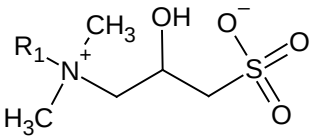
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Hydroxysultaines

General structure:

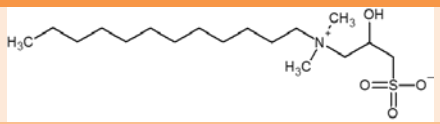
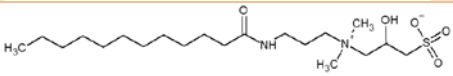
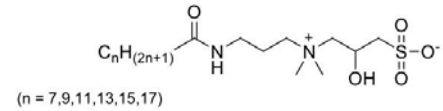
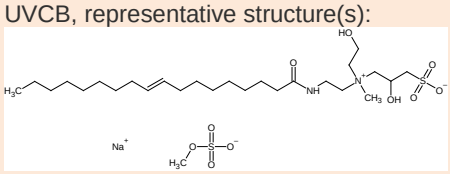
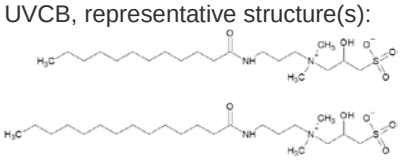


R1= alkyl or alkyl amido propyl

Revision history

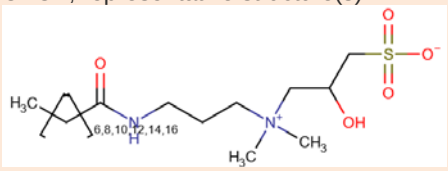
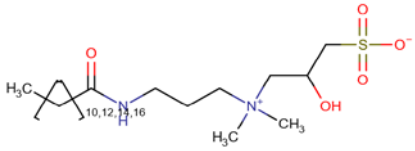
Version	Date	Description
1	21/12/2021	

Substances within this group:

EC / List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1, 2]
236-164-7	13197-76-7	Dodecyl(2-hydroxy-3-sulphonatopropyl)dimethylammonium		Full, n/a
242-893-1	19223-55-3	(2-hydroxy-3-sulphopropyl)dimethyl[3-[(1-oxododecyl)amino]propyl]ammonium hydroxide		Full, n/a
264-390-6	63663-12-7	[2-hydroxy-3-sulphopropyl]dimethyl[3-[(1-oxooctadecyl)amino]propyl]ammonium hydroxide		Not registered
268-761-3	68139-30-0	1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-coco acyl derivs., hydroxides, inner salts	UVCB, representative structure(s): 	Full, n/a
277-607-4	73791-62-5	Sodio(2-hydroxyethyl)[2-hydroxy-3-sulphonatopropyl](methyl)[2-[(1-oxooctadec-9-enyl)amino]ethyl]ammonium methyl sulphate	UVCB, representative structure(s): 	Full, n/a
293-878-1	91648-19-0	1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-C12-14 acyl derivs., hydroxides, inner salts	UVCB, representative structure(s): 	Full, n/a

[1] n/a: not publicly available

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

939-455-3	1469983-49-0	1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-C8-18 acyl derivs., inner salts	UVCB, representative structure(s): 	Full, 100-1000 t/y
939-457-4	1469983-50-3	1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-C12-18 acyl derivs., inner salts	UVCB, representative structure(s): 	Full, 100-1000 t/y

This table does not contain group members that are not registered (yet) but have a C&L notification under the CLP Regulation. However, the list is currently non-exhaustive. Once further regulatory risk management action on one or more registered substances is being considered, ECHA will make an additional search for related C&L notified substances to be included in the group and develop a regulatory strategy for them.

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DISCLAIMER

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 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, 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 website[3].

[3] https://echa.europa.eu/understanding-assessment-regulatory-needs

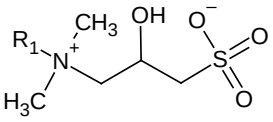
Glossary

A	Article service life
ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
C	Consumer use
DEv	Dossier evaluation
ED	Endocrine disruptor
F	Formulation
I	Industrial use
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

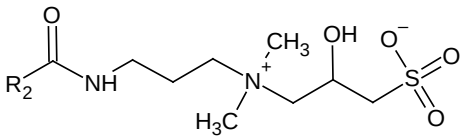
ECHA has grouped together structurally similar substances based on the presence of the moiety shown in the figure (A) below.

(A)



R1= alkyl or alkyl amido propyl

(B)



R2= alkyl

The group includes 8 substances. One substance (EC 236-164-7) has a C8 alkyl group as “R1”, and six substances have “alkyl amido propyl” as “R1”; the generic structure of the alkyl amido propyl-bearing substances is shown also separately above in (B). The alkyl amido propyl groups in these six substances include alkanoyl (acyl) moieties with carbon numbers primarily even numbered and between C8 and 18. The alkyl chains are mainly linear and saturated. One substance (EC 277-607-4) deviates from the other substances in the group as e.g. there is larger variability in the composition and the constituents include mainly unsaturated chains. It was nevertheless sufficiently similar to the other substances to be included in the group. There are mainly multi-constituent substances and UVCB substances in the group.

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.

Based on information reported in the REACH registration dossiers, the substances in the group are mainly used as surfactants, but also as lubricants and corrosion inhibitors. The substances can be associated with both high potential for human exposure and high releases to the environment. The main applications are in washing and cleaning products and cosmetics and personal care products according

to the registrations. However, only two substances (EC 236-164-7 and 268-761-3) are listed in the Cosmetic ingredient database[4]. There are very wide variety of use applications including formulation, industrial, professional and consumer uses for most of the substances in the group, except for two substances. One substance (EC 277-607-4) is used only in textile dyes and impregnating products (F, I, A) as a softener, antistatic agent or as a crosslinking agent. Another substance (EC 242-893-1) is used only in cosmetics and personal care products (F, C) and oil and gas exploration production (F, I). Article service life is relevant for three substances (EC 268-761-3, EC 277-607-4 and EC 293-878-1) which are used to produce either paper and board articles, surface treated metal articles, cosmetics and personal care articles or textiles (see Annex 2).

2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management – harmonised classification for skin sensitisation hazard due to the potential for release/ exposure of EC 277-607-4.

ECHA concludes that harmonised classification for skin sensitisation is needed for EC 277-607-4 due to potential for exposure via textile use. The substance is used only in textile dyes and impregnating products (textile applications) as a softener, an antistatic or a cross-linking agent and is present in the textile articles. The use of **skin sensitisers** in textile and leather articles, intended to come into direct and prolonged contact with the skin is covered in a restriction proposal as supported by ECHA's committees[5]. The restriction proposal targets substances that have harmonised classification as skin sensitisers, Category 1/1A/1B according to the CLP Regulation. Therefore, a harmonised classification as skin sens. 1 would ensure that the substance would fall under this potential restriction of skin sensitisers in textiles.

As regards skin sensitisation, EC 277-607-4 is claimed to be a sensitiser based on *in vitro* testing and is self-classified accordingly by the registrant(s) as Skin Sens. 1, H317. However, the identity of the test substance used which indicated a sensitising potential for EC 277-607-4 is unclear and it needs clarification which can be done under CCH. It is assumed that substitution is not likely in the group, since only EC 277-607-4 is used in textile and it differs structurally from other substances in the group. The first step of the regulatory risk management action proposed is CCH and based on the results, a harmonised classification (CLH) process could be proposed. CLH for skin sensitisation is needed to ensure that ongoing restriction on skin sensitisers in textiles would apply for the substance.

Based on currently available information, there is no need for (further) EU regulatory risk management for carcinogenicity, mutagenicity, reproductive toxicity, ED, skin sensitiser, STOT RE, PBT/vPvB and aquatic toxicity hazards for any other substances in the group.

Based on ECHA's assessment of currently available hazard information, no likely human health hazards were identified for carcinogenicity, mutagenicity,

[4] Cosmetic ingredient database (europa.eu)

[5] https://echa.europa.eu/it/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136

reproductive toxicity and ED. These conclusions are based on the following considerations:

No data for carcinogenicity was available for any substance of the group. No carcinogenic property is, however, expected due to the assumed absence of mutagenicity and absence of carcinogenicity related repeated dose toxicity. The available mutagenicity studies for substances tested with the registered substances are predominantly negative. No clear mutagenicity alert is evident based on the provided negative studies for the group of substances were read across is used or the test substance is unclear. The only *in vivo* micronucleus study which is available was negative. A CCH could be considered for some substances of the group (EC 242-893-1, EC 939-457-4) to clarify whether the presented read across approaches for mutagenicity are viable.

A concrete concern for reproductive toxicity is not indicated for any substance of the group which is based on either negative findings or not yet available CCH triggered, incoming results.

No direct data for ED is available for any substance of the group. No ED effect is however expected due to absence of ED related repeated dose toxicity.

Three substances of the group (EC 236-164-7, 268-761-3, 939-455-3) showed negative in vitro/in vivo test results for skin sensitisation. Currently, the available information is only slightly indicative for skin sensitisation potential which is based on the only positive results of EC 277-607-4. Data generated for EC 939-455-3 (not sensitising) is used to fulfil the information requirements for other members of the group (EC 242-893-1, 293-878-1 and 939-457-4). Hence, there is some uncertainty regarding the skin sensitisation potential of the substances in the group using read-across data.

Therefore, a CCH is suggested for EC 242-893-1, 293-878-1 and 939-457-4 to clarify the skin sensitisation potential of this group of substances since all these substances are included in cosmetics and personal care products and in cleaning and washing products which are used by consumers and industrial and professional workers. In case the hazard is confirmed, for industrial and professional uses, sufficient and consistent self-classification by registrants should trigger adequate risk management measures according to workplace legislation.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing sensitising substance.

However, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern.

Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

The substances in the group are unlikely to fulfil the PBT criteria, because they are very likely readily biodegradable, and therefore, unlikely to fulfil the P criterion.

All substances in the group are likely to be classified for long-term aquatic hazards. The potential for aquatic toxicity is mainly based on the data available for EC 236-164-7, EC 268-761-3, and EC 939-455-3, and on structural similarity with the other

currently non-classified substances in the group. Therefore, EC 242-893-1, EC 277-607-4, EC 939-455-3 and 939-457-4 will be further assessed under CCH. It is expected that following data generation for aquatic toxicity, registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

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
EC 277-607-4	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity	Formulation and industrial uses in textile applications. Substance is used as softener, antistatic or cross-linking agent and is present in the textile articles.	Need for EU RRM: CLH Justification: CLH for skin sensitisation would ensure that the ongoing restriction on skin sensitisers in textiles will apply.	**First step:** CCH **Next steps (if hazard confirmed):** CLH
EC 236-164-7 EC 242-893-1 EC 268-761-3 EC 293-878-1 EC 939-455-3 EC 939-457-4	No hazard or unlikely hazard	Known or potential hazard for aquatic toxicity	Widespread uses - Industrial, professional and consumer uses as surfactants and lubricants in wide range of products e.g. washing and cleaning products, cosmetics[6] and personal care products or metal surface treatment products.	Currently no need for EU RRM Justification: Correct self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace. The concern related to the presence	**First step:** CCH for EC 242-893-1, EC 939-455-3 and 939-457-4 (await ongoing data generation for EC 293-878-1) **Next steps (if hazard confirmed):** No action

[6] Only two substances are listed in the Cosmetic ingredient database, see Section 1.

				of skin sensitisers in consumer mixtures is under investigation.	

Annex 1: Harmonised classifications and self-classifications reported by registrants

Data consulted on 11 October 2021

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
236-164-7	*13197-76-7*	*Dodecyl(2-hydroxy-3-sulphonatopropyl)dimethylammonium*	*No entry*	*Eye Damage 1 H318* *Aquatic Acute 2 H401* *Aquatic Chronic 3 H412*	*Eye Irrit. 2 H319 [3 out of 7]* *Aquatic Chronic 2 H411[1 out of 7]* *Aquatic Acute 1 H400[1 out of 7]*
242-893-1	*19223-55-3*	*(2-hydroxy-3-sulphopropyl)dimethyl[3-[(1-oxododecyl)amino]propyl]ammonium hydroxide*	*No entry*	*Eye Damage 1, H318*	*Skin Irrit. 2 H315 [1 out of 6]* *Eye Irrit. 2 H319[1 out of 6]*
264-390-6 *(Not registered)*	*n.a.*	*[2-hydroxy-3-sulphopropyl]dimethyl[3-[(1-oxooctadecyl)amino]propyl]ammonium hydroxide*	*n.a.*	*n.a.*	*n.a.*
268-761-3	*68139-30-0*	*1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-coco acyl derivs., hydroxides, inner salts*	*No entry*	*Eye Irrit. 2 H319* *Aquatic Acute 1 H400* *Aquatic Chronic 2 H411*	*Skin Irrit. 2 H315 [12 out of 27]* *Eye Damage 1 H318 [3 out of 27]* *Acute Tox. 4 H302 [1 out of 27]*
277-607-4	*73791-62-5*	*sodio(2-hydroxyethyl)[2-hydroxy-3-sulphonatopropyl](methyl)[2-[(1-oxooctadec-9-enyl)amino]ethyl]ammonium methyl sulphate*	*No entry*	*Skin Irrit. 2, H315* *Eye Irrit. 2, H319* *Skin Sens. 1, H317*	-
293-878-1	*91648-19-0*	*1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-C12-14 acyl derivs., hydroxides, inner salts*	*No entry*	*Eye Damage 1 H318* *Aquatic Chronic 2 H411*	-

939-455-3	*14699 83-49-0*	*1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-C8-18 acyl derivs., inner salts*	*No entry*	*Eye Damage 1 H318* *Aquatic Chronic 2 H411*	-
939-457-4	*14699 83-50-3*	*1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-C12-18 acyl derivs., inner salts*	*No entry*	*Eye Damage 1 H318* *Aquatic Chronic 2 H411*	-

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers, therefore the number may differ from the C&L inventory which displays number of notifiers.

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

Data consulted on 11.10.2021.

EC number	236-164-7	242-893-1	268-761-3	277-607-4	293-878-1	939-455-3	939-457-4
REACH Annex	Annex VIII	Annex VIII	Annex VII	Annex VII	Annex IX	Annex IX	Annex IX
PC 2: Adsorbents						P	P
PC 11: Explosives			P				
PC 12: Fertilisers			C				
PC 27: Plant protection						F, I, P	F, I, P
PC 4: Anti-freeze and de-icing			P, C				
PC 35: Washing and cleaning	F, I, P, C		F, I, P, C		F, I, P	F, I, P, C	F, I, P, C
PC 8: Biocidal	I				F, I, P	F, I, P	F, I, P
PC 28: Perfumes, fragrances			F, I, P, C			C	C
PC 3: Air care			C			C	C
PC 39: Cosmetics, personal care	F, P, C	F, C	F, I, P, C		F, P, C, A	F, I, P, C	F, I, P, C
PC 29: Pharmaceuticals			F, I, P, C		I		F, P, C
PC 31: Polishes and wax blends			C		P	P, C	P, C
PC 15: Non-metal-surface treatment						I, P	I, P
PC 24: Lubricants, greases, release			I, P, C			F, I	F, I
PC 17: Hydraulic fluids			I, P				
PC 13: Fuels			I, P, C				
PC 32: Polymer preparations and compounds			I, P		I		
PC 1: Adhesives, sealants			I, P, C			F	F

PC 9c: Finger paint			**C**				
PC 9b: Fillers, putties, plasters, modelling clay			**C**			**F, I, P**	**F, I, P**
PC 9a: Coatings and paints, thinners, paint removes			**F, I, P, C**			**F, I, P**	**F, I, P**
PC 18: Ink and toners			**I, P, C**			**F, I, P**	**F, I, P**
PC 26: Paper and board treatment			**I, A**			**F, I, P**	**F, I, P**
PC 34: Textile dyes, and impregnating				**F, I, A**			
PC 23: Leather treatment						**C**	**C**
PC 14: Metal surface treatment			**F, I, P, A**		**I**	**F, I, P**	**F, I, P**
PC 21: Laboratory chemicals	**F**		**F, I, P**		**F**	**I, P**	**I, P**
PC 19: Intermediate			**I**				
PC41: Oil and gas exploration or production	**I**	**F, I**				**F, P**	**F, P**

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

No relevant completed or ongoing regulatory risk management activities for any of the substances.