Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

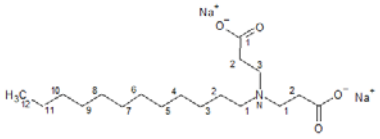
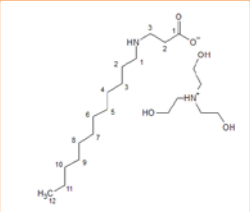
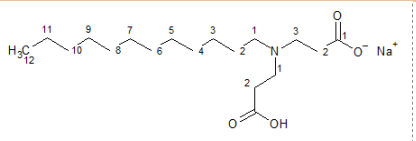
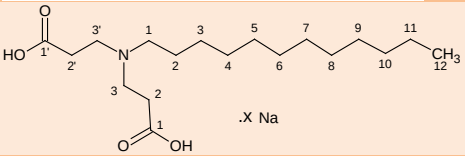
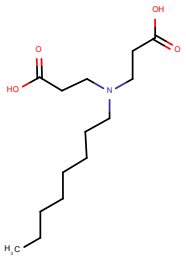
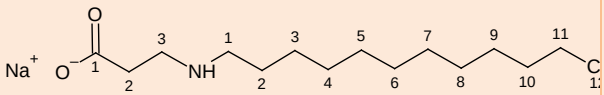
Date: 02/05/2022

Group Name: Long chain aliphatic amino-acetic, -propionic and -succinic acids and their salts

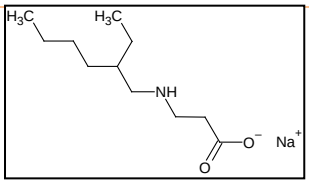
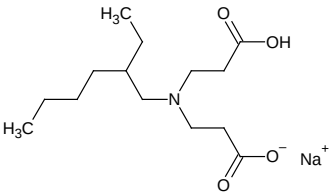
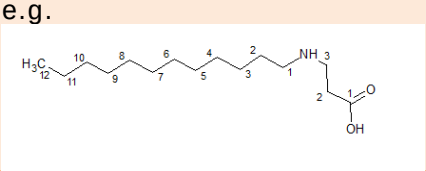
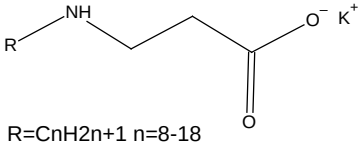
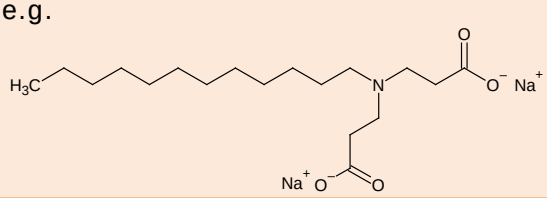
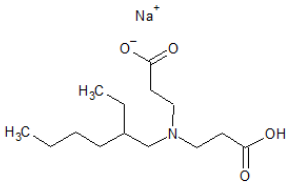
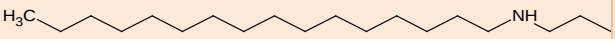
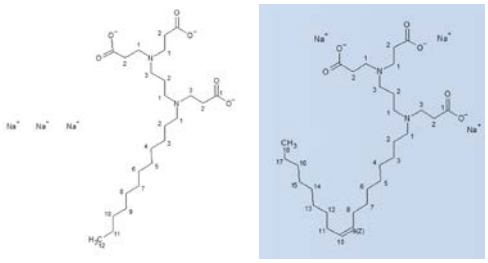
Revision history

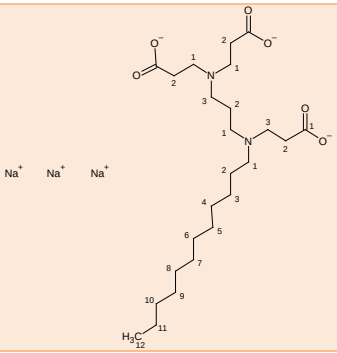
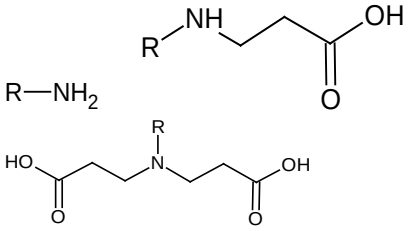
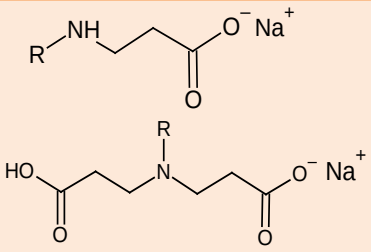
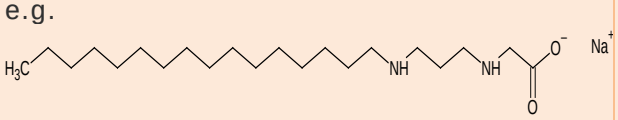
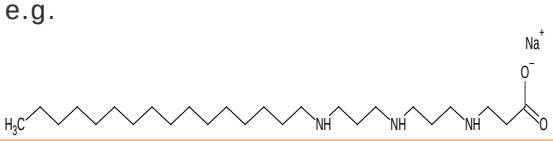
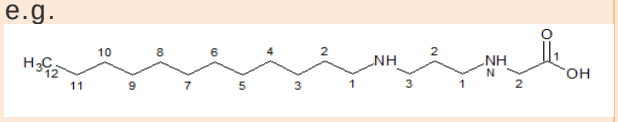
Version	*Date*	*Description*
1.0	15/06/2022	

Substances within this group:

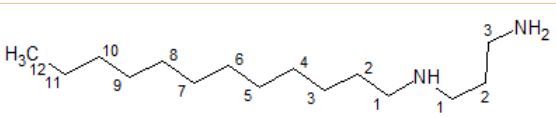
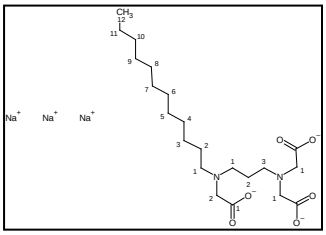
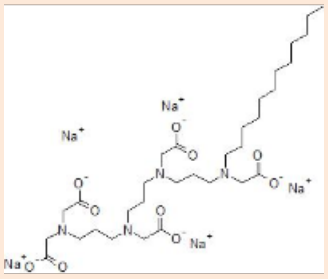
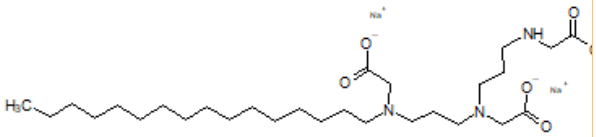
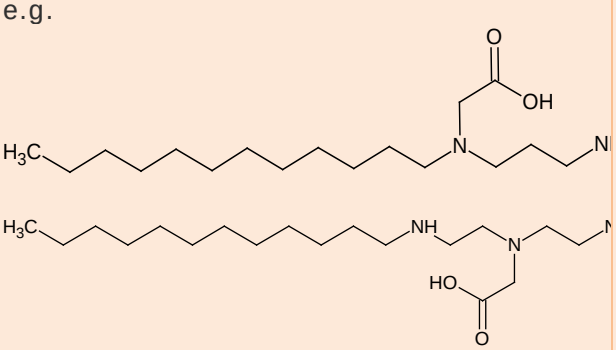
EC / List number	CAS number	Substance name [and / or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t / y) [1]
Sub-group 1: (Poly) Aminopropionates				
222-899-0	3655-00-3	Disodium *N*-(2-carboxyethyl)-*N*-dodecyl-β-alaninate		C&L notification
238-015-1	14171-00-7	*N*-dodecyl-β-alanine, compound with 2,2',2''-nitrilotriethanol (1:1)		Full, not (publicly) available
239-032-7	14960-06-6	Sodium *N*-(2-carboxyethyl)-*N*-dodecyl-β-alaninate		Full, 10-100
247-552-0	26256-79-1	3,3'-(dodecylimino)dipropionic acid, sodium salt		Not registered
258-081-5	52663-87-3	*N*-(2-carboxyethyl)-*N*-octyl-β-alanine		Full, not (publicly) available
271-795-1	68608-68-4	β-Alanine, *N*-coco alkyl derivs., sodium salts	e.g. 	C&L notification
271-865-1	68610-44-6	2-Propenoic acid, methyl ester, reaction products	e.g.	Full, not (publicly) available

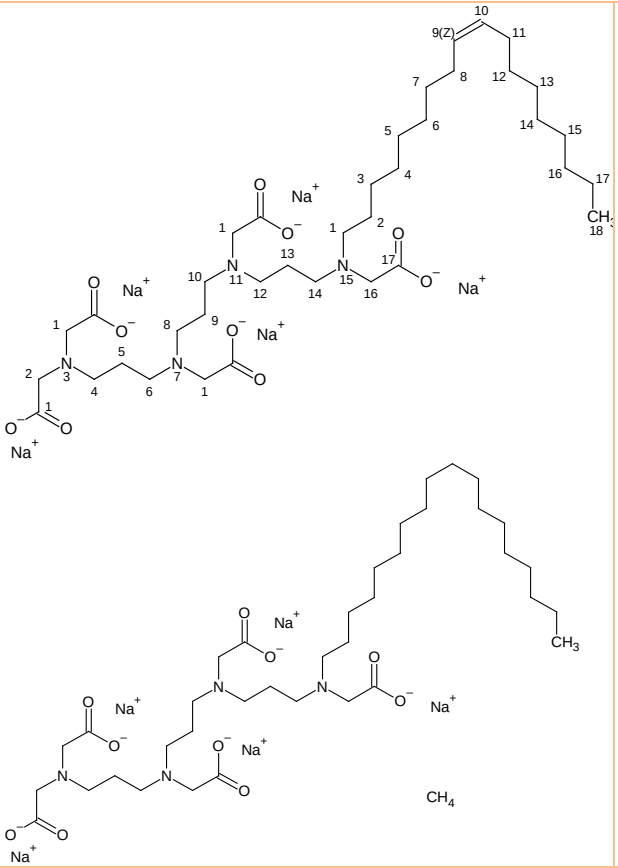
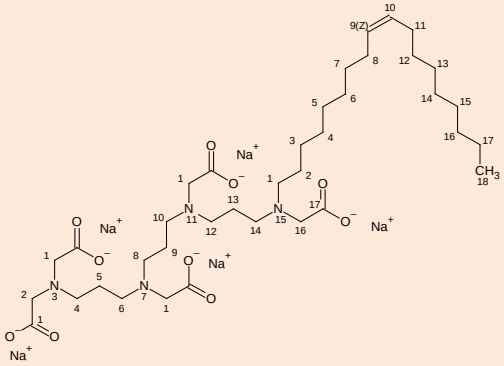
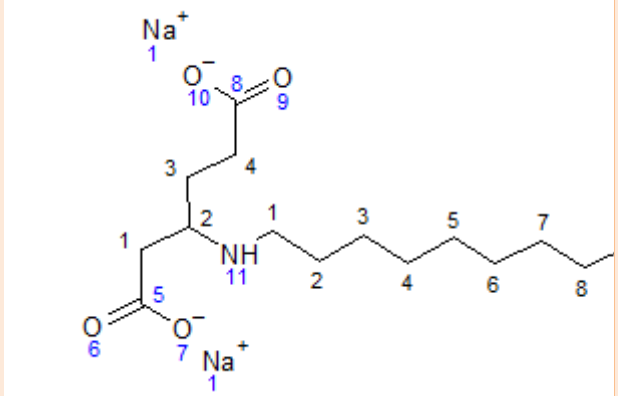
[1] Note that the total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

		with 2-ethyl-1-hexanamine and sodium hydroxide	 	
284-219-9	84812-94-2	β-Alanine, *N*-coco alkyl derivs.	e.g. 	Full, not (publicly) available
290-475-2	90170-42-6	β-Alanine, *N*-C8-18-alkyl derivs., monopotassium salts	 R=CnH2n+1 n=8-18	Full, not (publicly) available
290-476-8	90170-43-7	β-Alanine, *N*-(2-carboxyethyl)-, *N*-coco alkyl derivs., disodium salts	e.g. 	Full, 100-1000
305-318-6	94441-92-6	Sodium *N*-(2-carboxyethyl)-*N*-(2-ethylhexyl)-β-alaninate		Full, 100-1000
307-455-7	97659-50-2	Amines, *N*-C8-22-alkyltrimethylenedi-, acrylated, sodium salts	e.g. 	C&L notification
701-354-5	-	β-Alanine, N-(2-carboxyethyl)-N-[3-[(2-carboxyethyl)amino] propyl]-, N-C12-18-(even numbered) and C18-(unsaturated) alkyl derivs., trisodium salts	e.g. 	Full, not (publicly) available
825-841-8	2136366 30-6	trisodium 3-[{3-[bis(2-carboxylatoethyl)amino]propyl}(C12-18	e.g.	Not registered

		alkyl)amino]propanoate[2]		
915-790-0	-	Reaction mass of Amines, coco alkyl and ß-Alanine, *N*-(2-carboxyethyl)-, *N*-coco alkyl derivs. and ß-Alanine, *N*-coco alkyl derivs	 R = C12-18 (even numbered) and C18 unsaturated	Full, 100-1000
939-647-7	1474044-68-2	Amines, C12-18-alkyl, reaction products with acrylic acid, sodium salts	 R= C12-18	Full, not (publicly) available
Sub-group 2: Aminoacetates from polyamines				
307-456-2	97659-51-3	Amines, *N*-C8-22-alkyltrimethylenedi-, reaction products with sodium chloroacetate, sodium salts	e.g. 	C&L notification
307-458-3	97659-53-5	Amines, *N*-C8-22-alkylpolytrimethylene poly-, carboxymethyl derivs., sodium salts	e.g. 	C&L notification
701-317-3	139734-65-9	Amines, N-C10–C16-alkyltrimethylenedi-, reaction products with chloroacetic	e.g. 	Full, not (publicly) available

[2] This substance: trisodium 3-[{3-[bis(2-carboxylatoethyl)amino]propyl}(C12-18 alkyl)amino]propanoate corresponds to one of the groups of constituents of the substance associated to List 701-354-5, trisodium 3-[{3-[bis(2-carboxylatoethyl)amino]propyl}(C12-18-(even numbered) and C18-(unsaturated) alkyl)amino]propanoate

		acid; “Ampholyt” under BPR		
825-246-3	2098351-38-1	Amines, *N*-C12-18-alkyltrimethylenedi-, reaction products with chloroacetic acid, sodium salts	e.g. 	Full, not (publicly) available
825-403-6	2060541-51-5	pentasodium 3,7,11-tris(carboxylatomethyl)-15-(C12-18)-alkyl-3,7,11,15-tetraazaheptadecane-1,17-dioate	e.g. 	Full, not (publicly) available
825-518-1	2060541-47-9	trisodium ({3-[(carboxylatomethyl)amino]propyl}{3-[(carboxylatomethyl)(C16-18, C18 unsat alkyl)amino]propyl}amino)acetate	e.g. 	Full, not (publicly) available
947-917-0	-	Amines, *N*-C12–14 (even numbered)-alkyltrimethylenedi-, reaction products with chloroacetic acid and diethylenetriamine, *N*-C12–14 (even numbered)-alkyl derivs.	e.g. 	Full, not (publicly) available
947-979-9	-	1,3-Propanediamine, N^1-(3-aminopropyl)-N^3-[3-(C18, C18 unsat) alkylamino]propyl]-, *N*-(carboxymethyl) derivs., sodium salts	e.g.	Full, not (publicly) available

				
	2060541-49-1	1,3-Propanediamine, N^1-(3-aminopropyl)-N^3-[3-[(9*Z*)-9-octadecen-1-ylamino]propyl]-, *N*-(carboxymethyl) derivs., sodium salts	e.g. 	Not registered
Sub-group 3: Aminosuccinates				
411-250-9	-	A mixture of: sodium 2-(C12-18-n-alkyl)amino-1,4-butandioate; sodium 2-octadecenyl-amino-1,4-butandioate		NONS

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 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.

Contents

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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 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

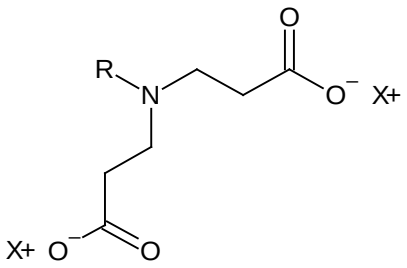
Glossary

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
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

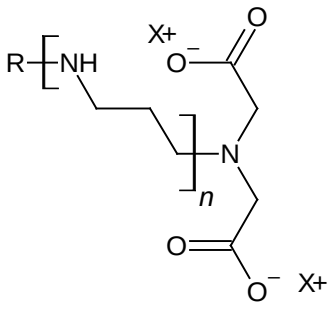
ECHA has grouped together structurally similar substances based on the presence of amine and a carboxylate moiety separated by one or more carbon atoms as shown in the examples of structures below. The substances have been subdivided into the following subgroups:

- Aminopropionates (subgroup 1):



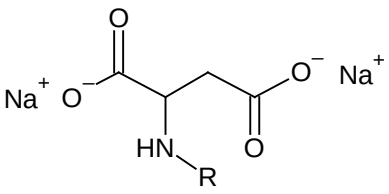
X=H^+, Na^+, K^+, $HN(EtOH)_3^+$
R=C8-18

- Aminoacetates from polyamines (subgroup 2):



X=H^+, Na^+
R=C8-22

- Aminosuccinates (subgroup 3):



R=C12-18

The group consists of 26 substances: 18 have a full registration, one of them is an unclaimed NONS and 8 of the substances are not registered. Most of the substances included in this group have been identified as UVCB.

Based on information reported in the REACH registration dossiers, most of the substances in the group have a similar use profile. Many of the substances are used in washing and cleaning products, cosmetics and personal care products, polishes and waxes and similar use applications. There is a high potential for release to the environment from use of down-the-drain products and a high potential for human exposure, particularly due to the many professional and consumer uses reported. For some of the substances in the group (ECs 239-032-7, 825-246-3, 290-476-8, 305-318-6) also widespread, professional and/or consumer uses have been reported in applications such as fillers, putties, plasters, modelling clay, coatings and paints, thinners, paint removers, ink and toners and paper and board treatment products, and in similar use applications, such as metal surface treatment and leather treatment products. Consequently, release and exposure potential are suspected for all members in the group regardless of the specific use applications reported. All the substances in the group are used as surface-active agent. It can therefore be preliminarily assumed that some degree of interchangeability may be possible for some of the uses reported, for example in formulation of detergents.

Within the whole group, article service life has only been reported for one substance: EC 825-246-3 (Adhesives, sealants, Coatings and paints, thinners, paint removes, Ink and toners). For the use in coatings and paints, thinners, paint removers article service life has been reported in addition to professional and consumer uses, which overall already suggests a high potential for release. There is the potential for leaching out of the painted article. For the other two applications no information on consumer uses has been reported, which indicates that potential exposure cannot be excluded from the end-product whereas the substance itself is not used by consumers.

One of the substances in the group, EC 701-317-3 (referred to as ‘Ampholyt’ in the Biocides dossier), has been approved under the Biocidal Product Regulation in 2015 to be used by professionals as a hard surface disinfectant

- in hospitals, institutional and industrial areas (including public health areas)
- in treatments to surfaces, walls, and floors in animal health and veterinary areas (including footbaths), and
- in treatments to surfaces, walls, and floors in industrial food and feed preparation areas

to prevent the spread of various micro-organisms.[4]

[4] The Biocidal Products Committee adopted its opinion on approval of this active substances for the following product-types: PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals, PT 3 - Veterinary hygiene and PT 4 - Food and feed area.

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 – harmonised classification for reproductive toxicity **for all Aminoacetates from polyamines** (subgroup 2).

The Biocidal Products Committee (BPC) concluded for the substance EC 701-317-3 (CAS: 139734-65-9), in its proposal for approval of the active substance, a classification of reproductive toxicity 2. The substance is not self-classified for this hazard. The final submission of the CLH dossier is still pending on this substance.

The reproductive toxicity for the biocidal active substance is due to findings in reproductive parameters in studies performed in a 90-day dog study and a two-year mouse study with effects on mesenteric lymph nodes, male/female genital systems; the reproductive toxicity findings are not observed in the available rat studies. The available information for the remaining substances in this subgroup regarding reproductive toxicity in rats does not indicate a potential for reproductive toxicity; however, due to structural similarity with the biocidal active substance, the findings in the dog and mice studies from that substance are extrapolated with remaining uncertainty to all subgroup members. Depending on the outcome of the CLH for EC 701-317-3 the needs for regulatory risk management actions for this whole subgroup will be revisited.

Potential harmonised classification for Repro. 2 (following CCH/CLH) would result in company level risk management measures (RMM) under the OSH legislation for workers. In addition, the harmonised classification as Repro. 2 will prohibit the use

of the substance EC 947-979-9, for which consumer uses in cosmetics and personal care products have been reported, under the Cosmetic Products Regulation (EC) No 1223/2009 unless an exemption is granted upon assessment of safe use of the substances in cosmetic products by the Scientific Committee on Consumer Safety (SCCS). For the substance EC 825-246-3 used in finger paints by consumers the harmonised classification will restrict the use of this substances in toys. According to the safety requirements set for chemicals in toys under the Toy Safety Directive (2009/48/EC), substances or mixtures that are classified as CMR category 2 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys unless they meet the criteria for a derogation. In addition, harmonised classification will facilitate conformity assessment and declaration, particularly when the toy manufacturer bearing obligations is located outside the EU and therefore self-classification in registration dossiers is not applicable to them.

The harmonised classification for Repro. 2 will not trigger any further relevant regulatory consequences for the subgroup members apart from the above.

No hazard for mutagenicity, has been identified for any subgroup members based on the available data. No indications of potential carcinogenicity or endocrine disruption potential is evident from the available systemic toxicity studies. The substances in the subgroup have the potential for STOT RE (target organ: mesenteric lymph nodes) based on the available information on some subgroup members and extrapolation to the remaining substances due to structural similarity. EC 701-317-3 induced foci of necrosis, acute inflammation and lymphoid hyperplasia of the mesenteric lymph nodes in 90-days repeat dose toxicity (RDT) studies and large macrophages in mesenteric lymph nodes and the small intestine in OECD TG (Combined Chronic Toxicity / Carcinogenicity Study). In both studies the effects were observed at low doses, <10 mg/kg bw. EC 947-917-0 showed treatment-related changes in the mesenteric lymph nodes in Combined Chronic Toxicity / Carcinogenicity Studies. In 90-days RDT studies effects on mesenteric lymph nodes and deformed lymphocytes.

Based on ECHA's assessment of currently available hazard information the substances in subgroup 2 are considered unlikely PBT/vPvB with remaining high uncertainty.

Currently, only EC 701-317-3 and EC 947-917-0 meet the T criteria set in Annex XIII: NOEC or EC_{10} < 0.01 mg/L and/or classification as STOT RE 1 or 2. Nevertheless, there is indication that all subgroup 2 members are potentially Repro. 2 hence T is likely met for all substances in this subgroup. Uncertainty regarding persistency is flagged for all substances in the group, as screening criteria on persistency are not considered enough to extrapolate for UVCB substances. Furthermore, as all (registered) substances are ionisable surfactants uncertainty regarding bioaccumulation is also present. Three of the other substances in this subgroup (ECs 947-917-0, 947-979-9, 825-403-6) have widespread professional or consumer uses in washing and cleaning products, or in polishes and waxes. Based on information available in the REACH registration dossiers, all these substances are not readily biodegradable, and the biodegradability of their constituents needs to be further clarified via CCH. All these substances are used as surfactants and are therefore subject to the Detergents Regulation (EC) No 648/2004. The regulation stipulates that substances used as surfactants in detergents must meet the biodegradability criteria set out in Annex III in order to be placed on the market, with the option to apply for derogation for industrial and institutional detergents not meeting the criteria for ultimate biodegradability. Hence, uncertainty regarding PBT/vPvB hazard is present.

PMT/vPvM hazard is foreseen unlikely based on reported adsorption potential and in line with substances' properties i.e., surfactants.

Aquatic Toxicity is considered likely for all substances in subgroup 2.

According to ECHA's assessment of currently available hazard information, aquatic toxicity hazard is considered likely for all group members of subgroup 2 based on data available in the registration dossiers (mainly aquatic acute studies) and self-classification as aquatic toxic (Acute 1, Chronic 1/3) for 6 group members (ECs 701-317-3, 825-246-3, 825-403-6, 825-518-1, 947-917-0 and 947-979-9). Nevertheless, experimental data, read-across and the impact of substances impurities on the toxicity merits further assessment.

CCH is proposed for all the substances to clarify PBT/vPvB and aquatic toxicity (except for ECs 701-317-3, an approved biocide and for 701-354-5, for which data generation is already ongoing).

It is expected that following data generation for aquatic toxicity and human health endpoints registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use. The need for regulatory measures will need to be revisited in case new data indicates PBT/vPvB hazard.

Based on currently available information, there is no need for (further) EU regulatory risk management for **all Aminopropionates** (subgroup 1) and **Aminosuccinates** (subgroup 3: EC 411-250-9).

Based on ECHA's assessment of currently available information on hazard in the registration dossier, considerations of structural similarity and the presence of a common functional moiety, all the substances in subgroup 1 have (potentially) the following human health/environmental hazards: Aquatic toxicity and STOT RE (mesenteric lymph nodes).

According to ECHA's assessment of currently available hazard information, aquatic toxicity hazard is considered likely for all group members of sub-groups 1 based on data available in the registration dossiers (mainly aquatic acute studies) and self-classification as aquatic toxic (Acute 1/3, Chronic 1/3/4) for 6 group members (ECs 239-032-7, 271-865-1, 284-219-9, 290-476-8, 701-354-5 and 915-790-0) and likely for 4 additional group members based on the presence of impurities (ECs 238-015-1, 258-081-5, 305-318-6 and 939-647-7).

The substances in subgroup 1 are considered unlikely to fulfil the screening PBT/vPvB criterion, because 8 out of 16 members (including 5 non-registered) are readily biodegradable (*i.e.*≥70% degradation in an OECD 301B/D or DIN 38414) hence the substances screen as unlikely persistent or very persistent (P/vP). Nevertheless, considering the multitude of constituents present in each substance, uncertainty remains if some constituents may be P/vP.

The substance in subgroup 3 is also considered unlikely to fulfil the screening PBT/vPvB criterion since it is reported as readily biodegradable (*i.e.* ≥60% degradation in a Close Bottle method). However, uncertainty regarding the degradability potential of its constituents remains.

For four substances in subgroup 1 (the mono-constituent EC 239-032-7 and the 3 substances previously subject to compliance check) ready biodegradability (no P/vP) was concluded.

Uncertainty regarding persistency is flagged for the remaining substances, as screening criteria are not considered enough to extrapolate for UVCB substances. Furthermore, as all (registered) substances are ionisable surfactants uncertainty regarding bioaccumulation is also present. Hence, uncertainty regarding PBT/vPvB hazard is present. Nevertheless, ready biodegradability data on some members of subgroup 1 indicate some potential for biodegradation. As different biodegradability

levels can be observed within the constituents of a UVCB substance and branching level is also variable, further data is required to conclude on PBT/vPvB hazard.

PMT/vPvM hazard is foreseen unlikely based on surface activity properties.

For two of the substances in subgroup 1 (ECs 701-354-5 and 915-790-0) effects on mesenteric lymph nodes were found. However, based on potential systemic toxicity for mesenderic lymph nodes all substances in subgroups 1 and 3 have potential STOT RE, based on some data and extrapolation to all subgroup members based on presence of same/similar functional group.

Both subgroups (aminopropionates and aminosuccinates) are unlikely to be mutagenic, carcinogenic endocrine disrupters or reproductive toxicants with some remaining uncertainty.

It is expected that following data generation for aquatic toxicity and human health endpoints (STOT RE) 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.

Currently it is not possible to assess the needs for regulatory risk management for the substance EC 411-250-9 in subgroup 3 as information on hazard is not sufficient to conclude on Aquatic Toxicity.

Due to unclaimed NONS it is not possible to clarify the potential hazards of this substance (EC 411-250-9). Therefore, it is proposed that there is currently no need for EU RRM action on this substance. If the registration status changes, data generation and potentially follow-up actions will be re-considered when the assessment will be revisited. A change in registration status will only be possible until 17 July 2022 as ECHA will end the possibility to claim registration numbers for NONS by that date.[5]

For some of the substances in the group data generation is ongoing to investigate their potential toxicity for reproduction (EC 290-476-8 and 305-318-6) and aquatic toxicity (ECs 290-476-8, 305-318-6 and 701-354-5).

[5] https://echa.europa.eu/-/last-chance-to-claim-reach-registration-numbers-for-your-nons-notifications

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
Subgroup 1: Aminopropionates *222-899-0* 238-015-1 239-032-7 *247-552-0* 258-081-5 *271-795-1* 271-865-1 284-219-9 290-475-2 290-476-8 305-318-6	Known or potential hazard for STOT RE	Known or potential hazard for aquatic toxicity	Widespread industrial, professional and consumer uses in washing and cleaning products with high potential for release/exposure of all the substances; the substances 239-032-7 and 290-476-8 also have widespread uses (P and/or C) in Biocidal products, Perfumes, fragrances, Air care products, Cosmetics, personal care products, Polishes and wax blends; the same widespread uses have also been	Currently no need for EU RRM <u>Justification:</u> Harmonised/self classification followed by implementation of necessary RRMs should be sufficient to ensure safe use for environment	CCH for all registered members except for ECs 290-476-8, 305-318-6, 701-354-5 and 915-790-0

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
307-455-7 701-354-5 *825-841-8* 915-790-0 939-647-7			reported for 305-318-6, 701-354-5, 258-081-5 (the latter three in polishes and wax blends), 915-790-0 (air care products), 238-015-1 (cosmetics, personal care products, coatings and paints, thinners, paint removes);widespread uses have also been reported for the substances 239-032-7 (I, P) and 290-476-8 (I, P, C) in fillers, putties, plasters, modelling clay, coatings and paints, thinners, paint removes, Ink and toners, paper and board treatment products, metal surface treatment products; 701-354-5: Widespread industrial, professional and		

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			consumer uses in washing and cleaning products, finger paints, polishes and wax blends, Coatings and paints, thinners, paint removes with high potential for release/exposure;		
Subgroup 2: Aminoacetates from polyamines *307-456-2* *307-458-3* 701-317-3 825-246-3 825-403-6 825-518-1 947-917-0 947-979-9 *CAS 2060541-49-1*	Known or potential hazard for reproductive toxicity and STOT RE	Known or potential hazard for aquatic toxicity	For ECs 825-518-1, 947-979-9 and 825 consumer uses in cosmetics and personal care products, polishes and wax blends have been reported; EC 825-246-3 (ASL): ends up in coatings and inks, adhesives and sealants 947-917-0: professional uses in washing and cleaning products EC 701-317-3: active biocide under BPR, and consumer uses in	Need for EU RRM: CLH <u>Justification:</u> Harmonised/self classification followed by implementation of necessary RRMs should be sufficient to ensure safe use for environment; the need for regulatory measures will need to be revisited in case new data indicates PBT/vPvB hazard. For EC 701-317-3 harmonised	**First step:** CCH for all members (except for ECs 701-317-3, 307-456-2, 307-458-3 and CAS 2060541-49-1) **Second step:** CLH (depending on outcome of CLH for EC 701-317-3)

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			washing and cleaning products	classification is ongoing by IE; depending on the outcome of the CLH for EC 701-317-3 the needs for regulatory risk management actions for this whole subgroup will be revisited.	
Subgroup 3: Aminosuccinates *411-250-9*	Known or potential hazard for STOT RE	Inconclusive hazard for aquatic toxicity	No information on uses	Currently no need for EU RRM <u>Justification:</u> Due to unclaimed NONS no data generation is possible to clarify the hazards currently. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change.	

Annex 1: Overview of classifications

Data extracted on 1 February 2022

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
222-899-0	3655-00-3	Disodium N-(2-carboxyethyl)-N-dodecyl-β-alaninate			Skin Corr. 1B
238-015-1	14171-00-7	N-dodecyl-β-alanine, compound with 2,2',2''-nitrilotriethanol (1:1)		Eye Irrit. 2	
239-032-7	14960-06-6	Sodium N-(2-carboxyethyl)-N-dodecyl-β-alaninate		Skin Irrit. 2, Eye Damage 1, Eye Irrit. 2, Aquatic Acute 3	
247-552-0	26256-79-1	3,3'-(dodecylimino)dipropionic acid, sodium salt			
258-081-5	52663-87-3	N-(2-carboxyethyl)-N-octyl-β-alanine			
271-795-1	68608-68-4	β-Alanine, N-coco alkyl derivs., sodium salts			Eye Irrit. 2
271-865-1	68610-44-6	2-Propenoic acid, methyl ester, reaction products with 2-ethyl-1-hexanamine and sodium hydroxide		Flam. Liquid 2, Acute Tox. 3, Acute Tox. 4, Skin Irrit. 2, Eye Damage 1, STOT Single Exp. 1, Aquatic Chronic 3	
284-219-9	84812-94-2	β-Alanine, N-coco alkyl derivs.		Eye Damage 1, Aquatic Acute 1	Skin Irrit. 2 Eye Irrit. 2
290-475-2	90170-42-6	β-Alanine, N-C8-18-alkyl derivs., monopotassium salts			
290-476-8	90170-43-7	β-Alanine, N-(2-carboxyethyl)-, N-coco alkyl derivs., disodium salts		Eye Irrit. 2, Aquatic Acute 3	
305-318-6	94441-92-6	Sodium N-(2-carboxyethyl)-N-(2-ethylhexyl)-β-alaninate			Eye Irrit. 2 Skin Irrit. 2 Eye Damage 1 Aquatic Chronic 3
307-455-7	97659-50-2	Amines, N-C8-22-alkyltrimethylenedi-, acrylated, sodium salts			Eye Irrit. 2
307-456-2	97659-51-3	Amines, N-C8-22-alkyltrimethylenedi-, reaction products with			Eye Irrit. Aquatic Chronic 2 Aquatic Acute 1 Skin Irrit. 2

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
		sodium chloroacetate, sodium salts			
307-458-3	97659-53-5	Amines, N-C8-22-alkylpolytrimethylenepoly-, carboxymethyl derivs., sodium salts			Skin Irrit. 2 Eye Damage 1 Aquatic Acute 1
411-250-9	-	A mixture of: sodium 2-(C12-18-n-alkyl)amino-1,4-butandioate; sodium 2-octadecenyl-amino-1,4-butandioate	Skin Sens. 1		
701-317-3	139734-65-9	Amines, N-C10–C16-alkyltrimethylenedi-, reaction products with chloroacetic acid; “Ampholyt” under BPR		Acute Tox. 4, Acute Tox. 3, Skin Corr. 1C, Eye Damage 1, STOT RE 2, Aquatic Acute 1, Aquatic Chronic 1	
701-354-5	-	β-Alanine, N-(2-carboxyethyl)-N-[3-[(2-carboxyethyl)amino]propyl]-, N-C12-18-(even numbered) and C18-(unsaturated) alkyl derivs., trisodium salts		Eye Irrit. 2, Aquatic Chronic 4	
825-246-3	2098351-38-1	Amines, N-C12-18-alkyltrimethylenedi-, reaction products with chloroacetic acid, sodium salts		Aquatic Acute 1, Aquatic Chronic 3	
825-403-6	2060541-51-5	pentasodium 3,7,11-tris(carboxylatomethyl)-15-(C12-18)-alkyl-3,7,11,15-tetraazaheptadecane-1,17-dioate		Aquatic Acute 1, Aquatic Chronic 1	
825-518-1	2060541-47-9	trisodium ({3-[(carboxylatomethyl)amino]propyl}{3-[(carboxylatomethyl)(C16-18, C18 unsat alkyl)amino]propyl}amino)acetate		Aquatic Acute 1, Aquatic Chronic 1	
825-841-8	2136366-30-6	trisodium 3-[{3-[bis(2-carboxylatoethyl)amino]propyl}(C12-18 alkyl)amino]propanoate			
915-790-0	-	Reaction mass of Amines, coco alkyl and ß-Alanine, N-(2-carboxyethyl)-, N-coco alkyl derivs. and ß-		Skin Corr. 1C, Eye Damage 1, Aquatic Acute 1, Aquatic Chronic 3	

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
		Alanine, N-coco alkyl derivs			
939-647-7	1474044-68-2	Amines, C12-18-alkyl, reaction products with acrylic acid, sodium salts		Skin Irrit. 2, Eye Damage 1	
947-917-0	-	Amines, N-C12–14 (even numbered)-alkyltrimethylenedi-, reaction products with chloroacetic acid and diethylenetriamine, N-C12–14 (even numbered)-alkyl derivs.		Acute Tox. 4, Skin Corr. 1, Eye Damage 1, STOT RE 1, Aquatic Acute 1, Aquatic Chronic 1	
947-979-9	-	1,3-Propanediamine, N^1-(3-aminopropyl)-N^3-[3-(C18, C18 unsat) alkylamino]propyl]-, N-(carboxymethyl) derivs., sodium salts		Aquatic Acute 1, Aquatic Chronic 1	
	2060541-49-1	1,3-Propanediamine, N^1-(3-aminopropyl)-N^3-[3-[(9Z)-9-octadecen-1-ylamino]propyl]-, N-(carboxymethyl) derivs., sodium salts			

Annex 2: Overview of uses based on information available in registration dossiers (data extracted on 31 January 2022)

EC number / tonnage band	947-979-9 (N/A)	939-647-7 (N/A)	284-219-9 (N/A)	947-917-0 (N/A)	701-317-3 (N/A)	239-032-7 (Annex VIII)	825-518-1 (N/A)	825-246-3 (Annex VIII)	701-354-5 (N/A)	915-790-0 (Annex IX)	271-865-1 (N/A)	825-403-6 (N/A)	290-476-8 (Annex IX)	258-081-5 (N/A)	305-318-6 (Annex IX)	238-015-1 (N/A)	290-475-2 (N/A)
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents																I	
PC 36: Water softeners															C		
PC 37: Water treatment chemicals													C		I	C	
PC 2: Adsorbents						P											
PC 27: Plant protection products						F, I, P							F, I, P, C				
PC 35: Washing and cleaning products		F, I, P, C	F, I, P	P	C	F, I, P, C	C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C		F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C
PC 8: Biocidal products (e.g. disinfectants, pest control)		P	F, I, P		F, P	F, I, P							F, I, P		P, C		
PC 28: Perfumes, fragrances		C													C		
PC 3: Air care products		F, I, P, C				C				F, I, P, C					C		
PC 39: Cosmetics, personal care products	C	P, C				F, I, P, C							F, I, P, C		F, P, C	F, C	
PC 31: Polishes and wax blends	C	F, I, P, C				P, C	C	C	C			C		I, P, C	F, I, P, C		F, I, P, C
PC 15: Non-metal-surface treatment products			I, P			I, P											
PC 24: Lubricants, greases, release products			F, I, P			F, I							F		F, I		
PC 25: Metal working fluids															I		
PC 32: Polymer preparations and compounds															I		
PC 1: Adhesives, sealants						F		A					F, I		F, I, P		
PC 9c: Finger paint								C									
PC 9b: Fillers, putties, plasters, modelling clay						F, I, P		C					F, I, P, C		I		
PC 9a: Coatings and paints, thinners, paint removes			F, I, P			F, I, P		F, I, P, C, A					F, I, P, C		F, I, P, C	C	
PC 18: Ink and toners						F, I, P		F, I, P, A					F, I, P, C		F, I, P		
PC 26: Paper and board treatment products						F, I, P							F, I, P, C				
PC 34: Textile dyes, and impregnating products															F		
PC 23: Leather treatment products		C													F, C		
PC 14: Metal surface treatment products			F, I, P			F, I, P					F, I		I			I	
PC 21: Laboratory chemicals		I, P								I, P			F		I, P	I	
PC41: Oil and gas exploration or production products			F, I, P			F, P			I	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

Data consulted on 03/02/2022

EC / List number	RMOA	Authorisation		Restriction *	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
701-317-3						BPR approved

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40).

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