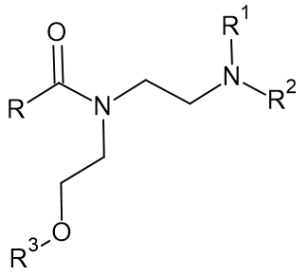
Assessment of regulatory needs

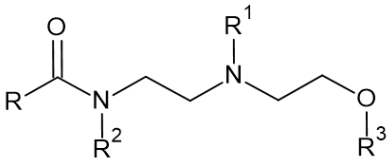
Authority: European Chemicals Agency (ECHA)

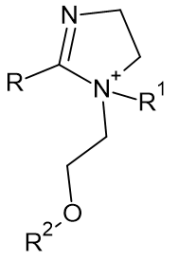
Date: 11/05/2022

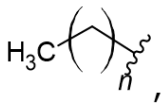
Group Name: Amphoacetate and amphopropionate derivatives of N-hydroxyethylimidazolines

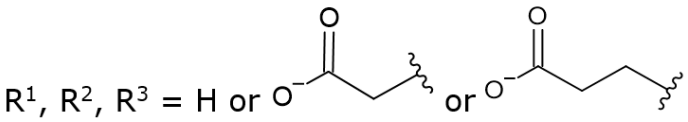
General structure:







R =  , n = 2 – 16



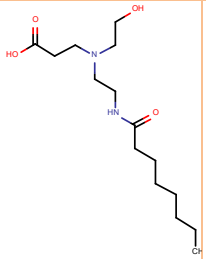
Revision history

Version	Date	Description
1.0	21/06/2022	

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]
Subgroup 1: Amphoacetates				
271-792-5	68608-64-0	Acetic acid, chloro-, reaction products with 2-heptyl-4,5-dihydro-1H-imidazole-1-ethanol and sodium hydroxide	No structure available	Only C&L notifcation
271-794-6	68608-66-2	Acetic acid, chloro-, sodium salt, reaction products with 4,5-dihydro-2-undecyl-1H-imidazole-1-ethanol and sodium hydroxide	UVCB	Full, 100-1000
931-291-0		Reaction products of 1H-Imidazole-1-ethanol, 4,5-dihydro-, 2-(C7-C17 odd-numbered, C17-unsatd. alkyl) derivs. and sodium hydroxide and chloroacetic acid	UVCB	Full, >1000
938-645-3	1689515-39-6	Acetic acid, 2-chloro-, reaction products with 2-C11-13-alkyl-4,5-dihydro-1H-imidazole-1-ethanol and sodium hydroxide	UVCB	Full, 100-1000
942-589-5		Reaction products of fatty acids, C12-14 (even numbered) alkyl and triglycerides, C16 and C18 (unsaturated) alkyl with 2-(2-aminoethylamino)ethanol and sodium chloroacetate	UVCB	Full, not (publicly) available
943-154-2		Reaction products of triglycerides, C18 (unsaturated) alkyl with 2-(2-aminoethylamino)ethanol and sodium chloroacetate	UVCB	Full, not (publicly) available
944-415-3		Reaction products of fatty acids, C12 alkyl and triglycerides, C18 (unsaturated) alkyl with 2-(2-aminoethylamino)ethanol and sodium chloroacetate	UVCB	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

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]
946-565-5		Reaction products of 1H-Imidazole-1-ethanol, 4,5-dihydro-, 2-(C7 odd-numbered alkyl) derivs. and sodium hydroxide and chloroacetic acid	UVCB	Full, not (publicly) available
947-998-2		Reaction products of 1H-Imidazole-1-ethanol, 4,5-dihydro-, 2-(C7-C9 odd-numbered alkyl) derivs. and sodium hydroxide and chloroacetic acid	UVCB	Full, not (publicly) available
		Subgroup 2: Amphopropionates		
264-761-2	64265-45-8	N-(2-hydroxyethyl)-N-[2-[(1-oxooctyl)amino]ethyl]-β-alanine		Full, not (publicly) available
267-569-7	67892-37-9	1-(2-carboxylatoethyl)-2-(heptadec-8-enyl)-4,5-dihydro-1-(2-hydroxyethyl)-1H-imidazolium	UVCB	Full, not (publicly) available
272-897-9	68919-40-4	Imidazolium compounds, 1-[2-(2-carboxyethoxy)ethyl]-1(or 3)-(2-carboxyethyl)-4,5-dihydro-2-norcoco alkyl	UVCB	Full, not (publicly) available
273-535-2	68988-63-6	Imidazolium compounds, 2-C7-18-alkyl-1-(2-carboxyethyl)-4,5-dihydro-3-(hydroxyethyl), hydroxides, sodium salts	UVCB	Full, not (publicly) available
275-085-2	70983-43-6	Imidazolium compounds, 2-C4-8-alkyl-1-(2-carboxyethyl)-4,5-dihydro-3-(hydroxyethyl), hydroxides, sodium salts	UVCB	Full, not (publicly) available
298-632-7	93820-52-1	β-alanine, N-(2-aminoethyl)-N-(2-hydroxyethyl)-, N-coco acyl derivs., monosodium salts	No structure available	Only C&L notification
485-090-3		[No public or meaningful name is available]	UVCB	NONS

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]
-		C8-18 alkylampho(di)propionates	UVCB	Full, not (publicly) available
946-533-0		Reaction products of 1H-Imidazole-1-ethanol, 4,5-dihydro-, 2-(C11-17 and C17 unsatd. alkyl) derivs. and sodium hydroxide and 2-propenoic acid	UVCB	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 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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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

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 alkylamidoamine substituted with a hydroxyethyl moiety on the amino or amido functional group (Fig. 1). Some group members contain imidazoline ring instead of alkylamidoamine moiety (Fig. 2).

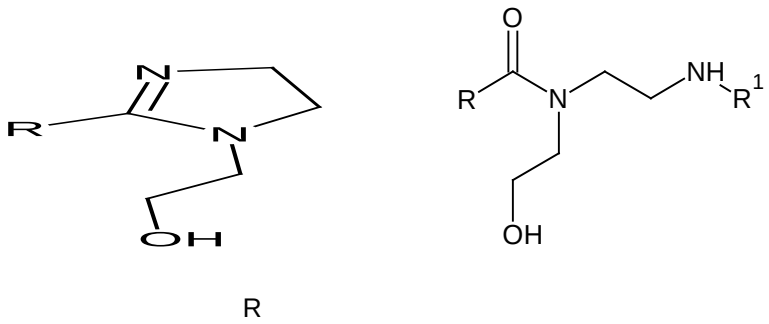

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Figure 1

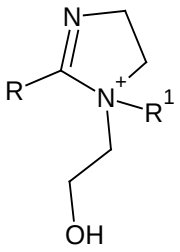

Figure 2

The group consists of 18 substances: 15 have a full registration, 2 have a C&L notification and 1 has ceased manufacture. Out of the 18 group members, 1 is identified as mono-constituent, 14 as UVCB. Two subgroups were defined based on structural similarity and potential hazardous properties: (1) amphoacetates and (2) amphopropionates. In amphoacetates, the R1 substituent (see figure 1) consists of an acetyl group; in amphopropionates, the same substituent consists of a propionyl group: thus, they include, respectively, two and three carbon atoms.

Based on information reported in the REACH registration dossiers, most of the members registered according to Article 10 have a similar use profile. These substances are mainly used in the formulation of washing and cleaning products and/or cosmetics and personal care products. 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 professional and consumer uses. One member (C8-18 alkylampho(di)propionate) is only used as a co-formulant in plant protection products with a high potential for release and exposure. The remaining substances have varied uses however with a generally lower potential for release/exposure: EC 272-897-9 is used only in the industrial setting in surface treatment products and as a pH-regulator; EC 267-569-7 is used industrially in spin finishes for textiles where it is not clear whether article service life may also be relevant; and EC 275-085-2 is used in formulation of in vitro diagnostic reagents used by professionals for research or in the health services sector. All of the substances in this group are amphoteric surfactants with similar chemical properties. 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. Consequently, release/exposure potential are suspected for all members in the group regardless of current registration status or reported uses.

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 information reported in the REACH registration dossiers, most substances in the group are self-classified for aquatic toxicity and some (EC/List 264-761-2, 272-897-9, C8-18 alkylampho(di)propionate, 946-533-0) for skin sensitisation properties. In addition, two substances are self-classified as STOT SE based on the presence of impurities: C8-18 alkylampho(di)propionate is self-classified STOT SE 2 H371 (optical nerve, central nervous system) based on the presence of methanol and List 946-533-0 is self-classified STOT SE 3 H335 (lungs) based on the presence of acrylic acid. For List 931-291-0 data generation for reproductive toxicity is currently ongoing (pre-natal developmental toxicity in a 2nd species and extended one-generation reproductive toxicity study); however, the substance is already suspected as Repro. 1B due to severe heart and lung malformations observed in a prior pre-natal developmental toxicity (PNDT) study in rats.

Data generation is currently ongoing for several members in the group. Although the substances in the overall group are chemically similar, available data indicate a different hazard profile at the subgroup level. Based on the limited data provided it was not possible to attribute the observed difference to a particular constituent nor to fully clarify the driver of the toxicity; therefore, hazards were extrapolated at the subgroup level to reflect the structural similarities (e.g. common functional groups, composition) as well as the observed effects in provided studies.

Based on currently available information, there is a need for (further) EU regulatory risk management – namely **restriction** to address the potential reproductive toxicity (Repro. 1B) hazard and high potential for release/exposure for **all amphoacetates**.

Based on ECHA's assessment of currently available hazard information provided in the registration dossiers, as well as considerations of structural similarity and presence of common functional moiety all substances in the amphoacetate subgroup are potential reproductive toxicants. List 931-291-0 is a known reprotoxicant due to severe cardiovascular malformations observed in a PNDT study in rats and would likely warrant a classification as Repro. 1B. It should be noted that effects on the thyroid were also observed however available data are not sufficient to conclude on potential ED properties for human health (ED HH). Due to the high level of uncertainty, the strategy will not cover the potential ED HH properties at this time and will be revised after clarification from the ongoing data generation. PNDT 2nd species and extended one-generation reproductive toxicity (EOGRT) studies are currently ongoing. The substance is used as a source substance in read across for several other subgroup members further suggesting that similar effects could be expected for the entire subgroup. PNDT 1st species and 90-day studies are currently ongoing to clarify the reprotoxic and ED HH potential for EC/List 271-794-6 and 938-645-3.

As a first step, the reproductive toxicity potential will require data generation to clarify and support hazard extrapolation to the subgroup. Relevant studies are already ongoing for several members (EC/List 271-794-6, 938-645-3, 931-291-0) and it is suggested to wait for the ongoing data generation before proceeding with the proposed regulatory action(s). In addition, a compliance check will be initiated in parallel for selected members (EC/List 942-589-5, 943-154-2, 944-415-3, 946-565-5) to address data gaps and further reduce uncertainties.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Repro 1B.

CLH as Repro 1B 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 and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 30.

CLH will also support regulatory action under other regulations. For instance, in this specific case harmonised classification as Repr. 1B will trigger regulatory action under the Cosmetic products regulation (EC) No 1223/2009 for uses as perfume/fragrance, cosmetic and personal care product, since Repr. 1B substances are restricted by this regulation.

Several substances in this subgroup are used by consumers, professionals and industrial workers in washing and cleaning products with a high potential for human exposure. Although this use has not been reported for all members in the subgroup, it is preliminarily expected that any of the amphoacetate substances may be

substituted due to their shared properties as amphoteric surfactants. Therefore, it is suggested to consider the same regulatory approach for all amphoacetates where the hazard is confirmed in order to avoid regrettable substitution.

The professional uses in washing and cleaning products are expected to be 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 substances as such or in mixtures (concentration limit in mixtures) used by professionals in washing and cleaning products** is suggested after CLH.

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.

It is suggested to further clarify and possibly cover industrial use of washing and cleaning products as part of the restriction.

Based on currently available information, there is no need for (further) EU regulatory risk management for **all amphopropionates**.

Based on ECHA's assessment of currently available hazard information provided in the registration dossiers and considerations of structural similarity and presence of common functional moiety all the substances in the amphopropionate subgroup have (potentially) the following human health/environmental hazards: skin sensitisation properties and aquatic toxicity. These hazards are identified based on several observed effects from the majority of substances in this subgroup. Based on structural similarity the findings from the toxicity studies are extrapolated to other amphopropionates where there is limited information for these endpoints. Based on the available data and despite uncertainies that will be adressed under CCH, other human health and environmental hazards including environmental ED activity are considered unlikely. At the same time, it was not possible to conclude on the PBT hazard for substances of the subgroup, due to lack of information on the biodegradability of constituents. A compliance check will be opened for all members except EC 272-897-9 in order to further clarify the hazards, address data gaps and reduce uncertainties.

Most of the amphopropionates are used in the industrial setting or by highly trained professionals in the research or health services sector where exposure is likely to be adequately controlled. In addition, C8-18 alkylampho(di)propionate is used as a co-formulant in plant protection products and based on the potential hazards identified would not need additional regulatory action under REACH to support safe use under the Plant Protection Products Regulation.

For EC 267-569-7, the registrant only reports industrial use in spin finishes for textiles however information on the technical function is insufficient to conclude whether article service life would be relevant. According to publicly available external sources, amphoteric surfactants may be used as dispersing agents in textile finishing processes[3,4]. It is therefore likely, although with some uncertainty,

[3] https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1478-4408.1981.tb03710.x#:~:text=Dispersing%20agents%20are%20used%20in,such%20as%20scouring%20and%20cleansing

[4] https://www.clariant.com/en/Solutions/Products/2015/01/13/18/06/Dispersogen-LEC

that the substance is not intended to remain in the textile and would be washed out prior to use.

Several members (EC/List 264-761-2, 273-535-2, 946-533-0) have widespread professional and/or consumer uses in washing and cleaning products, cosmetics and personal care products. Based on information available in the REACH registration dossiers, two of the substances are not readily biodegradable and the biodegradability of constituents for two of them needs to be further clarified via CCH. All three 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. For those substances further scrutiny may be warranted under the Detergents Regulation.

For industrial and professional uses, sufficient and consistent self-classification by registrants for skin sensitisation and aquatic toxicity should require adequate risk management measures to be in place according to workplace and environmental legislation and results in an exposure and risk assessment requirement in the Chemical Safety Assessment (CSA) including the generation of exposure scenarios and communication on associated operational conditions (OCs) and risk management measure (RMM). It is expected that following data generation registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing substances EC/List 264-761-2, 273-535-2, 946-533-0.

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.

Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management for any substance in the amphopropionate subgroup. However, should the results of data generation lead to identification of additional hazards e.g. similar to those observed for amphoacetates, the strategy will be revised accordingly and a similar approach potentially suggested for the overall group.

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
Amphoacetates: **271-792-5** **271-794-6** **931-291-0** **938-645-3** **942-589-5** **943-154-2** **944-415-3** **946-565-5** **947-998-2**	Known or potential hazard for reproductive toxicity Inconclusive hazard for ED	Known or potential hazard for aquatic toxicity Inconclusive hazard for ED	Washing and cleaning products (F,I,P,C); cosmetics and personal care products (F,C); perfumes, fragrances (C) – high potential for human exposure and release to environment. 271-792-5 only C&L notification *Potential for substitution within substances in the group based on chemical structure and properties e.g. as surfactant in washing and cleaning products.*	**Need for EU RRM: Restriction** Justification: The harmonised classification as Repro. 1B would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration.	**First step:** Wait for ongoing data generation for EC/List 271-794-6 and 938-645-3 CCH in parallel on selected members (EC/List 942-589-5, 943-154-2, 944-415-3, 946-565-5) **Next steps (if hazard confirmed):** • CLH • Restriction

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				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. Industrial uses to be considered as part of the restriction.	
<u>Amphopropionates</u>: **264-761-2** **267-569-7** **272-897-9** **273-535-2** **275-085-2** **298-632-7** **485-090-3** **C8-18 alkylampho(di)propionate** **946-533-0**	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity Inconclusive hazard for PBT	For 264-761-2, 273-535-2, 946-533-0, C8-18 alkylampho(di)propionate : widespread uses with high potential for release/exposure. Varied uses with lower potential for exposure: for 267-569-7 industrial use in spin finishes for textiles; for 272-897-9 industrial use in surface treatment products and pH-regulators; for 275-085-2 use as in vitro diagnostic reagant in	**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 at the workplace. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation. EC/List 264-761-2, 273-535-2, 946-533-0 subject to	CCH for all members except EC 272-897-9

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			research and health services sector. 298-632-7 only C&L notification; 485-090-3 cease manufacture *Potential for substitution within substances in the group based on chemical structure and properties e.g. as surfactant in washing and cleaning products.*	Detergents Regulation.	

Annex 1: Overview of classifications

Data extracted on 14/01/2022

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
264-761-2	64265-45-8	N-(2-hydroxyethyl)-N-[2-[(1-oxooctyl)amino]ethyl]-β-alanine	-	*Eye Irrit. 2 H319* *Skin Sens. 1B H317* *Aquatic Chronic 2 H411*	*Skin Irrit. 2 H315[1 out of 3]*
267-569-7	67892-37-9	1-(2-carboxylatoethyl)-2-(heptadec-8-enyl)-4,5-dihydro-1-(2-hydroxyethyl)-1H-imidazolium	-	-	-
271-792-5	68608-64-0	Acetic acid, chloro-, reaction products with 2-heptyl-4,5-dihydro-1H-imidazole-1-ethanol and sodium hydroxide		-	*Skin Irrit. 2 H315[3 out of 7]* *Eye Irrit. 2 H319[3 out of 7]*
271-794-6	68608-66-2	Acetic acid, chloro-, sodium salt, reaction products with 4,5-dihydro-2-undecyl-1H-imidazole-1-ethanol and sodium hydroxide	-	*Eye Irrit. 2 H319, specific concentration: >16* *Aquatic Chronic 3 H412*	*Eye Irrit. 2 H319[8 out of 11]*
272-897-9	68919-40-4	Imidazolium compounds	-	*Eye Damage 1 H318* *Skin Sens. 1*	*Skin Irrit. 2 H315[2 out of 2]*

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
		, 1-[2-(2-carboxyethoxy)ethyl]-1(or 3)-(2-carboxyethyl)-4,5-dihydro-2-norcoco alkyl		*H317* *Aquatic Chronic 2 H411*	
273-535-2	68988-63-6	Imidazolium compounds, 2-C7-18-alkyl-1-(2-carboxyethyl)-4,5-dihydro-3-(hydroxyethyl), hydroxides, sodium salts		*Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Aquatic Chronic 2 H411*	*Eye Damage 1 H318[1 out of 1]*
275-085-2	70983-43-6	Imidazolium compounds, 2-C4-8-alkyl-1-(2-carboxyethyl)-4,5-dihydro-3-(hydroxyethyl), hydroxides, sodium salts	-	*Skin Irrit. 2 H315* *Eye Damage 1 H318* *Aquatic Chronic 3 H412*	-
298-632-7	93820-52-1	β-Alanine, N-(2-aminoethyl)-N-(2-hydroxyethyl)-, N-cocoacyl derivs., monosodium salts	-	-	*Eye Irrit. 2 H319[3 out of 5]*
931-291-0	-	Reaction products of 1H-Imidazole-1-ethanol, 4,5-dihydro-, 2-(C7-C17 odd-	-	*Eye Damage 1 H318* *Aquatic Chronic 3 H412*	-

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
		numbered, C17-unsatd. alkyl) derivs. and sodium hydroxide and chloroacetic acid			
938-645-3	16895 15-39-6	Acetic acid, 2-chloro-, reaction products with 2-C11-13-alkyl-4,5-dihydro-1H-imidazole-1-ethanol and sodium hydroxide	-	*Eye Irrit. 2 H319, specific concentration: >16* *Aquatic Chronic 3 H412*	-
-	-	C8-18 alkylampho (di)propion ates	-	*Eye Damage 1 H318, specific concentration: >=40* *Eye Damage 1 H318, specific concentration: >=16* *Skin Sens. 1B H317* *STOT Single Exp. 2 H371, affected organs: optical nerve, central nervous system (because of the methanol content in the substance)* *Aquatic Chronic 2 H411*	-
942-589-5	-	Reaction products of fatty acids, C12-14 (even numbered) alkyl and triglyceride s, C16 and C18 (unsaturate d) alkyl	-	*Eye Damage 1 H318*	-

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
		with 2-(2-aminoethylamino)ethanol and sodium chloroacetate			
943-154-2	-	Reaction products of triglycerides, C18 (unsaturated) alkyl with 2-(2-aminoethylamino)ethanol and sodium chloroacetate	-	*Eye Damage 1 H318*	-
944-415-3	-	Reaction products of fatty acids, C12 alkyl and triglycerides, C18 (unsaturated) alkyl with 2-(2-aminoethylamino)ethanol and sodium chloroacetate		*Eye Damage 1 H318*	-
946-565-5	-	Reaction products of 1H-Imidazole-1-ethanol, 4,5-dihydro-, 2-(C7 odd-numbered alkyl) derivs. and sodium hydroxide and chloroacetic acid		*Eye Damage 1 H318* *Skin Sens. 1B H317* *STOT Single Exp. 3 H335, affected organs: lungs* *Aquatic Chronic 3 H412*	-

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
946-533-0	-	Reaction products of 1H-Imidazole-1-ethanol, 4,5-dihydro-, 2-(C11-17 and C17 unsatd. alkyl) derivs. and sodium hydroxide and 2-propenoic acid	-	*Aquatic Chronic 3 H412*	-
947-998-2	-	Reaction products of 1H-Imidazole-1-ethanol, 4,5-dihydro-, 2-(C7-C9 odd-numbered alkyl) derivs. and sodium hydroxide and chloroacetic acid	-	*Eye Irrit. 2 H319*	-

(*) 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 extracted on 14/01/2022

Main types of applications structured by product or article types	264-761-2	267-569-7	272-897-9	273-535-2	275-085-2	C8-18 alkylampho(di) propionate	946-533-0	271-794-6	931-291-0	938-645-3	942-589-5	943-154-2	944-415-3	946-565-5	947-998-2
	Amphopropionates							Amphoacetates							
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents			F, I						I	F, I					
PC 14: Metal surface treatment products			F, I						I						I
PC 35: Washing and cleaning products	F, **P**, **C**			F, I, **P**, **C**			F, **P**, **C**	F, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**				F, I, **P**	I, **P**, **C**
PC 28: Perfumes, fragrances	**C**						**C**		**C**						
PC 39: Cosmetics, personal care products	F, **C**			F, **P**, **C**			F, **C**	F, **P**, **C**	F, **C**	F, **P**, **C**	F, **C**	F, **C**	F, **C**		
PC 27: Plant protection products						F, **P**									
PC 31: Polishes and wax blends				F, **P**											
PC 37: Water treatment chemicals				F, I											
PC 15: Non-metal-surface treatment products			F, I												
PC 25: Metal working fluids				F, I											
PC 34: Textile dyes, and impregnating products		I (**A**?)													
PC 21: Laboratory chemicals				F, **P**	F, I, **P**				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

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