



Model Alternatives Assessment

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**PRELIMINARY
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

February 11, 2014

PREFACE

One of the environmental challenges facing industry is the reduction of "substances (or chemicals) of concern" in products, and at the same time responsibly finding alternatives that maintain positive attributes – such as performance – but present less toxic and environmentally adverse effects.

In the process of assessing viable alternatives, an important option to consider 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.

In order to address these issues, the California Department of Toxic Substances Control (DTSC) has issued the Safer Consumer Product Regulations, which require businesses to assess alternatives for chemicals of concern in priority products, both of which will be defined by DTSC. This document models the completion of a Preliminary Alternatives Assessment in accordance with the draft regulations.

NPE was chosen as the subject Chemical of Concern for this model document because the use of products containing NPE can result in the release of more-toxic nonylphenol (NP) and other degradates to the environment, potentially exposing aquatic life to these compounds. NP is lethal to fish and other aquatic organisms at low concentrations (lower than for the parent compound) in both acute and chronic fish studies, and effects on growth and reproduction have been documented. The model alternatives assessment is 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 draft regulations should be met.

For the purposes of this report, it was assumed that the combination of all-purpose cleaners and nonylphenol ethoxylates (NPE) was designated by the State of California as a Priority Product/Chemical of Concern combination that requires preparation of an alternatives assessment. It is further assumed that the concentration of NPE in the products exceeds the alternative analysis threshold specified by the DTSC. It is expected that this alternatives assessment would normally be prepared in accordance with the scheduling and submittal requirements identified in the DTSC regulations. The regulations stipulate that the alternatives assessment is to be prepared in two separate stages, and specifies schedules for the preparation of each.

Per the United States Environmental Protection Agency (USEPA) Nonylphenol (NP) and Nonylphenol Ethoxylates (NPE) Action Plan, NPE was once commonly used in household laundry detergents, but has largely been eliminated by cooperation between the USEPA and detergent manufacturers.¹ It is in the process of being phased out in industrial laundry detergents through the mechanism of an agreement between USEPA and the Textile Rental Services Association of America (TRSA). It is expected that use in liquid detergents will be largely eliminated in 2013, and use in powder detergents will be largely eliminated in 2014.

¹ US Environmental Protection Agency. [Nonylphenol \(NP\) and Nonylphenol Ethoxylates \(NPE\) Action Plan. 8/18/2010. http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/RIN2070-ZA09_NP-NPEs%20Action%20Plan_Final_2010-08-09.pdf](http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/RIN2070-ZA09_NP-NPEs%20Action%20Plan_Final_2010-08-09.pdf)

As the anticipated State of California DTSC regulations are intended to deal with “Safer Consumer Products” - those consumer goods manufactured and sold in California, the choice of product categories is limited to consumer products such as those “household applications” referenced above, rather than those intended for industrial use. Per the DTSC, formulated products will be prioritized according to three criteria: whether they are applied to the body, whether they are dispersed as aerosol or vapor, and whether they are applied to hard surfaces (where there exists a possibility of runoff or volatilization). In the absence of market data on the relative market size for each type of consumer product listed, and as NPE has been phased out of laundry detergents, all-purpose cleaners (which are likely to meet all of the prioritization criteria) are proposed as the recommended Priority Product. An all-purpose cleaner is one that works on multiple surfaces and accomplish many types of cleaning needs; a very familiar example of an all-purpose cleaner would be Formula 409®.

This document is a project of the BizNGO Working Group for Safer Chemicals and Sustainable Materials (BizNGO), a collaboration of business and non-governmental organization (NGO) leaders working to create a roadmap to the widespread use of safer chemicals and sustainable materials in our economy. BizNGO has prepared this model document to illustrate an alternatives assessment for chemicals of concern in a formulated product. A second model alternatives assessment is being prepared for deca-BDE and HBCDD in electronics housings to illustrate an alternatives assessment for a chemical of concern in a fabricated product.

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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
CAN/CGSB	Canadian General Standards Board
CAS	Chemical Abstracts Service
CASRN	Chemical Abstracts Service Registry Number
CHA	comparative hazard assessment
CSMA	Chemical Specialties Manufacturers Association
D	developmental toxicity
d	day
deca-BDE	decabromodiphenyl ether
DfE	Design for the Environment
DG	data gap
DOC	dissolved organic carbon
DOT	Department of Transportation (US)
DTSC	Department of Toxic Substances Control
E	endocrine activity
EC ₅₀	half maximal effective concentration
ED	endocrine disruptor
EO	ethylene oxide
USEPA	US Environmental Protection Agency
EU	European Union
F	flammability
Fp	flash point
GHS	Globally Harmonized Standard
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
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
N	neurotoxicity
NA	not available
NGO	non-governmental organization
NOAEL	No Observed Adverse Effect Level
NOEC	No Observable Effect Concentration
NOEL	No Observable Effect Level
NP	nonylphenol
NPE	nonylphenol ethoxylates
NPEC	nonylphenol ether-carboxylate
OECD	Organization for Economic Cooperation and Development
OPE	octylphenol ethoxylate
OSPAR	Oslo and Paris Commissions
P	persistence
PAA	Preliminary Alternatives Assessment
PBT	persistent, bioaccumulative, and toxic
PEG	polyethylene glycol
ppm	parts per million
R	reproductive toxicity
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical Substances
Rx	reactivity
SCIL	Safer Chemical Ingredients List
SIN	Substitute It Now

SnR	respiratory sensitization
SnS	skin sensitization
SPC	sulfophenyl carboxylates
ST	systemic toxicity
STP	sewage treatment plan
T	toxic
ThCO ₂	theoretical carbon dioxide production
ThOD	theoretical oxygen demand
TM	trademark
TRSA	Textile Rental Services Association of America
U	undetermined
UN	United Nations
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

EXECUTIVE SUMMARY

The Preliminary Alternatives Assessment (PAA) for nonylphenol ethoxylates (NPE) in all-purpose cleaners has been completed in accordance with the State of California Safer Consumer Products regulations - Chapter 55, Division 4.5 of Title 22, California Code of Regulations.

The Department of Toxic Substances Control (DTSC) of the State of California 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 PAA 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 PAA is to identify an appropriate alternative chemical(s) as a substitute surfactant. 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.

Functional requirements for all-purpose cleaning products are to clean a surface by wetting the surface, and 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 this PAA was based upon information gathered by the USEPA Design for the Environment Program (DfE) in their 2012 Alternatives Assessment for Nonylphenol Ethoxylates. The DfE NPE Alternatives Assessment identified nine representative alternatives, including one – octylphenol ethoxylate – which was not considered in this PAA due its more-hazardous toxicological profile. The remaining eight alternatives considered by the USEPA are listed in the following table.

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

Relevant factors to be considered for relevancy and compliance with the Safer Consumer Product regulations, along with their associated exposure pathways and life cycle segments, were identified as the following: adverse environmental impact, adverse public health impact, environmental fate, materials and resource consumption impact (which are not required to be evaluated until the Final Alternatives Assessment, or FAA), and physical chemical hazards. Technical and performance factors were deemed to

be equivalent or better to make the list of alternatives. The following table summarizes the assessment of relevancy of the various factors that were required to be considered in the PAA.

RELEVANT ASSESSMENT FACTORS		RELEVANT?	ANALYSIS METHOD
ADVERSE ENVIRONMENTAL IMPACTS	<i>Air quality impact</i>	NO	NONE
	<i>Ecological impact</i>	YES	GreenScreen <input type="checkbox"/>
	<i>Soil quality impact</i>	NO	NONE
	<i>Water quality impact</i>	NO	NONE
ADVERSE PUBLIC HEALTH IMPACT	<i>Potential for exceedance of standards</i>	NO	NONE
	<i>Carcinogenicity</i>	YES	GreenScreen <input type="checkbox"/>
	<i>Developmental toxicity</i>	YES	GreenScreen <input type="checkbox"/>
	<i>Reproductive toxicity</i>	YES	GreenScreen <input type="checkbox"/>
	<i>Cardiovascular toxicity</i>	YES	GreenScreen <input type="checkbox"/>
	<i>Dermatotoxicity</i>	YES	GreenScreen <input type="checkbox"/>
	<i>Endocrine toxicity</i>	YES	GreenScreen <input type="checkbox"/>
	<i>Epigenetic toxicity</i>	YES	GreenScreen <input type="checkbox"/>
	<i>Genotoxicity</i>	YES	GreenScreen <input type="checkbox"/>
	<i>Hematotoxicity</i>	YES	GreenScreen <input type="checkbox"/>
	<i>Digestive system toxicity</i>	YES	GreenScreen <input type="checkbox"/>
	<i>Immunotoxicity</i>	YES	GreenScreen <input type="checkbox"/>
	<i>Musculoskeletal toxicity</i>	YES	GreenScreen <input type="checkbox"/>
	<i>Nephrotoxicity</i>	YES	GreenScreen <input type="checkbox"/>
<i>Neurodevelopmental toxicity</i>	YES	GreenScreen <input type="checkbox"/>	
ADVERSE WASTE AND END-OF-LIFE IMPACTS		IMPACT MEASURED BY OTHER FACTORS	NONE
ENVIRONMENTAL FATE	<i>Persistence and bioaccumulation</i>	YES	GreenScreen <input type="checkbox"/>
PHYSICAL CHEMICAL HAZARDS	<i>Reactivity and flammability, etc.</i>	YES	GreenScreen <input type="checkbox"/>
PHYSICAL PROPERTIES	<i>Density, viscosity, vapor pressure, etc.</i>	TO THE EXTENT THAT THEY AFFECT OTHER FACTORS	NONE

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 the following table. In addition to the eight alternatives from the USEPA AA, this table includes NPE and NP (as a transformation product of NPE).

		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	D G	M	D G	H	M	M	DG	DG	DG	DG	DG	H	vH	H	H	M	D G	L	L	
Nonylphenol	84852-15-3	D G	L	D G	D G	H	M	DG	M	DG	DG	DG	DG	v H	vH	vH	H	vH	H	L	L	
Sorbitan monostearate	1338-41-6	L	L	D G	D G	D G	L	DG	L	DG	DG	DG	DG	H	D G	H	H	L	vL	L	L	
Sodium lauryl sulfate	151-21-3	L	L	L	L	D G	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	D G	D G	D G	D G	D G	D G	DG	DG	DG	DG	DG	DG	D G	vH	M	M	L	D G	L	L	
C12-15 alcohols, ethoxylated (9EO)	68131-39-5	L	L	D G	D G	D G	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	D G	D G	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	D G	D G	M	DG	DG	DG	DG	L	DG	H	vH	H	H	vL	D G	L	L	
D-glucopyranose, oligomeric, decyloctyl glycosides	68515-73-1	D G	L	L	L	D G	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	D G	M	DG	DG	DG	DG	L	DG	H	vH	vH	vH	L	D G	L	L	

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

CHEMICAL	DRAFT BENCHMARK	REASON
Nonylphenol ethoxylates (CASRN 127087-87-0)	1	Draft Benchmark Score = 1 for NP transformation product
Sorbitan monostearate (CASRN 1338-41-6)	U	Does not meet minimum data requirements for Group I or Group II Human Health endpoints
Sodium lauryl sulfate (CASRN 151-21-3)	2	GreenScreen [□] Criterion 2f: Very High Eye Irritation
Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether) (CASRN 64366-70-7)	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) (CASRN 68131-39-5)	U	Does not meet minimum data requirements for Group I Human Health
Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt (CASRN 68411-30-3)	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) (CASRN 68439-46-3)	U	Does not meet minimum data requirements for Environmental Fate endpoints
D-glucopyranose, oligomeric, decyloctyl glycosides (CASRN 68515-73-1)	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 (CASRN 9004-82-4)	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 the following table, 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.

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	<i>Acute ecotoxicity</i>	H	=	-	+	-	=	=	+	-
	<i>Chronic ecotoxicity</i>	H	=	=	+	=	=	=	+	-
ADVERSE PUBLIC HEALTH IMPACT	<i>Carcinogenicity</i>	L	=	=	?	=	=	=	?	=
	<i>Mutagenicity</i>	UNK*	+	+	?	+	+	+	+	+
	<i>Reproductive toxicity</i>	M	?	+	?	?	?	+	+	+
	<i>Developmental toxicity</i>	UNK*	?	+	?	?	?	?	+	+
	<i>Endocrine activity</i>	H	?	?	?	?	+	?	?	?
	<i>Acute mammalian toxicity</i>	M	+	-	?	=	=	=	+	=
	<i>Systemic toxicity – single dose</i>	M	?	=	?	?	?	?	?	?
	<i>Systemic toxicity – repeated dose</i>	UNK*	+	+	?	?	?	?	+	?
	<i>Neurotoxicity – single dose</i>	UNK	?	?	?	?	?	?	?	?
	<i>Neurotoxicity – repeated dose</i>	UNK	?	?	?	?	?	?	?	?
	<i>Skin sensitization</i>	UNK*	?	+	?	+	+	+	+	+
	<i>Respiratory sensitization</i>	UNK	?	?	?	?	?	?	?	?
	<i>Skin irritation</i>	H	=	=	?	=	=	=	=	=
<i>Eye irritation</i>	vH	?	=	=	=	+	=	=	=	
ENVIRONMENTAL FATE	<i>Persistence</i>	M	+	+	+	+	+	+	+	+
	<i>Bioaccumulation</i>	H*	+	+	?	+	+	?	+	?
PHYSICAL CHEMICAL HAZARDS	<i>Reactivity</i>	L	=	=	=	=	=	=	=	=
	<i>Flammability</i>	L	=	-	=	=	=	=	=	=

* 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 following table summarizes the data from the hazard assessment and the consideration of additional information, and proceeds to rank the alternatives to NPE in order of preference from highest to lowest.

CHEMICAL	DRAFT BENCHMARK	CLEAN-GREDIENTS STATUS	SCIL RANKING	OVERALL RANKING
Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt (CASRN 68411-30-3)	2DG	Not Listed	Not Listed	1
D-glucopyranose, oligomeric, decyloctyl glycosides (CASRN 68515-73-1)	2DG	Listed	Low Concern	
Sodium lauryl sulfate (CASRN 151-21-3)	2	Listed	Low Concern	2
Sorbitan monostearate (CASRN 1138-41-6)	U	Not Listed	Low Concern	3
Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether) (CASRN 64366-70-7)	U	Not Listed	Low Concern	
C12-15 alcohols, ethoxylated (9EO) (CASRN 68131-39-5)	U	Listed	Low Concern	
C9-11 alcohols, ethoxylated (6EO) (CASRN 68439-46-3)	U	Listed	Low Concern	
Polyoxy (1,2-ethanediyl), alpha-sulfo-omega-dodecyloxy-, sodium salt (CASRN 9004-82-4)	U	Not Listed	Low Concern	

The CleanGredients listing and the SCIL ranking are not sufficient to distinguish between any of the alternatives, so the final ranking is based solely on the draft benchmarks. 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. The following conclusions were reached and are reflected in the table:

- NPE is a chemical of very high concern whose use should be avoided, due its ranking 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 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.

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.

The following actions will be completed to support completion of the Final Alternatives Assessment Report:

- Re-evaluation of relevant factors from this PAA
- Review of production function and performance factors
- Consideration of materials and resource consumption impacts
- Review of economic factors
- Review of the comparison of priority product and alternatives/alternative selection decision
- Submittal of Final Alternatives Assessment Report

These activities are expected to be completed within 26 weeks after approval of this PAA.

This PAA 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.

PREPARER INFORMATION

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Responsible Entity Data

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

Other Involved Parties

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

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.

RESPONSIBLE 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.

ALTERNATIVES ASSESSMENT

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:²

- 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 PAA. 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

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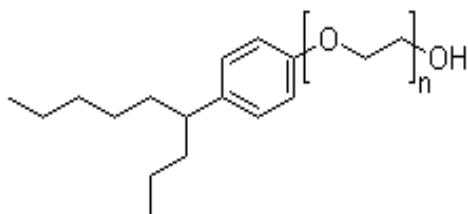
Davis, G.A. et al. Household Cleaners: Environmental Evaluation and Proposed Standards for General Purpose Household Cleaners. University of Tennessee Center for Clean Products and Clean Technologies. July 1992. <http://isse.utk.edu/ccp/pubs/pdfs/HouseholdCleaners-wofigsandapps.pdf>. Accessed May 2013.

be used and for which ones their use should be avoided. The benefit of an all-purpose cleaner is that it 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.

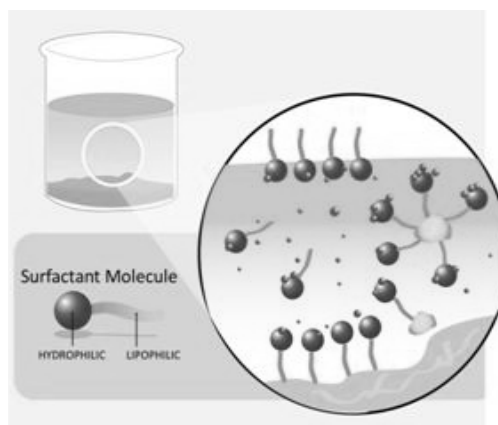
The function of detergency or cleaning is a complex combination of functions. The surface to be cleaned and the soil to be removed must initially be wetted and the soils suspended, solubilized, dissolved or separated in some way so that the soil will not just redeposit on the surface being cleaned.

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).³ 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.⁴ 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 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



³ 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>

⁴ 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.

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 USEPA 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”, 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. It can be found at the following website:

http://ec.europa.eu/environment/ecolabel/ecolabelled_products/categories/purpose_cleaners_en.htm.

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 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 PAA adopts the alternatives to NPE identified by the USEPA in their 2012 DfE Alternatives

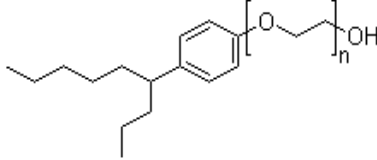
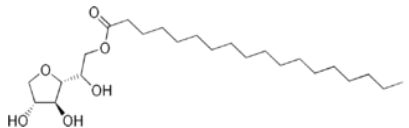
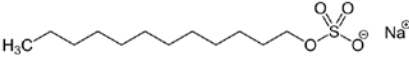
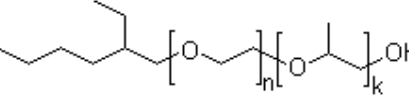
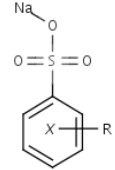
Assessment for Nonylphenol Ethoxylates.⁵ USEPA identified nine representative alternatives to NPE surfactants, including one – octylphenol ethoxylate (OPE10) – which will not be considered herein due to its more-hazardous toxicological profile (as characterized by USEPA).

These alternatives are not all drop-in substitutes, and may need to be blended in order to achieve the necessary functionality. USEPA 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.

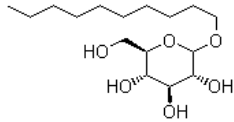
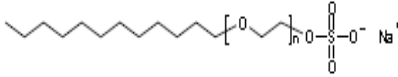
NOTE: Throughout this document, it should be understood that the actual alternatives being evaluated are all-purpose cleaners with a substitute surfactant. However, for the sake of simplicity, this PAA discusses the alternatives as the potential substitute surfactants themselves.

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

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	$\text{CH}_3\text{-(CH}_2\text{)}_{n=12-15}\text{-CH}_2\text{-(O-CH}_2\text{-CH}_2\text{)}_9\text{-OH}$
Linear alkylbenzene sulfonate (LAS)	Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt	68411-30-3	Solid	anionic	

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>

CHEMICAL CLASS	REPRESENTATIVE CHEMICAL NAME	CASRN	DESCRIPTION	TYPE	MOLECULAR STRUCTURE
Linear alcohol ethoxylate (LAE)	C9-11 alcohols, ethoxylated (6EO)	68439-46-3	Colorless liquid	nonionic	$\text{CH}_3-(\text{CH}_2)_{n-9,11}-\text{CH}_2-(\text{O}-\text{CH}_2-\text{CH}_2)_6-\text{OH}$
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; and
- Physicochemical properties.

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 stormwater treatment facilities, or
- release to the environment.

These **are not** directly-relevant factors, nor are they required to be included as such in the PAA. 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, but is not required to be included as such in the PAA. 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.

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).

Preliminary Evaluation and Screening of Alternative Replacement Chemicals

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 USEPA 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 PAA, 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.⁶ No new data was generated for this alternatives assessment. In addition to the eight alternatives from the USEPA AA, this table 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 USEPA, 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.

⁶ Clean Production Action. GreenScreenTM for Safer Chemicals Version 1.2 Criteria. 2012.
<http://www.cleanproduction.org/library/greenscreen-hazard-criteria-2012-03.pdf>

Table 2: Hazard Assessment Summary

Chemical	CASRN	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											
Nonylphenol ethoxylate	127087-87-0	L	DG	M	DG	H	M	M	DG	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	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	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	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	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	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	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	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	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	L

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

Table 3: Preliminary Hazard Assessments of NPE and its Alternatives

CHEMICAL	DRAFT BENCHMARK	REASON
Nonylphenol ethoxylates (CASRN 127087-87-0)	1 _{TP}	Draft Benchmark Score = 1 for NP transformation product
Sorbitan monostearate (CASRN 1138-41-6)	U	Does not meet minimum data requirements for or Group I or Group II Human Health endpoints
Sodium lauryl sulfate (CASRN 151-21-3)	2	GreenScreen [□] Criterion 2f: Very High Eye Irritation
Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether) (CASRN 64366-70-7)	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) (CASRN 68131-39-5)	U	Does not meet minimum data requirements for Group I or Group II Human Health
Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt (CASRN 68411-30-3)	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) (CASRN 68439-46-3)	U	Does not meet minimum data requirements for Group II Human or Environmental Fate endpoints
D-glucopyranose, oligomeric, decyloctyl glycosides (CASRN 68515-73-1)	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 (CASRN 9004-82-4)	U	Does not meet minimum data requirements for Group II Human or Environmental Fate endpoints

2.3 Preliminary Consideration of Additional Information

GreenBlue, in conjunction with USEPA, maintains a database of cleaning product ingredients that have been shown to satisfy the USEPA DfE program criteria (as detailed in the DfE Surfactant criteria (<http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Surfactants>)). 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 USEPA in its NPE alternatives assessment).

Table 4: 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 USEPA 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.

The USEPA also maintains a Safer Chemical Ingredient List (SCIL)⁷, which contains chemicals that meet the criteria of the Design for the Environment (DfE) Safer Product Labeling Program. This list includes

⁷ USEPA. Safer Chemical Ingredients for Use in DfE-Labeled Products. 2013.

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 USEPA 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 USEPA states specifically that there may be chemicals not included in this list that are also safer, and the latter chemical may be among these. All of the chemicals that are listed were rated as “low concern based on experimental and modeled data.”

3 Selected Alternative(s)

The following table summarizes the data from the hazard assessment and the consideration of additional information, and proceeds to rank the alternatives to NPE in order of preference from highest to lowest.

Table 5: Data Summary and Rankings

CHEMICAL	DRAFT BENCHMARK	CLEAN-GREDIENTS STATUS	SCIL RANKING	OVERALL RANKING
Benzenesulfonic acid, C10-13 alkyl derivs., sodium salt (CASRN 68411-30-3)	2DG	Not Listed	Not Listed	1
D-glucopyranose, oligomeric, decyloctyl glycosides (CASRN 68515-73-1)	2DG	Listed	Low Concern	
Sodium lauryl sulfate (CASRN 151-21-3)	2	Listed	Low Concern	2
Sorbitan monostearate (CASRN 1138-41-6)	U	Not Listed	Low Concern	3
Oxirane, methyl-, polymer with oxirane, mono(2-ethylhexyl ether) (CASRN 64366-70-7)	U	Not Listed	Low Concern	
C12-15 alcohols, ethoxylated (9EO) (CASRN 68131-39-5)	U	Listed	Low Concern	
C9-11 alcohols, ethoxylated (6EO) (CASRN 68439-46-3)	U	Listed	Low Concern	
Polyoxy (1,2-ethanediyl), alpha-sulfo-omega-dodecyloxy-, sodium salt (CASRN 9004-82-4)	U	Not Listed	Low Concern	

The CleanGredients listing and the SCIL ranking are not sufficient to distinguish between any of the alternatives, so the final ranking is based solely on the draft benchmarks. 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. The following conclusions were reached and are reflected in the table:

- NPE is a chemical of very high concern whose use should be avoided, due its ranking 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 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.

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.

4 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

APPENDICES

Appendix 1: Basic Information on Surfactants

Appendix 2: GreenScreen[®]

Appendix 3: GreenScreen[®] Assessment Reports

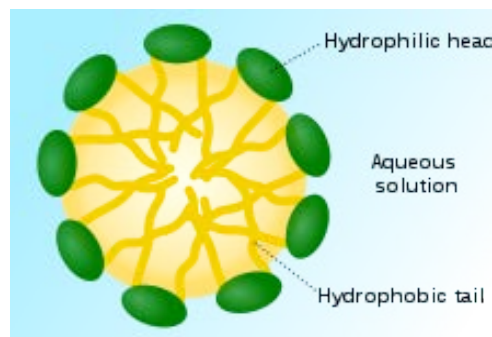
Appendix 4: Administrative Compliance

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.

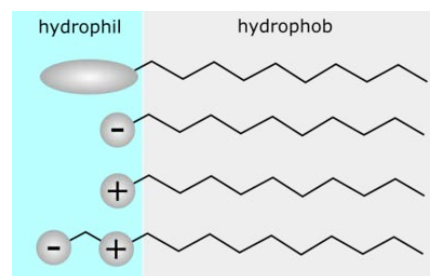
Surfactants are usually organic compounds that are amphiphilic, meaning they contain both hydrophobic groups (their *tails*) and hydrophilic groups (their *heads*). Therefore, a surfactant contains both a water-insoluble (or oil-soluble) component and a water-soluble (oil-insoluble) component. Surfactants 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?

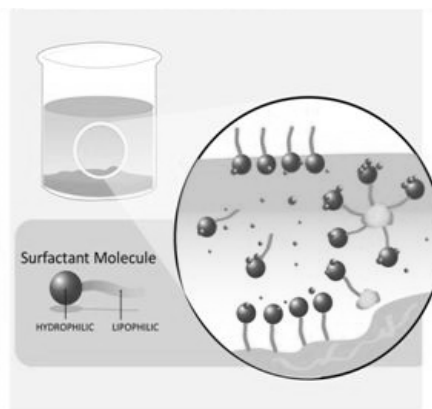
Surfactant classification according to the composition of their head: nonionic, anionic, cationic, amphoteric. Most commonly, surfactants are classified according to the polar head group (on the left in the adjacent diagram). A non-ionic surfactant has no charge groups in its head. The head of an ionic 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 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 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 (GreenScreenTM) 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.⁸

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

GreenScreenTM 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.

⁸ Clean Production Action website. <http://www.cleanproduction.org/Greenscreen.php>. Accessed May 2013.



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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

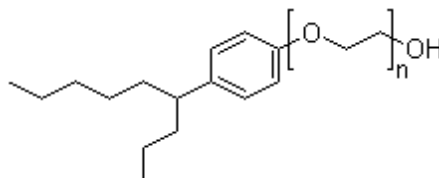
Confirm application of the *de minimus* rule: NA

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 USEPA alternatives assessment⁵ 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.

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	DG	M	DG	H	M	M	DG	DG	DG	DG	DG	H	vH	H	H	M	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:

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 nonylphenoxyethoxyacetic acid).⁹ 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 USEPA 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 USEPA AWQC and its scientific basis are consistent with similar findings and regulatory actions taken by governments in Europe, Canada and Japan. USEPA has rated the toxicity of NP as “very high,” based on experimental LC₅₀ values in the range of 0.13-1.4 ppm in fish, EC₅₀ values in the range of 0.14-0.47 ppm in daphnia and EC₅₀ 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.¹⁰

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:

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

⁹ ToxEcology Environmental Consulting Ltd. 2002. Alternatives to Nonylphenol Ethoxylates: Review of Toxicity, Biodegradation, and Technical-Economic Aspects. Prepared for Environment Canada.

a) ¹⁰ US Environmental Protection Agency. 2012. DfE Alternatives Assessment for Nonylphenol Ethoxylates. Washington, D.C. <http://www.epa.gov/dfepubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf>

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.

- USEPA 2006 -
 - Based on experimental oral LD₅₀ 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/EC₅₀ values in the >1-10 range.

- USEPA 2012 -

- Based on experimental LC₅₀ values for NPE9 in the range of 1.0-14 ppm in fish, EC₅₀ values for NPE9 in the range of 2.9-14.0 ppm in daphnia and an EC₅₀ 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.

- USEPA 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.

- USEPA 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.

- USEPA 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

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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

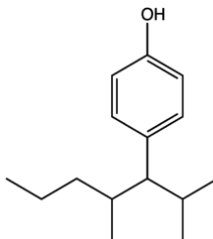
Confirm application of the *de minimus* rule: N/A

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 USEPA alternatives assessment⁵ 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.

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	DG	DG	H	M	--	M	DG	DG	DG	DG	vH	vH	vH	H	<i>vH</i>	<i>H</i>	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).

Note: See Appendix 2 for the hazard acronyms

Transformation Products and Ratings:

No data are available on transformation products of nonylphenol.

Hazard Classification Summary:

Group I Human Health Effects (Group I Human)

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.

- USEPA 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 LD₅₀ value of 1880 mg/kg-bw.

- USEPA 2009 -
 - Acute oral toxicity LD₅₀ 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.

- USEPA 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[□].

- USEPA 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[®].

- USEPA 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.

- USEPA 2005 -
 - In freshwater studies, observed EC₅₀ values for Daphnia magna ranged from 104-190 µg/l. Observed LC₅₀ values for 3 trout species and two trout subspecies ranged from 140-270 µg/l. Observed LC₅₀ values for 9 threatened/endorsed species or surrogates thereof ranged from 110-289 µg/l. Observed LC₅₀ values for fathead minnow ranged from 128-360 µg/l, and for bluegill the value was 209 µg/l.
 - In saltwater studies, observed LC₅₀ 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 LC₅₀ values (see Acute Aquatic Toxicity data summary above).

- USEPA 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 USEPA PBT Profiler tool. This was the most conservative score based on various sources of data and estimates.

- USEPA 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.

- USEPA 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

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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 I 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	A	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	<i>vL</i>	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:

USEPA 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.
- USEPA 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 LD₅₀ values in the >2000 mg/kg range.

- USEPA 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. LD₅₀ > 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.

- USEPA 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.

Ecotoxicity (Ecotox)**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/EC₅₀ values in the >1-10 range.

- USEPA 2012 -
 - Based on an experimental LC₅₀ value of > 6.3 ppm in fish, an EC50 value of >13 ppm in daphnia and an EC₅₀ 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.

- USEPA 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.

- USEPA 2012 -
 - Based on experimental data indicating that sorbitan monostearate achieves $\geq 75\%$ 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.

- USEPA 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.

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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

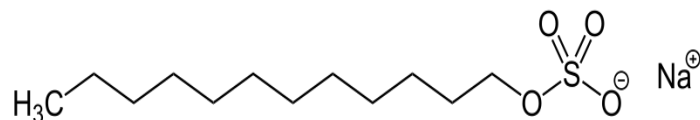
Confirm application of the *de minimus* rule: NA

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	<i>M</i>	<i>M</i>	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.¹¹

a) ¹¹ 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.

- USEPA 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, LD₅₀ data are found in the range of >50-300 mg/kg, placing them in the **HIGH** category.

- ESIS -
 - IUCLID data for oral LD₅₀ range from 200-2800 mg/kg (HIGH). Dermal LD₅₀ 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/EC₅₀ values in the <=1 range.

- USEPA 2012 -
 - Based on experimental LC₅₀ values ranging from 1.0-34.9 ppm in fish, EC₅₀ values ranging from 1.8-49 ppm in daphnia and EC₅₀ 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.

- USEPA 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.

- USEPA 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 that C12 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

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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>

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US Environmental Protection Agency. 2012. DfE Alternatives Assessment for Nonylphenol Ethoxylates. Washington, D.C. <http://www.epa.gov/dfepubs/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

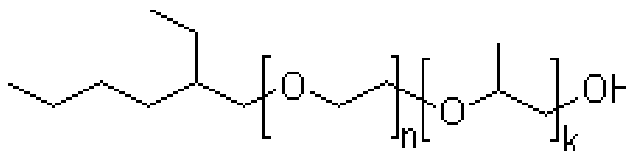
Confirm application of the *de minimus* rule: NA

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										
<i>DG</i>	<i>DG</i>	<i>DG</i>	<i>DG</i>	<i>DG</i>	<i>DG</i>	--	<i>DG</i>	<i>DG</i>	<i>DG</i>	<i>DG</i>	<i>DG</i>	<i>DG</i>	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:

USEPA 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 EC₅₀ values in the >10-100 range.

- USEPA -
 - Based upon an experimental 48-hr EC₅₀ data of > 100 ppm in daphnia and a 72-hr EC₅₀ 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.

- USEPA -
 - 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/EC₅₀ 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.

- USEPA -
 - 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.

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US Environmental Protection Agency. 2012. DfE Alternatives Assessment for Nonylphenol Ethoxylates. Washington, D.C. <http://www.epa.gov/dfepubs/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

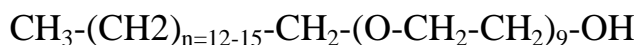
Confirm application of the *de minimus* rule: NA

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):



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 completely 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 <200,000 $\mu\text{g/L}$; 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 LD₅₀ 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 LD₅₀ 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 LD₅₀ values typically greater than the maximum applied dose, ranging from greater than 0.8 to greater than 5 g/kg in rats. LD₅₀ 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

Ecotoxicity (Ecotox)

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/EC₅₀ values in the <=1 ppm range.

- USEPA 2012 -
 - Based on experimental LC₅₀ values ranging from 1.2-11.0 ppm in fish, EC₅₀ values ranging from 1.3-1.6 ppm in daphnia and an EC₅₀ 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.

- USEPA 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.

- USEPA 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

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Chemwatch. 2010. Chemical Database and Management Systems.

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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

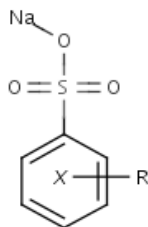
Confirm application of the *de minimus* rule: NA

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.¹²

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 LD₅₀ 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 USEPA 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 USEPA 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 USEPA 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/EC₅₀ values in the >1-10 ppm range.

- USEPA 2012 -
 - Based on experimental 96-hr LC₅₀ values in the range of 1.7-7.8 ppm in fish, 48-hr EC₅₀ values in the range of 1.62-9.3 ppm in daphnia, and 72-hr and 96-hr EC₅₀ 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.

- USEPA 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.

- USEPA 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

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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/dfepubs/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

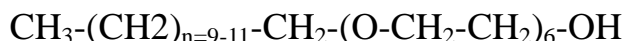
Confirm application of the *de minimus* rule: NA

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):



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	<i>M</i>	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 completely 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 <200,000 $\mu\text{g/L}$; 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

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"

Ecotoxicity (Ecotox)

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/EC₅₀ values in the >1-10 ppm range.

- USEPA 2012 -
 - Based on experimental LC₅₀ 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.

- USEPA 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.

- USEPA 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

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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

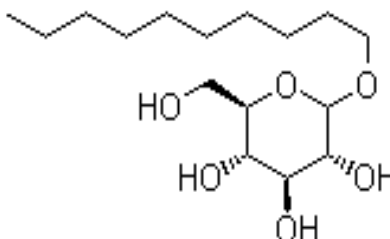
Confirm application of the *de minimus* rule: NA

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:

USEPA 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.

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

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/EC₅₀ values in the >10-100 ppm range.

- USEPA 2012 -
 - Based upon an experimental 96-hr LC₅₀ of 101 ppm in fish, an experimental 48-hr EC₅₀ of 20 ppm in daphnids and an experimental 72-hr EC₅₀ 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.

- USEPA 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.

- USEPA 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 Labelling Inventory. <http://clp-inventory.echa.europa.eu/SummaryOfClassAndLabelling.aspx?SubstanceID=135996&HarmOnly=no?DisclaimerAgree=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/dfepubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf>

GreenScreen[□] Assessment for Polyoxy (1,2-Ethanediy), 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: Poxoxy (1,2-Ethanediy), 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

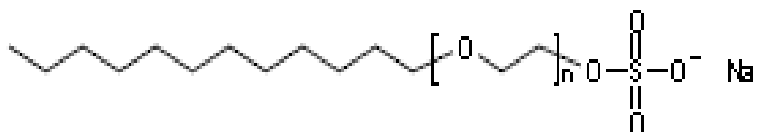
Date: NA

Confirm application of the *de minimus* rule: NA

Chemical Name (CAS #): Polyoxy (1,2-Ethanediy), 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-Ethanediy), 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 β -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.¹³

Hazard Classification Summary Section:

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M or L): L

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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%20web%20wd.pdf>

Polyoxy (1,2-Ethanediy), 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-Ethanediy), 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-Ethanediy), 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-Ethanediy), 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-Ethanediy), 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 LD₅₀ 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-Ethanediy), 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-Ethanediy), 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-Ethanediy), 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-Ethanediy), Alpha-Sulfo-Omega-Dodecyloxy-, Sodium Salt was assigned a score of **VERY HIGH** for acute aquatic toxicity based on LC/EC₅₀ values in the <=1 range.

- USEPA 2012 -
 - Based on experimental 96-hr LC₅₀ values in the range of 1.0-28 ppm in fish, a 96-hr EC₅₀ of 1.17 ppm in daphnia, and an LC₅₀ 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-Ethanediy), 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.

- USEPA 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-Ethanediy), 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.

- USEPA 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-Ethanediy), 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-Ethanediy), 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/dfepubs/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 PAA 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;
NA	(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 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;

COMPLIANCE LOCATION	TEXT
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.
NA	(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 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 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.
NA	(2) The name of, and contact information for, any known responsible entity(ies).

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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	
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: <ol style="list-style-type: none"> <li data-bbox="576 1879 1435 1921">1. The replacement chemical(s) is/are not on the list of Candidate Chemicals; or <li data-bbox="576 1921 1435 1953">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

COMPLIANCE LOCATION	TEXT
NA	Priority Product; has the same intended use(s) and targeted customer base(s) as the
NA	Priority Product; and fulfills the functional, performance, and legal requirements of the Priority Product.
	(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
NA	(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	
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COMPLIANCE LOCATION	TEXT
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);
NA	(C) Information regarding the reformulated product has been provided to persons selling or distributing the Priority Product in California; and
NA	(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	(4)
NA	(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	(6) The source of the Chemical(s) of Concern in the Priority Product;
NA	(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	(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.
NA	(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

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	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 Entire Report	(α) AA Stages. (1) An AA must be conducted in two stages.
Entire Report	(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	
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.
NA	(C) The responsible entity submits an Alternate Process AA Work Plan to the Department 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.

COMPLIANCE LOCATION	TEXT
NA	<p>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.</p>
NA	<p>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.</p>
NA NA	<p>(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.</p>
NA	<p>(E)</p> <p>1. The responsible entity timely submits a Final AA Report to the Department that substantially complies with section 69505.7.</p> <p>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).</p>
NA	<p>(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.</p>
NA	<p>(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.</p>
NA	<p>(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).</p>
NA NA	<p>(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 AA Report requirements of section 69505.7.</p>
NA	<p>(ε) Revised Alternative Selection Decision.</p> <p>(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</p>

COMPLIANCE LOCATION	TEXT
NA	Final AA Report in accordance with the procedures and criteria set forth in section 69505.9.
	(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.
NA	(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
	<p>The first stage of the AA shall include the six (6) steps described below:</p>
Section 1.1	(α) Step 1, Identification of Product Requirements and Function(s) of Chemical(s) of Concern.
Sections 1.1, 1.2, 1.3	(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.
Section 1.1	(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).
Section 1.4 NA	(3)
NA	<p>(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).</p> <p>(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.</p>
Section 2.1	(β) Step 2, Identification of Alternatives.
Section 2.1	(1)
Section 2.1	<p>(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).</p> <p>(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.</p>
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).
Section 2.2	(γ) Step 3, Identification of Factors Relevant for Comparison of Alternatives.
Section 2.2	(1) A factor listed in paragraph (2), in conjunction with an associated exposure pathway and life cycle segment, if applicable, is relevant if:
Section 2.2	<p>(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</p>
Section 2.2	(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 or more alternatives.
	(2) The responsible entity shall use available quantitative information and analytical tools,

COMPLIANCE LOCATION	TEXT
Section 2.2.1	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:
Section 2.2.2	(A) Adverse environmental impacts;
Section 2.2.3	(B) Adverse public health impacts;
Section 2.2.4	(C) Adverse waste and end-of-life effects;
Section 2.2.5	(D) Environmental fate;
Section 2.2.6	(E) Materials and resource consumption impacts;
Section 2.2.7	(F) Physical chemical hazards; and
Section 2.2	(G) Physicochemical properties.
Section 2.2	(3) The responsible entity's identification of relevant exposure pathways shall consider both of the following:
Section 2.2	(A) Chemical quantity information:
Section 2.2	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
Section 2.2	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.
Section 2.3	(B) Exposure factors specified in section 69503.3(b).
Section 2.3	(δ) Step 4, Initial Evaluation and Screening of Alternative Replacement Chemicals.
Section 2.3	(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:
Section 2.3	(A) Adverse environmental impacts;
Section 2.3	(B) Adverse public health impacts;
Section 2.3	(C) Environmental fate;
Section 2.3	(D) Physical chemical hazards; and
NA	(E) Physicochemical properties.
Section 2.4	(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.

COMPLIANCE LOCATION	TEXT
Entire Report Section 4	<p>(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.</p>
Entire Report	<p>(φ) Step 6, Preliminary AA Report Preparation.</p> <p>(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.</p> <p>(2) The responsible entity shall prepare and submit to the Department a Preliminary AA Report as specified in section 69505.7.</p>

Compliance with Section 69505.6: Alternatives Analysis: Second Stage

COMPLIANCE LOCATION	TEXT
NA	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:
NA	(α) Step 1, Identification of Factors Relevant for Comparison of Alternatives.
NA	(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.
NA	(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:
NA	1. The useful life of the Priority Product, and that of the alternatives under consideration;
NA	2. The function and performance of each alternative relative to the Priority Product and other alternatives under consideration; and
NA	3. Whether an alternative exists that is functionally acceptable, technically feasible, and economically feasible.
NA	(3) Economic impacts.
NA	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:
NA	a. Public health and environmental costs; and
NA	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.
NA	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.
NA	(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 69505.5(c). The responsible entity shall compare each alternative with the Priority Product and with each of the other alternatives under consideration.
NA	(γ) 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

COMPLIANCE LOCATION	TEXT
NA	<p>section. This may include, but is not limited to, reconsideration of the factors and information identified in section 69505.5.</p>
NA	<p>(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).</p> <p>(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.</p>

Compliance with Section 69505.7: Alternatives Analysis Reports

COMPLIANCE LOCATION	TEXT
Entire Report	<p>(α) General Requirements.</p> <p>(1) Preliminary and Final AA Reports and Abridged AA Reports must each include all of the applicable information specified in subsections (b) through (k).</p> <p>(2) The responsible entity shall include in the AA Reports sufficient information for the Department to determine:</p>
Appendix 4 NA	<p>(A) Compliance with the substantive and administrative requirements of this article; and</p> <p>(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.</p>
NA	<p>(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.</p>
Entire Report NA	<p>(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.</p>
NA	<p>(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.</p> <p>(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.</p>
Page 1	<p>(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.</p>
Page 4	
Page 4	<p>(χ) Preparer Information. This section of the AA Report must include:</p>
Page 4	<p>(1) The name of, and contact information for, the person submitting the AA Report;</p>
Page 4	<p>(2) If applicable, the name of, and contact information for, all responsible entities on whose behalf the AA Report is being submitted; and</p>
Page 5	<p>(3) The names of the parties that were involved in funding, directing, overseeing, preparing, and/or reviewing the AA.</p>
Page 5	<p>(δ) Responsible Entity and Supply Chain Information. This section of the AA Report must include:</p>
Page 5	<p>(1) The name of, contact information for, and headquarters location of the manufacturer(s) and 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;</p>
Page 5	

COMPLIANCE LOCATION	TEXT
Page 5	(2) The name of, and contact information for, any person(s) identified on the Priority Product label as the manufacturer, importer, or distributor;
Section 1	(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.
Section 1	(ε) Priority Product Information. This section of the AA Report must include:
Section 1	(1) The brand name(s) and product name(s) under which the Priority Product is placed into the stream of commerce in California;
Section 1	(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;
Section 1	(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).
Section 2.3	(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.
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.
NA	(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.
NA	(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
Section 2.3,	

COMPLIANCE LOCATION	TEXT
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.
Entire Report	(3) The responsible entity shall demonstrate in the Final AA Report that all of the requirements of section 69505.6 have been met.
NA	
NA	(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.
NA	(t) Supporting Information.
NA	
NA	(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).
NA	
Section 3	
Section 3	(2) The Final AA Report must identify information that is not currently available but, if it were available, could be used to:
NA	(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.
NA	(φ) Selected Alternative(s).
NA	(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.
NA	(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 more selected alternatives retains the Chemical(s) of Concern or uses one or more replacement chemicals.
NA	(C) A list of all chemicals known, based on available information, to be in the selected 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 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	

COMPLIANCE LOCATION	TEXT
NA NA NA NA NA NA NA NA NA	<p>2. Hazard trait and environmental and toxicological endpoint information that has not already been provided to the Department under this chapter;</p> <p>3. Information about the chemical purity, meaning the relative absence of extraneous matter, and identification of known impurities and additives in the chemical;</p> <p>4. Physicochemical properties; and</p> <p>5. Substance identification information, including all of the following that are applicable:</p>
NA NA NA NA	<p>a. Chemical abstract services number;</p> <p>b. Structural formula;</p> <p>c. Molecular weight;</p> <p>d. Synonyms;</p> <p>e. International Union of Pure and Applied Chemistry name;</p>
NA	<p>f. European Commission number;</p> <p>g. Registry of Toxic Effects of Chemical Substances number;</p>
Section 4	<p>h. International Union of Biochemistry and Molecular Biology number;</p>
Section 4	<p>i. Japan Ministry of International Trade and Industry number;</p> <p>j. Number assigned by the United Nations Experts on the Transport of Dangerous Goods;</p> <p>k. North America Department of Transportation number;</p>
Section 4	<p>l. European Inventory of Existing Commercial Chemical Substances number;</p> <p>m. European List of Notified Chemical Substances number;</p> <p>n. European Commission Directive 67/548/EEC No Longer Polymers number; and</p> <p>o. Other commonly recognized substance identification system numbers.</p>
	<p>(κ) Next Steps.</p>
	<p>(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).</p>
NA	
NA	<p>(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) months after the Department issues a notice of compliance for the Preliminary AA Report. If the Department approves an extended due date under section 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 later than twelve (12) months after the Department issues a notice of compliance for the Preliminary AA Report. Each progress report must include:</p>
NA	
NA	
NA	
NA	<p>1. Preparer information specified in subsection (c);</p>
NA	<p>2. Priority Product information specified in subsection (e);</p>
NA	<p>3. A summary of achievements since the last progress report;</p>
NA	<p>4. A summary and discussion of issues that have arisen and their resolutions;</p>
NA	<p>5. A summary of work that is pending; and</p>
NA	<p>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.</p>
NA	<p>(B) The responsible entity may request an extended due date for submittal of the Final AA</p>

COMPLIANCE LOCATION	TEXT
NA	<p>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, 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.</p> <p>(2) Implementation of selected alternatives. The Final AA Report must include a detailed plan for implementing any selected alternative(s).</p> <p>(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.</p> <p>(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.</p>

Compliance with Section 69505.8: Public Comments on AA Reports

COMPLIANCE LOCATION	TEXT
NA	<p>(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.</p>
NA	<p>(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.</p>
NA	<p>(γ) 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.</p>

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).
NA	(γ) 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 LOCATION	TEXT
NA NA	<p>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:</p>
NA NA	<p>(A) The close of the public comment period, if no public comments are received; or</p> <p>(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.</p>
NA NA	<p>(2) Notice of Deficiency.</p> <p>(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.</p>
NA	<p>(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.</p>
NA	<p>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.</p>
NA	<p>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.</p>
NA	<p>(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).</p>
NA	<p>(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.</p>
NA	<p>(ε) Issuance of Notices. All notices issued by the Department under this section shall be issued to the 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.</p>