Assessment of regulatory needs

Authority: ECHA

Date: 03/02/2021

Group Name: Sulfocarboxylic acids and esters (no succinates)

General structure: -

Revision history

Version	*Date*	*Description*
1	03/02/2021	

Substances within this group:

EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
Subgroup 1: Esters from alcohol sulfonates			
230-949-8	7381-01-3	sodium 2-sulphonatoethyl laurate	Full, >1000
263-052-5	61789-32-0	Fatty acids, coco, 2-sulfoethyl esters, sodium salts	Full, 100-1000
287-024-7	85408-62-4	Fatty acids, C12-18 and C18-unsatd., 2-sulfoethyl esters, sodium salts	Full, N/A
441-050-7	-	Ammonium 2-cocoyloxyethanesulfonate	NONS
700-150-3	156572-81-5	Dodecanoic acid, 1-methyl-2-sulfoethyl ester, sodium salt (1:1)	Full, N/A
827-581-0	-	Fatty acids, C8-14 (even numbered) methyl-2-sulfoethyl esters, sodium salts	Full, not (publicly) available
Subgroup 2: Alpha-sulfocarboxylates			
223-675-5	4016-22-2	Sodium 1-methyl 2-sulphonatotetradecanoate	C&L notifications
223-676-0	4016-24-4	Sodium 1-methoxy-1-oxohexadecane-2-sulphonate	C&L notifications
223-770-1	4062-78-6	Sodium methyl 2-sulphooctadecanoate	C&L notifications
911-616-2	-	Reaction mass of sodium 1-methoxy-1-oxohexadecane-2-sulphonate and sodium methyl 2-sulphooctadecanoate	Full, 100-1000
948-647-6	-	disodium 1-methoxy-1-oxohexadecane-2-sulfonate 1-methoxy-1-oxooctadecane-2-sulfonate	C&L notifications
947-394-9	-	Fatty acids, C12-18 (even numbered)-methyl esters, sulfonated, sodium salts	Full, not (publicly) available
942-523-5	-	Fatty acids, C12-14 (even numbered), α-sulfo, disodium salts	Full, not (publicly) available
Subgroup 3: Amides from sulfosuccinates			
261-222-3	58353-68-7	disodium (Z)-4-(9-octadecenylamino)-4-oxo-2(or 3)-sulphonatobutyrate	Full, 100-1000

[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]
273-537-3	68988-69-2	Butanoic acid, 4-amino-4-oxosulfo-, N-tallow alkyl derivs., disodium salts	C&L notifications
308-662-5	98171-53-0	Butanoic acid, 4-amino-4-oxosulfo-, N-coco alkyl derivs., monosodium salts, compds. with triethanolamine	Full, not (publicly) available
939-691-7	1474044-72-8	Butanoic acid, 4-amino-4-oxo-2(or 3)-sulfo-,N-(C16-C18 (even numbered), C18 unsaturated alkyl)), disodium salts	Full, 100-1000

This table contains also group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA will 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.

Contents

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

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[2].

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

Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
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
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together 18 structurally similar substances based on the presence of a sulfonate group and carboxylic salts or ester groups as shown in the figure below. Another common feature in the group is the presence of linear aliphatic chains that are mostly saturated. Half of the substances are well defined and the other half are UVCB substances. The substances are in majority sodium salts but in the group there is also an ammonium and a triethanolamine salt.

The group is divided in three sub-groups:

1- Esters from alcohol sulfonates,
2- Alpha-sulfocarboxylates and
3- Amides from sulfosuccinates.

The sub-grouping was done based on the common functional groups of the substances and on the read across used by registrants. Figure 1 shows the general structure for each of the sub-groups.

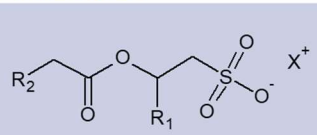
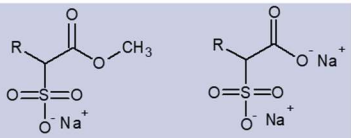
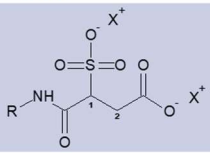
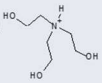
Esters from alcohol sulfonates **7 substances**	**Alpha-sulfocarboxylates** **7 substances**	**Amides from sulfosuccinates** **4 substances**
		
R1= CH3,H R2= C6-C16 (even number), C16' X= Na, NH4	R= C10-C16 (even numbered)	R= C12-C18 (even numbered); C18' X= Na;  Note: Sulfo group can be in position 1 or 2.

Figure 1: The three sub-groups of the sulfocarboxylic acids and esters (no succinates) group.

Based on information reported in the REACH registration dossiers, the substances in this group, across all three subgroups, have widespread uses. They are used mainly as surface active agents in industrial processes, by professionals and by consumers in a high variety of products and applications where exposure to both human and environment is expected. The substances in subgroup 1 and 2 are mainly used in household products and cosmetics whereas those in subgroup 3 in additives and in treatment of textile and leather.

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 need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management – namely **restriction** to address the potential reproductive toxicity and endocrine disrupting (ED) properties of **all substances in subgroup 3** used in many diverse applications having potential for exposure to workers and consumers.

Overall, a potential reproductive toxicity hazard is identified for all subgroup 3 members due to structural similarity to List 939-691-7, which is a known reproductive toxicant having a self-classification as Repro 1B. Similarly, the potential for endocrine disrupting properties for human health observed for EC 308-662-5 also applies to the other subgroup members.

Based on information available in registration dossiers, the substances in this subgroup seem to have low environmental hazard and do not meet the PBT/vPvB screening criteria as they seem to be readily biodegradable.

First the potential reproductive toxicity hazard will need to be clarified. Data generation on developmental and reproductive toxicity is ongoing for the substances EC/List 939-691-7 and 261-222-3.

For substance EC 308-662-5 the available data indicate potential reproductive toxicity and ED properties for human health, however this data is not conclusive. Substance evaluation would be needed to investigate further the potential reproductive toxicity and ED properties of this substance. This substance has professional and consumer uses reported in the registration dossiers and therefore there is clearly a concern with this substance which would need to be further investigated in substance evaluation.

All registered substances in subgroup 3 have industrial, professional and consumer uses and due to leather and textile applications also article service life.

The first step of the regulatory risk management action proposed, should the reprotoxicity hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Repr. 1B. The CLH i) will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place, ii) is needed or highly recommended for further regulatory processes under REACH (e.g. restriction) and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 30.

CLH is also a prerequisite to restrict the presence of the substances in clothing, other textiles, and footwear articles, by means of the restriction entry 72 of REACH Annex XVII (this would require addition of the relevant substances to Appendix 12 by the Commission through Article 68(2)).

If substance evaluation for EC 308-662-5 substantiates the ED properties for human health, the next steps would be to consider whether the other substances may have as well such properties.

SVHC identification may be considered for these substances.

Substances in subgroup 3 have consumer uses for which exposure is expected as well as diverse professional uses (e.g. lubricants, greases, construction chemicals, textile treatment, dispersive agent, laboratory uses). Only EC 273-537 has only a C&L notification however due to similarity in chemical structure it is suggested to consider this substance together with the three others due to potential for substitution. Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation.

Therefore, a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals** is suggested after CLH and potential SVHC identification.

Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[3] which aims to extend to professional users under REACH the level of protection granted to consumers.

The potential exposure from articles is uncertain therefore it is suggested that the possibility to restrict in addition substances in articles used by professionals or consumers should be considered in the context of the restriction of professional uses as potential exposure from articles needs further investigation first.

For the uses not in the scope of a potential restriction (e.g. industrial uses) authorisation could complement the restriction by pushing for substitution and ensuring proper control of risks until substitution is possible. The need for authorisation to complement restriction can be considered when a restriction proposal is being developed.

Based on currently available information, it is not possible to assess the need for regulatory risk management for substances in subgroup 2 from

[3] European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

human health perspective as there is not sufficient information to conclude on carcinogenicity, reproductive toxicity and ED properties for the substances included in this subgroup.

Testing has been proposed by the registrants on sub-chronic toxicity, pre-natal developmental toxicity for substances within this subgroup (EC 911-616-2, EC 942-523-5, EC 947-394-9) , as well as on long-term aquatic toxicity. The need for further testing for reproductive toxicity will be determined on the basis of the results obtained in the proposed tests.

Therefore, it is proposed to assess the regulatory needs for the substances in this subgroup once new hazard information has been generated.

Some substances are potentially hazardous to the aquatic environment and are used in many diverse applications where exposure to both humans and environment is expected. Some substances are also used as surface active agent in detergents. Therefore, correct self-classification and reliable biodegradation data should ensure environment safety in industrial and professional settings as well as correct product labelling, too.

Further assessment of the aquatic and biodegradation data will be done under the ongoing testing proposal.

Based on currently available information, there is no need for (further) EU regulatory risk management for **all substances in subgroup 1** as these substances are unlikely to be hazardous.

Some substances within the group are classified as hazardous for the aquatic environment and are used in many diverse applications on industrial and professional sites as well as by consumers. Some substances are readily biodegradable and none of the substances is expected to be persistent in the environment however this would need to be confirmed.

For industrial and professional settings sufficient and consistent self-classification by registrants should trigger risk management measures at company level according to environmental legislation that is assumed to be enough to address environment safety. Correct self-classification should also ensure adequate product labelling which should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing these substances. In addition, some substances are also used as surface active agent in detergent for which biodegradation is a key requirement under regulation (EC) No 648/2004 and therefore it is important to have adequate information on ready biodegradability of the substances.

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/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Subgroup 3					
261-222-3 308-662-5 939-691-7 273-537-3 (not registered)	Known or potential hazard for reproductive toxicity and ED	No hazard or unlikely hazard	Industrial and widespread uses by professional workers and consumers in e.g. lubricants, greases, construction chemicals, textile treatment, dispersive agent, laboratory uses and uses in articles with potential for exposure to workers and consumers and releases into the environment	**Need for EU RRM: Restriction** <u>Justification</u>: The harmonised classification as Repr. 1 would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above 0.3% w/w. Restriction is proposed to ensure same level of protection to professional users as to consumers. Specific restriction for use in articles.	**First step:** CCH ongoing for EC/List 939-691-7 and 261-222-3 Substance evaluation for EC 308-662-5 to clarify reproductive toxicity and ED properties **Next steps (if hazard confirmed):** CLH Potential SVHC identification of ED properties Restriction of uses by professionals and in articles

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Subgroup 1: 230-949-8 263-052-5 287-024-7 441-050-7 700-150-3 827-581-0	No hazard or unlikely hazard	No hazard or unlikely hazard, except EC 230-949-8 and EC 263-052-5 self-classified as Aq. Chronic 3	Industrial and widespread uses by professional workers and consumers in household products and cosmetics	**Currently no need for EU RRM** Justification: No or unlikely hazards For EC 230-949-8 and 263-052-5 correct self-classification for aquatic toxicity and product labelling as well as reliable biodegradation data should ensure environment safety	CCH ongoing for 230-949-8, 263-052-5, 287-024-7 and 700-150-3
Subgroup 2: 911-616-2 942-523-5 947-394-9 *Not registered:* 223-675-5 223-676-0 223-770-1	Inconclusive hazard for carcinogenicity, reproductive toxicity and ED	No hazard or unlikely PBT properties Inconclusive hazard for aquatic toxicity Known or potential hazard for aquatic toxicity for EC 911-616-2 and 947-394-9	Industrial and widespread uses by professional workers and consumers in household products and cosmetics	**Currently not possible to assess the regulatory needs** Justification: It is not possible to assess the needs for regulatory risk management for all substances in subgroup 2 as information on hazard is not sufficient to conclude on human health hazards. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).	TPE ongoing for 911-616-2, 942-523-5 and 947-394-9

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
948-647-6		Inconclusive hazard for aquatic toxicity			

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

Data consulted in March 2020

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
700-150-3	Dodecanoic acid, 1-methyl-2-sulfoethyl ester, sodium salt (1:1)	Not included in Annex VI	Eye Irrit. 2 H319	Eye Irrit. 2 H319
827-581-0	Fatty acids, C8-14 (even numbered) methyl-2-sulfoethyl esters, sodium salts	Not included in Annex VI	Eye Irrit. 2 H319	
441-050-7	Ammonium 2-cocoyloxyethanesulfonate	Skin Irrit. 2 H315 Eye Dam. 1 H318		
230-949-8	sodium 2-sulphonatoethyl laurate	Not included in Annex VI	Eye Irrit. 2 H319 Aquatic Chronic 3 H412	Eye Irrit. 2 H319 Aquatic Chronic 3 H412 Skin Irrit. 2 H315
287-024-7	Fatty acids, C12-18 and C18-unsatd., 2-sulfoethyl esters, sodium salts	Not included in Annex VI	Acute Tox. 4 H303 Eye Irrit. 2A H319	Not Classified
263-052-5	Fatty acids, coco, 2-sulfoethyl esters, sodium salts	Not included in Annex VI		
911-616-2	Reaction mass of sodium 1-methoxy-1-oxohexadecane-2-sulphonate and	Not included in Annex VI	Acute Tox. 4 H302 Eye Irrit. 2 H319 Aquatic Chronic 3 H412 Aquatic Acute 1 H400	
947-394-9	Fatty acids, C12-18 (even numbered)-methyl esters, sulfonated, sodium salts	Not included in Annex VI	Eye Dam. 1 H318 Aquatic Chronic 3 H412	
942-523-5	Fatty acids, C12-14 (even numbered), α-sulfo, disodium salts	Not included in Annex VI	Acute Tox. 4 H302 Eye Irrit. 2 H319 Skin Irrit. 2 H315	
939-691-7	Butanoic acid, 4-amino-4-oxo-2(or 3)-sulfo-,N-(C16-C18 (even numbered), C18	Not included in Annex VI		

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
	unsaturated alkyl)), disodium salts			
308-662-5	Butanoic acid, 4-amino-4-oxosulfo-, N-coco alkyl derivs., monosodium salts, compds. with triethanolamine	Not included in Annex VI		
261-222-3	disodium (Z)-4-(9-octadecenylamino)-4-oxo-2(or 3)-sulphonatobutyrate	Not included in Annex VI		

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

Data consulted in March 2020

Sub-group 1: Esters from alcohol sulfonates

Main types of applications structured by product or article types	700-150-3	827-581-0	441-050-7	230-949-8	287-024-7	263-052-5
use in cosmetic products and personal care products	F, I, **P, C**	F, I, **P, C**	F, I, **C**	F, **C**	F, **C**	F, **P, C**
use in fragrance/perfume products	F, I, **P, C**	F, I, **P, C**				
use in dishwashing products	F, I, **P, C**	F, I, **P, C**				
use in laundry products	F, I, **P, C**	F, I, **P, C**				
use in liquid washing and cleaning products	F, I, **P, C**	F, I, **P, C**				
use in biocidal products	F, I, **P, C**	F, I, **P, C**				
use in cleaning agents						F, I, **P, C**
use in cleaning and care products						F, I, **P, C**

Sub-group 2: Alpha-sulfocarboxylates

Main types of applications structured by product or article types	911-616-2	947-394-9	942-523-5
use in fragrance/perfume products			F, **P, C, A**
use in dishwashing products			F, **P, C, A**
use in laundry products	F, **C**		F, **P, C, A**
use in liquid washing and cleaning products	F, I, **P, C**	F, **P, C**	F, I, **P, C, A**
use in laboratory	F, I, **P**		
use in contact lens cleaning solutions		F, **C**	
use in disinfecting or maintenance products		F, **C**	F, I, **P**
use in construction chemicals			F, I, **P, C, A**
use in air fresheners, candles, diffusers			F, **C**
use in pest control			F, **C**

Sub-group 2: Alpha-sulfocarboxylates			
Main types of applications structured by product or article types	**911-616-2**	**947-394-9**	**942-523-5**
products insecticides and repellents			
use in polishes furniture floor & leather care			F, **C**

Sub-group 3: Amides from sulfosuccinates			
Main types of applications structured by product or article types	**939-691-7**	**308-662-5**	**261-222-3**
use in laboratory	F, I	F, I, **P**	
use in industrial chemical processes		F, I	
use as dispersing agent resulting in inclusion in to a matrix in several applications (e.g. adhesives, coatings and paints, fillers, putties, plasters, ink and toners…)		F, I, **P, C, A**	
use in treatment of textile	F, I, **P, A**		F, I, **A**
use in leather manufacturing process			F, I, **A**
use in processing aids			F, I, **P**
use in construction chemicals	F, I, **P, A**		
use in lubricants and greases	F, I, **P**		
use in waste water treatment	F, I		

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 (Data consulted on 11/03/2020)