

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 31 January 2020

Group Name: Alcohol ethoxylate sulfates (AES)

General structure: -

Revision history

Version	Date	Description
1.0	31 January 2020	

Substances within this group:

EC / List number	CAS number	Substance name Registra type (full, or TII, NO highest to band amo the registrat (t/y)	
221-416-0	3088-31-1	sodium 2-[2-(dodecyloxy)ethoxy]ethyl sulfate	Full, not (publicly) available
266-840-7	67656-24-0	sodium 2-butoxyethyl sulfate	Full, not (publicly) available
500-189-4	68081-91-4	Alcohols, C12-18, ethoxylated, sulfates, sodium salts	Full, not (publicly) available
500-233-2	68891-29-2	Alcohols, C8-10, ethoxylated, sulfates, ammonium salts	Full, not (publicly) available
500-234-8	68891-38-3	Alcohols, C12-14, ethoxylated, sulfates, sodium salts	Full, >1000
500-343-0	157627-92-4	Alcohols, C10-16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts	Full, not (publicly) available
500-344-6	157627-94-6	Alcohols, C10-16, ethoxylated, sulfates, triethanolammonium salts	Full, not (publicly) available
500-345-1	157627-95-7	Alcohols, C16-18 and C18-unsatd., ethoxylated, sulfates, sodium salts	Full, not (publicly) available
500-464-9	160901-27-9	Alcohols, C9-11, branched and linear, ethoxylated, sulfates, ammonium salts	Full, not (publicly) available
500-465-4	160901-28-0	Alcohols, C9-11, branched and linear, ethoxylated, sulfates, sodium salts	Full, 100-1000
500-513-4	161074-79-9	Alcohols, C12-13, branched and linear, ethoxylated, sulfates, sodium salts	Full, >1000
932-185-7	1187742-72- 8	Alcohols, C12-14 (even numbered), ethoxylated (<=2.5 moles EO), sulfated, monoisopropanolamine salt	Full, 100-1000
938-445-6	1469982-91- 9	Alcohols, C16-18 (even numbered, C18-unsatd.), ethoxylated, and alcohols C20-22 (even numbered), sulfates, ammonium salts	Cease manufacture
939-523-2	1471312-55- 6	Poly(oxy-1,2-ethanediyl), .alphasulfo- .omegahydroxy-, C8-10-alkyl ethers, sodium salts	Full, not (publicly) available

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¹ Note that the total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

EC / List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) 1
939-575-6	Not available	Alcohols, C12-14 (linear, even- numbered), ethoxylated, sulfates, ammonium salts, < 2.5 mol EO	Full, >1000
939-578-2	Not available	Alcohols, C12-14 (even-numbered), ethoxylated, magnesium salts, < 2.5 mol EO	Full, not (publicly) available
939-597-6	Not available	Alcohols, C10-12, ethoxylated (1-2.5 EO), sulfated, sodium salts	Full, not (publicly) available
236-091-0	13150-00-0	Sodium 2-[2-[2- (dodecyloxy)ethoxy]ethoxy]ethyl sulphate	Not registered
239-925-1	15826-16-1	Sodium 2-(dodecyloxy)ethyl sulphate	Not registered
244-737-8	22031-09-0	Sodium 2-(2-butoxyethoxy)ethyl sulphate	Not registered
246-985-2	25446-78-0	Sodium 2-[2-[2- (tridecyloxy)ethoxy]ethoxy]ethyl sulphate	Not registered
246-986-8	25446-80-4	Sodium 2-[2-[2- (tetradecyloxy)ethoxy]ethoxy]ethyl sulphate	Not registered
266-192-5	66161-57-7	Sodium 3,6,9,12,15,18,21,24,27,30,33,36-dodecaoxaoctatetracontyl sulphate	Not registered
500-172-1	67762-19-0	Alcohols, C10-16, ethoxylated, sulfates, ammonium salts	Not registered
500-173-7	67762-21-4	Alcohols, C10-16, ethoxylated, sulfates, magnesium salts	Not registered
500-223-8	68585-34-2	Alcohols, C10-16, ethoxylated, sulfates, sodium salts	Not registered
500-224-3	68585-40-0	Alcohols, C16-18, ethoxylated, sulfates, sodium salts	Not registered
500-298-7	110392-50-2	Alcohols, C12-13, ethoxylated, sulfates, sodium salts	Not registered
500-314-2	125301-92-0	Alcohols, C12-15, ethoxylated, sulfates, sodium salts	Not registered
500-487-4	161025-30-5	Alcohols, C12-16, ethoxylated, sulfates, sodium salts	Not registered
500-512-9	161074-78-8	Alcohols, C12-16, ethoxylated, sulfates, sodium salts	Not registered
605-725-1	174450-50-1	Alcohols, C12-14 (even numbered), ethoxyated, sulfated, triisopropanolamine-NH4 salt	Not registered
608-760-0	32612-48-9	Ammonium Laureth Sulfate	Not registered

EC / List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) 1
616-006-7	73665-22-2	Poly(oxy- 1,2-ethanediyl), .alphasulfo- .omegahydroxy-C6-10-alkyl ethers, sodium salts	Not registered
617-428-4	83016-76-6	2-hydroxypropan-1-aminium 12-{2-[2- (sulfonatooxy)ethoxy]ethoxy}dodecylidy ne	Not registered
618-398-5	9004-82-4	2-dodecoxyethyl hydrogen sulfate	Not registered
618-573-6	9051-57-4	Ammonium nonylphenyl polyoxyethylene sulfate	Not registered

This table does not contain group members that are only notified under the CLP Regulation. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

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Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on a different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, a more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website².

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² https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

Assessment of Regulatory Needs
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Compliance Check
Harmonised classification and labelling
Carcinogenic, mutagenic and/or toxic to reproduction
Dossier evaluation
Endocrine disruptor
Notified new substances
Occupational exposure limit
On-site isolated intermediate or transported isolated intermediate
Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
Regulatory management options analysis
Regulatory risk management
Substance evaluation
Specific target organ toxicity, repeated exposure
Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the alcohol ethoxy sulphate moiety.

The group of "alcohol ethoxylate sulphates" (AES) is composed of 37 members of which 16 have active registrations and one substance has inactive registration (cease manufacture) and 20 are non-registered substances. 16 substances are part of a registrant category "AESs C8-C18 category". One registered substance has alkyl chain C4.

Based on information reported in the REACH registration dossiers, AES are used as anionic surfactants and processing aids in a large variety of sectors that include e.g. uses in adhesives and sealings, washing and cleaning products, textile coating, cosmetics and personal care products.

The substances have industrial, widespread professional and consumer uses and article service life reported. In addition, several substances have high production volumes, thus exposure to humans and releases in the environment are expected.

There are no relevant completed or ongoing regulatory risk management activities for any of the substances.

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is à priori considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

2 Justification for the no need for regulatory risk management action at EU level

Based on currently available information, there is no need for (further) EU regulatory risk management for any of the hazard endpoints assessed for all group members.

All substances appear to be of low toxicological and environmental concern and therefore are considered as **low priority for further EU regulatory risk management action**.

Based on ECHA's assessment of currently available information on human health hazards, all substances are self-classified in registration dossiers as eye corrosive/irritant (H318/H319). All except one are classified as skin irritant (H315) and one is classified as skin sensitizer (H317) (one notifier out of many). However, based on the assessment the criteria for skin sensitisation for this substance are not met. Industry should consider to update the registration dossier.

The available information at this stage does not indicate a concern for mutagenicity or systemic toxicity. Therefore, there is currently no indication of potential CMR properties.

The validity of read-across used by registrants is proposed to be checked under compliance check to confirm the low hazard and eventually further data may be requested if needed.

Based on ECHA's assessment of currently available information on environmental hazards, most AESs are neither PBT nor vPvB substances, as they are shown to be readily biodegradable. However, there is currently no information on biodegradation for unsaturated members (C16-C18) of the group which should be addressed through the compliance check.

The registrants self-classify substances with C13 and longer C-chain length constituents present in the substance composition as Aquatic Chronic 3. Generation of missing aquatic toxicity data with substances with shorter C-chain length would be used to confirm registrants' hypothesis about the trend in aquatic toxicity (the toxicity of the AES increases with increasing carbon chain lengths) and would indicate the need (or not) for environmental classification of these substances.

All registered substances are proposed for compliance check to clarify their low hazard potential.

If the registration status changes for the non-registered substances, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
AES category C8-C18 (15 substances):	No hazard or	No hazard or	Uses e.g. in	Currently no	CCII for active
221-416-0	unlikely hazard	unlikely hazard	adhesives and sealings, washing	need for EU RRM	CCH for active registered
Sodium 2-(2-dodecyloxy-ethoxy)ethyl sulphate			and cleaning products, textile coating,	Justification:	substances
500-189-4			cosmetics and body care	Compliance check to confirm low	
Alcohols, C12-18, ethoxylated, sulfates, sodium salts			products. Widespread uses	hazard for HH and ENV	
500-233-2			with potential for exposure to both		
Alcohols, C8-10, ethoxylated, sulfates, ammonium salts			human and the environment, in industrial		
500-234-8			settings, by professional		
Alcohols, C12-14, ethoxylated, sulfates, sodium salt			workers and consumers as		
500-343-0			well as for uses in articles.		

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Alcohols, C10-16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts					
500-344-6					
Alcohols, C10-16, ethoxylated, sulfates, triethanolammonium salts					
500-345-1					
Alcohols, C16-18 and C18-unsatd., ethoxylated, sulfates, sodium salts					
500-464-9					
Alcohols, C9-11, branched and linear, ethoxylated, sulfates, ammonium salts					
500-465-4					
Alcohols, C9-11, branched and linear, ethoxylated, sulfates, sodium salts					
500-513-4					
Alcohols, C12-13, branched and linear, ethoxylated, sulfates, sodium salts					
932-185-7					

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Alcohols, C12-14 (even numbered), ethoxylated (<=2.5 moles EO), sulfated, monoisopropanolamine salt					
939-523-2					
Poly(oxy-1,2-ethanediyl), .alphasulfoomegahydroxy-, C8-10-alkyl ethers, sodium salts Alcohols, C8-10, ethoxylated, sulfates, sodium salts					
939-575-6					
Alcohols, C12-14 (linear, even-numbered), ethoxylated, sulfates, ammonium salts, < 2.5 mol EO					
939-578-2					
Alcohols, C12-14 (even-numbered), ethoxylated, magnesium salts, < 2.5 mol EO					
939-597-6					
Alcohols, C10-12, ethoxylated (1-2.5 EO), sulfated, sodium salts					
Substance with alkyl chain C4 (1 substance):					
266-840-7					

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
sodium 2-butoxyethyl sulphate					
Not registered substances (20 substances)					
236-091-0					
Sodium 2-[2-[2- (dodecyloxy)ethoxy]ethoxy]ethyl sulphate					
239-925-1					
Sodium 2-(dodecyloxy)ethyl sulphate					
244-737-8					
Sodium 2-(2-butoxyethoxy)ethyl sulphate					
246-985-2					
Sodium 2-[2-[2- (tridecyloxy)ethoxy]ethoxy]ethyl sulphate					
246-986-8					
Sodium 2-[2-[2- (tetradecyloxy)ethoxy]ethoxy]ethyl sulphate					
266-192-5					

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Sodium 3,6,9,12,15,18,21,24,27,30,33,36-dodecaoxaoctatetracontyl sulphate					
500-172-1					
Alcohols, C10-16, ethoxylated, sulfates, ammonium salts					
500-173-7					
Alcohols, C10-16, ethoxylated, sulfates, magnesium salts					
500-223-8					
Alcohols, C10-16, ethoxylated, sulfates, sodium salts					
500-224-3					
Alcohols, C16-18, ethoxylated, sulfates, sodium salts					
500-298-7					
Alcohols, C12-13, ethoxylated, sulfates, sodium salts					
500-314-2					

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Alcohols, C12-15, ethoxylated, sulfates, sodium salts					
500-487-4					
Alcohols, C12-16, ethoxylated, sulfates, sodium salts					
500-512-9					
Alcohols, C12-16, ethoxylated, sulfates, sodium salts					
605-725-1					
Alcohols, C12-14 (even numbered), ethoxyated, sulfated, triisopropanolamine- NH4 salt					
608-760-0					
Ammonium Laureth Sulfate					
616-006-7					
Poly(oxy- 1,2-ethanediyl), .alphasulfo- .omegahydroxy-C6-10-alkyl ethers, sodium salts					
617-428-4					

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
2-hydroxypropan-1-aminium 12-{2-[2- (sulfonatooxy)ethoxy]ethoxy}dodecylidyne					
618-398-5					
2-dodecoxyethyl hydrogen sulfate					
618-573-6					
Ammonium nonylphenyl polyoxyethylene sulfate					
Cease manufacture					
938-445-6					
Alcohols, C16-18 (even numbered, C18-unsatd.), ethoxylated, and alcohols C20-22 (even numbered), sulfates, ammonium salts					

Annex 1: Overview of classifications

Data extracted on 28 October 2019.

EC/List No			Self-classification					
	name	Harmo nised classifi cation	Self-classification in registration dossier	Additional classification in C&L notifications				
221-416-0	sodium 2-[2- (dodecyloxy) ethoxy]ethyl sulfate	./.	Eye irrit 2 H319 Skin sens, H317 Skin irrit 2, H315	Acute Tox 4 oral, H302 STOT SE 3, H335 (resp. irritation) Aquatic Chronic 2, H411				
266-840-7	sodium 2- butoxyethyl sulfate	./.	Eye dam 1, H318	Eye irrit 2, H319				
500-189-4	Alcohols, C12-18, ethoxylated, sulfates, sodium salt	./.	Eye dam 1, H318 Skin irrit 2, H315 Aquatic chronic 3, H412	Eye irrit 2, H319				
500-233-2	Alcohols, C8- 10, ethoxylated, sulfates, ammonium salts	./.	Eye dam 1, H318 Skin irrit 2, H315	Skin sens, H317 Eye irrit 2, H319				
500-234-8	Alcohols, C12-14, ethoxylated, sulfates, sodium salts	./.	Eye dam 1, H318 Skin irrit 2, H315 Aquatic chronic 3, H412	Eye irrit 2, H319				
500-343-0	Alcohols, C10-16, ethoxylated, sulfates, mono (hydroxyeth yl) ammonium salts	.1.	Eye dam 1, H318 Skin irrit 2, H315 Aquatic chronic 3, H412	.1.				
500-344-6	Alcohols C12-14,	./.	Eye dam 1, H318	./.				

EC/List No	Substance name		Self-classification							
	Tiame	Harmo nised classifi cation	Self-classification in registration dossier	Additional classification in C&L notifications						
	ethoxylated, sulfated, triethanolam monium salts		Skin irrit 2, H315 Aquatic chronic 3, H412							
500-345-1	Alcohols, C16-18 and C18-unsatd., ethoxylated, sulfates, sodium salts	./.	Eye dam 1, H318 Skin irrit 2, H315 Aquatic chronic 3, H412	Eye irrit 2, H319						
500-464-9	Alcohols C9- 11, branched and linear, ethoxylated, sulfates, ammonium salts	./.	Eye dam 1, H318 Skin irrit 2, H315	Eye irrit 2, H319						
500-465-4	Alcohols, C9- 11, branched and linear, ethoxylated, sulfates, sodium salts	./.	Eye dam 1, H318 Skin irrit 2, H315	Eye irrit 2, H319						
500-513-4	Alcohols, C12-13, branched and linear, ethoxylated, sulfates, sodium salts	.1.	Eye dam 1, H318 Skin irrit 2, H315 Aquatic chronic 3, H412	./.						
932-185-7	Alcohols, C12-14 (even numbered), ethoxylated (<=2.5 moles EO), sulfated, monoisoprop anolamine salt	.I.	Eye dam 1, H318 Skin irrit 2, H315 Aquatic chronic 3, H412	./.						

EC/List No	Substance name		Self-classification	
	Tiame	Harmo nised classifi cation	Self-classification in registration dossier	Additional classification in C&L notifications
938-445-6	Alcohols, C16-18 (even numbered, C18- unsatd.), ethoxylated, and alcohols C20-22 (even numbered), sulfates, ammonium salts	.1.	No entries	
939-523-2	Poly(oxy- 1,2- ethanediyl), .alpha sulfo- .omega hydroxy-, C8-10-alkyl ethers, sodium salts	./.	Eye dam 1, H318 Skin irrit 2, H315	./.
939-575-6	Alcohols, C12-14 (linear, even- numbered), ethoxylated, sulfates, ammonium salts, < 2.5 mol EO	.1.	Eye dam 1, H318 Skin irrit 2, H315 Aquatic chronic 3, H412	./.
939-578-2	Alcohols, C12-14 (even- numbered), ethoxylated, magnesium salts, < 2.5 mol EO	./.	Eye dam 1, H318 Skin irrit 2, H315 Aquatic chronic 3, H412	./.
939-597-6	Alcohols, C10-12 (even numbered), ethoxylated	./.	Eye dam 1, H318 Skin irrit 2, H315	./.

	EC/List No	Substance name		Self-classification	
		Harrie	Harmo nised classifi cation	Self-classification in registration dossier	Additional classification in C&L notifications
		(1-2.5 EO), sulfated, sodium salts			

Annex 2: Overview of uses based on information available in registration dossiers

Data extracted on 22 March 2019.

EC number	F	,	P	С	A S L	Detergent, washing and cleaning products	Lubricant and greases	Antifreeze	Polyester/polyurethane resin. Polymer dispersion (processing aid).	Cosmetics and body care products (soaps, creams, shampoos, etc.)	Coating, inks, toner, varnishes	Textiles and leather	Laboratory	Construction chemicals, concrete and cement	Air care products/ air freshener	Fertiliser and plant protection	Adhesives and sealants	Paper and board products	Metal treatment (degreaser, descaler)	Food beverage and pharma products	Polishes and waxes	Medical devices
221-416-0	Х	Х				х	Х	Х	х	Х												
266-840-7	Х	Х	Х	Х	Х	х	Х				Х	Х	Х									
500-189-4	Х	Х	Х	Х	Х	Х				Х			Х	х	х							
500-233-2	Х	Х	Х		Х								Х	х								
500-234-8	Х	Х	Х	Х	Х	Х	х		х	Х	Х	Х		х	Х	Х	Х	Х	х	Х		
500-343-0	Х	Х	Х	Х		Х				Х						Х					Х	
500-344-6	Х	Х	Х	Х		Х				х					Х						Х	
500-345-1	Х			X						Х												

500-464-9	Х	Х	Х	Х	Х								Х						
500-465-4	Х	Х	X		Х							Х	Х						
500-513-4	Х	Х	X	X		Х			Х			Х		Х	Х	Х	Х	Х	Х
932-185-7	Х	Х	X	X		Х			Х	Х		Х	Х		Х	Х	Х		
939-523-2	Х	Х	X	X	X						X		X						
939-575-6	Х	Х	X	Х	X	Х		Х	Х	Х	Х		Х						
939-578-2	Х	Х	X	X		Х			Х			Х					(x)	·	
939-597-6	Х	Х	X	X	X								Х						

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data extracted on 23 May 2019.

There are no relevant completed or ongoing regulatory risk management activities for any of the substances.