, as applicable, for each alternative considered.
NA	
	(B) An explanation of the rationale for retaining the Chemical(s) of Concern or using the alternative replacement chemical(s), if section 69505.5(a)(3)(B) applies, and one or

COMPLIANCE LOCATION	TEXT
	more selected alternatives retains the Chemical(s) of Concern or uses one or more replacement chemicals.
	(C) A list of all chemicals known, based on available information, to be in the selected
NA	alternative(s) that are Chemicals of Concern, that differ from the chemicals in the Priority Product, or that are present in the selected alternative(s) at a higher
NA	concentration than in the Priority Product relative to other chemicals in the Priority Product other than the Chemical(s) of Concern. The following information, to the extent available, must be provided for those chemicals:
NA	
	1. Environmental fate;
NA	2. Hazard trait and environmental and toxicological endpoint information that has not already been provided to the Department under this chapter;
NA	
	3. Information about the chemical purity, meaning the relative absence of extraneous matter, and identification of known impurities and additives in the
NA	chemical;
NA	
NA	4. Physicochemical properties; and
NA	
NA	5. Substance identification information, including all of the following that are
NA	applicable:
NA	
NA	a. Chemical abstract services number;
NA	b. Structural formula;
NA	c. Molecular weight;
	d. Synonyms;
NA	e. International Union of Pure and Applied Chemistry name;
NA	f. European Commission number;
NA	g. Registry of Toxic Effects of Chemical Substances number;
NA	h. International Union of Biochemistry and Molecular Biology number;
	i. Japan Ministry of International Trade and Industry number;
NA	j. Number assigned by the United Nations Experts on the Transport of Dangerous Goods;
Section 4	k. North America Department of Transportation number;
	l. European Inventory of Existing Commercial Chemical Substances number;
NA	m. European List of Notified Chemical Substances number;
	n. European Commission Directive 67/548/EEC No Longer Polymers number; and
	o. Other commonly recognized substance identification system numbers.
NA	
	(κ) Next Steps.
	(1) Work plan. The Preliminary AA Report must include the work plan and proposed implementation schedule for completion of the second AA stage required to be prepared under section 69505.5(f)(1).
	(A) The work plan and implementation schedule must specify the proposed submission date for the Final AA Report and must ensure that the Final AA Report or progress report, if applicable, will be submitted to the Department no later than twelve (12)
NA	months after the Department issues a notice of compliance for the Preliminary AA Report. If the Department approves an extended due date under section
NA	69505.9(b)(4)(A), the responsible entity shall provide a yearly progress report until the Final AA Report is submitted. The first yearly progress report shall be submitted no
NA	later than twelve (12) months after the Department issues a notice of compliance for

COMPLIANCE LOCATION	TEXT
	the Preliminary AA Report. Each progress report must include:
NA	1. Preparer information specified in subsection (c);
NA	2. Priority Product information specified in subsection (e);
NA	3. A summary of achievements since the last progress report;
	4. A summary and discussion of issues that have arisen and their resolutions;
NA	5. A summary of work that is pending; and
	6. An assessment of whether the milestones in the schedule set forth in the Preliminary AA Report or Alternate Process AA Work Plan are anticipated to be completed on time and any contingency plans to ensure timely completion.
	(B) The responsible entity may request an extended due date for submittal of the Final AA
Section 4	Report. Any requested extension shall not exceed twenty-four (24) months from the
	date the Department issues a notice of compliance for the Preliminary AA Report,
Section 4	unless additional time is needed to conduct regulatory safety and/or performance
	testing on multiple alternatives prior to making an AA selection decision, in which case
	the requested extension shall not exceed thirty-six (36) months. The extended due date
	request must include a detailed explanation of why additional time is needed.
Section 4	(2) Implementation of selected alternatives. The Final AA Report must include a detailed plan for implementing any selected alternative(s).
	(A) The implementation plan must include key milestones and dates for implementing the selected alternative(s), if applicable, and identify steps that will be taken to ensure compliance with applicable federal, state, and/or local laws.
	(B) The implementation plan may also include the identification of and implementation plan(s) for any regulatory response(s) that the responsible entity wishes to propose that would best limit exposure to, or reduce the level of adverse impacts or adverse waste and end-of-life effects posed by, any Chemical(s) of Concern or replacement Candidate Chemical(s) that will be in the selected alternative(s) or the Chemical(s) of Concern that is/are in the Priority Product if the decision resulting from the AA is to retain the Priority Product.

Compliance with Section 69505.8: Public Comments on AA Reports

COMPLIANCE LOCATION	TEXT
NA	(α) Public Notice of Opportunity for Comment. Upon receipt of a Final AA Report or an Abridged AA Report, the Department shall post on its website, and send to persons on the electronic mailing list(s) that the Department establishes related to this chapter, a notice regarding the availability for public review and comment of the Final AA Report or Abridged AA Report. The notice shall include the last day for the public to submit written comments to the Department, the method(s) for submitting comments, and a link to the location on the Department's website where a copy of the Final AA Report or Abridged AA Report may be viewed. The last day for submission of public comments shall be no sooner than forty-five (45) days from the date the notice of availability of the Final AA Report or Abridged AA Report is posted on the Department's website or the date the notice is sent to persons on the electronic mailing list(s), whichever is the later date.
NA	(β) Department Review of Public Comments. No later than thirty (30) days after the close of the public comment period established under subsection (a), the Department shall review the public comments received and notify the person that submitted the Final AA Report or Abridged AA Report of those issues that the Department determines must be addressed in an AA Report Addendum. The notice shall include the due date by which the person must submit an AA Report Addendum to the Department under subsection (c). In determining the due date for the AA Report Addendum, the Department shall take in to consideration the scope and complexity of the issues the Department is requiring the person to address.
NA	(χ) AA Report Addendum. A person that receives a notice under subsection (b) shall prepare, and submit to the Department by the due date specified under subsection (b), an AA Report Addendum that addresses the issues identified by the Department as requiring further attention. The AA Report Addendum shall also include any revisions to the Final AA Report or Abridged AA Report determined necessary based on consideration of the issues identified by the Department.

Compliance with Section 69505.9: Department Review and Determinations for AA Reports and Work Plans

COMPLIANCE LOCATION	TEXT
NA	(α) Review Criteria. In reviewing AA Reports and Alternate Process AA Work Plans for compliance with the substantive and administrative requirements of this article, the Department shall consider:
NA	(1) Whether the AA Report or Alternate Process AA Work Plan was submitted timely;
NA	(2) Whether, and to what extent, the responsible entity considered and addressed all applicable provisions of this article pertaining to the preparation and submittal of an AA Report or Alternate Process AA Work Plan, whichever is applicable;
NA	(3) Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA were based on reliable information, when applicable; and
NA	(4) Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA Report were determined using reliable information.
NA	(β) Preliminary AA Reports and Alternate Process AA Work Plans.
NA	(1) Within sixty (60) days of receiving a Preliminary AA Report or Alternate Process AA Work Plan, the Department shall review the report or work plan for compliance with this article, and issue a notice of compliance, notice of deficiency, notice of disapproval, or notice of ongoing review.
NA	(2) Notice of Deficiency.
NA	(A) The Department shall specify in a notice of deficiency the areas of deficiency, the information required to cure the deficiency(ies), and the due date for submitting the necessary information, which may not exceed sixty (60) days from the date the notice of deficiency is issued. The responsible entity shall submit a revised report or work plan, whichever is applicable, by the due date specified, and address the areas of deficiency.
NA	(B) Within thirty (30) days of receipt of the additional information requested in the notice of deficiency, the Department shall issue a notice of compliance, a notice of disapproval, or a 28 notice of ongoing review for the report or work plan.
NA	(3) Notice of Disapproval. If the revised report or work plan does not fully address the identified areas of deficiency, the Department shall issue a notice of disapproval. The Department shall also issue a notice of disapproval if a revised report or work plan is not submitted by the due date specified under paragraph (2)(A). If the report or work plan is disapproved, the Department shall explain the basis for the disapproval. A disapproved report or work plan is not in compliance with section 69505.1(b).
NA	(4) Notice of Compliance. The Department shall specify in a notice of compliance for a Preliminary AA Report or Alternate Process AA Work Plan the due date for submitting the Final AA Report. The Department shall specify a due date twelve (12) months from the date the Department issues the notice of compliance, except that the Department may specify an extended due date for submission of the Final AA Report if it determines based on information in the Preliminary AA Report or Alternate Process AA Work Plan that more time is needed. The Department may also specify an extended due date for submission of the Final AA Report if the responsible entity submits a request under section 69505.7(k)(1)(B).

COMPLIANCE LOCATION	TEXT
	(χ) Final AA Reports and Abridged AA Reports.
NA	(1) Within sixty (60) days of receiving an AA Report Addendum, the Department shall review the Final AA Report or Abridged AA Report, including the AA Report Addendum, for compliance with this article, and shall issue a notice of compliance, notice of deficiency, notice of disapproval, or notice of ongoing review. If no AA Report Addendum is required under section 69505.8, the Department shall complete its review of the Final AA Report or Abridged AA Report within sixty (60) days of whichever of the following dates is applicable:
NA	(A) The close of the public comment period,if no public comments are received; or
NA	(B) Thirty (30) days after the close of the public comment period, if the Department determines after reviewing the public comments that there are no issues that need to be addressed in an AA Report Addendum.
	(2) Notice of Deficiency.
NA	(A) The Department shall specify in a notice of deficiency the areas of deficiency, the information required to cure the deficiency(ies), and the due date for submitting the necessary information to complete the Final AA Report or Abridged AA Report, which may not exceed sixty (60) days from the date of the notice of deficiency. The responsible entity shall submit a revised Final AA Report or revised Abridged AA Report by the due date specified, and address all areas of deficiency. The responsible entity may request and the Department may approve, under section 69505.1(c), a one-time extension of not more than ninety (90) days for submission of the revised Final AA Report or revised Abridged AA Report to correct the deficiencies.
NA	(B) Within sixty (60) days of receipt of the requested additional information, the Department shall issue a notice of compliance, a second notice of deficiency, or a notice of ongoing review.
NA	1. If the Department issues a second notice of deficiency, the Department may grant no more than thirty (30) days for submission of the requested information.
NA	2. Within sixty (60) days of receipt of the additional information requested in the second notice of deficiency, the Department shall issue a notice of compliance, a notice of disapproval, or a notice of ongoing review for the Final AA Report or Abridged AA Report.
NA	(3) Notice of Disapproval. If the Final AA Report or Abridged AA Report does not fully address the areas of deficiency identified in the second notice of deficiency, the Department shall issue a notice of disapproval. The Department shall also issue a notice of disapproval if a revised Final AA Report or revised Abridged AA Report is not submitted by the due date specified under paragraph (2)(A) or paragraph (2)(B)1., whichever is applicable. If the Final AA Report or Abridged AA Report is disapproved, the Department shall explain the basis for the disapproval. A disapproved Final AA Report or Abridged AA Report is not in compliance with section 69505.1(b).
NA	(δ) Notice of Ongoing Review. The Department shall specify in a notice of ongoing review the estimated date by which the Department expects to issue a notice of compliance or notice of deficiency, which shall be based on its available resources and the complexity of the document under review.
	(ε) Issuance of Notices. All notices issued by the Department under this section shall be issued to the

COMPLIANCE LOCATION	TEXT
	person who submitted the document, and a copy of the notice shall be sent by the Department to all persons identified in the document under subsections (c)(2) and (c)(3) of section 69505.7.