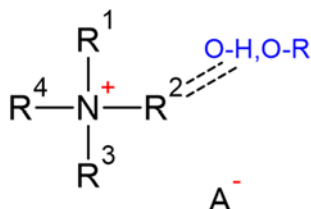


## Assessment of regulatory needs

**Authority:** European Chemicals Agency

**Group Name:** Quaternised alcohol amines and their esters

**General structure:**

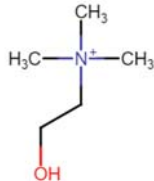
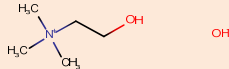
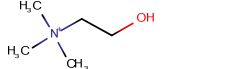
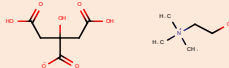


**Revision history**

<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	14 January 2025	

## ASSESSMENT OF REGULATORY NEEDS

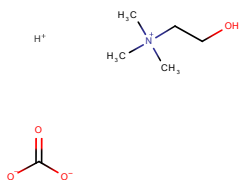
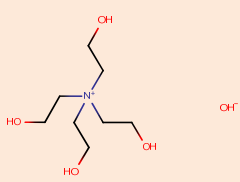
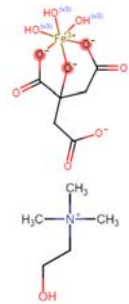
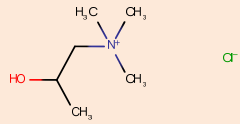
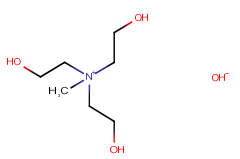
### Substances within this group:

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) <sup>1</sup>
<b>Subgroup 1: compounds with short alkyl chain</b>				
200-535-1*	62-49-7	Choline		OSII or TII
204-625-1*	123-41-1	Choline hydroxide		Full, >1000
200-655-4	67-48-1	Choline chloride		Full, >1000
201-068-6	77-91-8	Choline dihydrogen citrate		OSII or TII

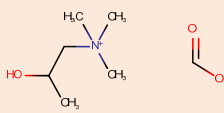
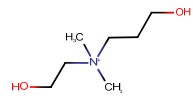
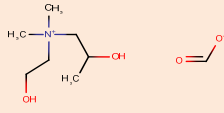
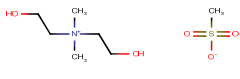
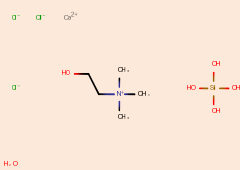
<sup>1</sup> The total aggregated tonnage band may be available on ECHA's webpage at <https://echa.europa.eu/information-on-chemicals/registered-substances>

\* Based on substance identity information included in submission dossiers, in this Group the following are considered duplicate entries: 200-535-1 and 204-625-1.

ASSESSMENT OF REGULATORY NEEDS

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) <sup>1</sup>
201-137-0	78-73-9	Choline hydrogen carbonate		Full, not (publicly) available
211-158-7	631-41-4	Tetrakis (2-hydroxyethyl) ammonium hydroxide		OSII or TII
215-649-7	1336-80-7	Ferrocholate		Full, not (publicly) available
219-183-5	2382-43-6	(2-hydroxypropyl) trimethylammonium chloride		OSII or TII
251-624-7	33667-48-0	Tris(2-hydroxyethyl) methylammonium hydroxide		C&L notification

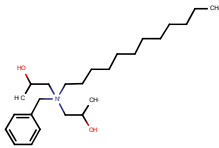
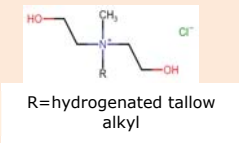
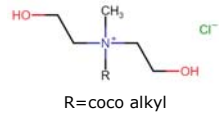
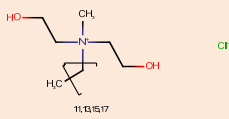
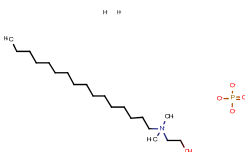
ASSESSMENT OF REGULATORY NEEDS

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) <sup>1</sup>
263-503-6	62314-25-4	(2-hydroxypropyl) trimethylammonium formate		Full, 10-100
278-860-3	78182-00-0	(2-hydroxyethyl) (3-hydroxypropyl) dimethylammonium chloride		Cease manufacture
400-300-5	-	DABCO XE-8442		NONS
604-846-7	152390-17-5	N, N-bis-(2-hydroxyethyl) dimethyl ammonium methane sulfonate		Full, not (publicly) available
902-537-4	-	Reaction mass of tetrahydroxysilane and choline chloride and calcium chloride and water		Full, not (publicly) available

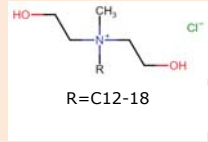
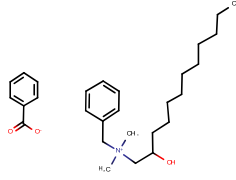
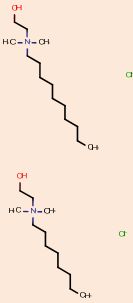
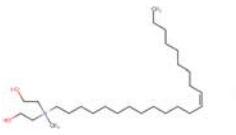
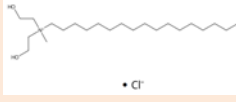
ASSESSMENT OF REGULATORY NEEDS

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) <sup>1</sup>
947-985-1	-	Reaction mass of 2-hydroxy-N-(2-(2-hydroxyethoxy)ethyl)-N-(2-hydroxyethyl)-N-methylethan-1-aminium hydroxide and 2-hydroxy-N,N-bis(2-hydroxyethyl)-N-methyl ethanaminium hydroxide		Full, not (publicly) available
<b>Subgroup 2: compounds with long alkyl chain/aryl group</b>				
242-332-0	18448-65-2	Bis(hydroxyethyl) methyloley l ammonium chloride		Full, not (publicly) available
243-008-1	19379-90-9	Benzoxonium chloride		Cease manufacture
244-921-8	22340-01-8	Dodecylbis (2-hydroxyethyl) methylammonium chloride		C&L notification
262-380-6	60687-90-3	Bis(2-hydroxyethyl) methyltetradecyl ammonium chloride		Not registered

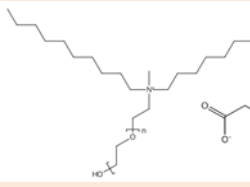
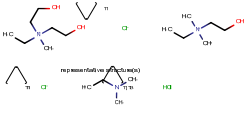
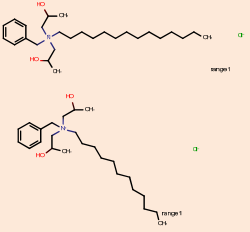
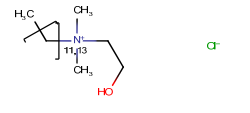
ASSESSMENT OF REGULATORY NEEDS

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) <sup>1</sup>
265-345-3	65059-91-8	Benzyl-dodecylbis (2-hydroxypropyl) ammonium chloride		C&L notification
271-760-0	68607-27-2	Quaternary ammonium compounds, (hydrogenated tallow alkyl) bis(hydroxyethyl) methyl, chlorides	 R=hydrogenated tallow alkyl	Not registered
274-846-6	70750-47-9	Quaternary ammonium compounds, coco alkylbis(hydroxyethyl)methyl, chlorides	 R=coco alkyl	C&L notification
276-038-9	71808-53-2	Quaternary ammonium compounds, C12-18-alkylbis(hydroxyethyl)methyl, chlorides		Full, not (publicly) available
287-619-1	85563-48-0	Hexadecyl(2-hydroxyethyl) dimethylammonium dihydrogen phosphate		Full, not (publicly) available

ASSESSMENT OF REGULATORY NEEDS

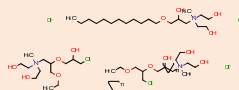
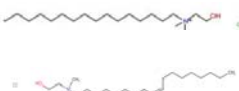
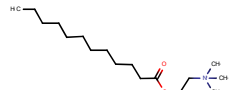
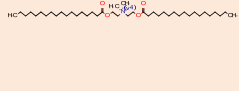
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288-474-7	85736-63-6	Quaternary ammonium compounds, C12-18-alkyl(hydroxyethyl) dimethyl, chlorides		C&L notification
402-610-6	113694-52-3	Benzyl-2-hydroxydodecyl dimethylammonium benzoate		NONS
417-360-3	1379678-84-8	C8-10 alkyl dimethyl hydroxyethyl ammoniumchloride (chain < C8: <3%, chain = C8: 15%-70%, chain = C10: 30%-85%, chain > C10: <3%)		Full, not (publicly) available
426-210-6	120086-58-0	(Z)-13-docosenyl-N,N-bis(2-hydroxyethyl)-N-methyl-ammonium chloride		C&L notification
608-443-7	3010-24-0	1-Octadecanaminium, N,N-bis(2-hydroxyethyl)-N-methyl-, chloride (1:1)		Not registered

ASSESSMENT OF REGULATORY NEEDS

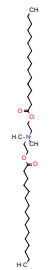
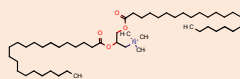
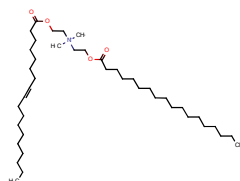
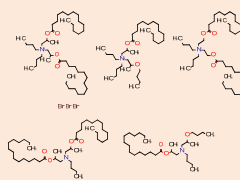
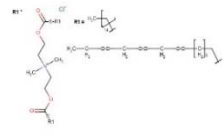
EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
615-231-8	70983-58-3	Poly(oxy-1,2-ethanediyl), $\alpha, \alpha'$ -(iminodi-2,1-ethanediyl) bis[.omega.-hydroxy-, N-[3-(C10-16-alkyloxy)propyl] derivs., di-Et sulfate-aternized	structure not available	Full, not (publicly) available
619-057-3	94667-33-1	Poly(oxy-1,2-ethanediyl), $\alpha$ -[2-(didecylmethylammonio)ethyl]-.omega.-hydroxy-, propanoate (salt) (Bardap 26)		Full, 100-1000
701-357-1	-	Quaternary ammonium compounds, C12-14 (even numbered) alkyl(hydroxyethyl)dimeethyl, C12 alkylbis(hydroxyethyl)methyl, chlorides and amines, C12-14 (even numbered) alkyldimethyl, chlorides		Full, not (publicly) available
916-226-6	-	Reaction mass of benzyldodecylbis(2-hydroxypropyl) ammonium chloride and benzylbis(2-hydroxypropyl)tetradecylammonium chloride		Full, not (publicly) available
931-275-3	1125503-33-4	N-(2-hydroxyethyl)-N,N-dimethyl alkyl-C12-14-(even numbered)-1-aminium chloride		Full, not (publicly) available



ASSESSMENT OF REGULATORY NEEDS

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) <sup>1</sup>
947-953-7	-	Reaction mass of Reaction product of 1-chloro-3-{[1-chloro-3-(dodecyloxy)propan-2-yl]oxy}propan-2-ol with methyl diethanolamine and [3-(dodecyloxy)-2-hydroxypropyl]bis(2-hydroxyethyl)methylammonium chloride		Full, not (publicly) available
948-061-0	-	Quaternary ammonium compounds, C14-18 (even numbered) and C18 unsaturated-alkyl-hydroxyethyl-dimethyl, chlorides		Full, not (publicly) available
<b>Subgroup 3: esters</b>				
246-745-7	25234-60-0	2-lauroyloxyethyl trimethylammonium chloride		Full, not (publicly) available
267-382-0	67846-68-8	Dimethylbis[2-[(1-oxooctadecyl)oxy]ethyl]ammonium chloride		Full, not (publicly) available

ASSESSMENT OF REGULATORY NEEDS

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) <sup>1</sup>
306-361-3	97158-31-1	Dimethylbis[2-[(1-oxohexadecyl)oxy]ethyl]ammonium chloride		Full, not (publicly) available
405-660-7	220609-41-6	N,N,N-trimethyl-2,3-bis(stearoyloxy)propylammonium chloride		NONS
418-120-0	-	ADOGEN CDMC		Not registered
431-530-4	1380226-29-8	N,N-bis(cocoyl-2-oxypropyl)-N,N-dibutylammonium bromide		Not registered
620-174-7	1079184-43-2	Ethanaminium, 2-hydroxy-N-(2-hydroxyethyl)-N,N-dimethyl-, esters with C16-18 and C18-unsatd. fatty acids, chlorides		Full, not (publicly) available

ASSESSMENT OF REGULATORY NEEDS

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) <sup>1</sup>
939-685-4	1474044-71-7	1-Propanaminium, 2-hydroxy-N-(2-hydroxypropyl)-N,N-dimethyl-, esters with C18-unsatd. fatty acids, Me sulfates (salts)		Full, not (publicly) available
941-174-6	-	1-Propanaminium, 2-hydroxy-N-(2-hydroxypropyl)-N,N-dimethyl-, esters with fatty acids, C16-18 (even numbered) and C18 unsatd., Me sulfates (salts)		Full, not (publicly) available
947-057-6	-	Reaction mass of 2-hydroxy-3-[(1-oxodocosyl)oxy]propyltrimethyl ammonium chloride and 2-methyl pentane-2,4-diol		Full, not (publicly) available
951-974-7	-	Reaction mass of Ethanaminium, 2-hydroxy-N,N-dimethyl-N-[2-[(1-oxooctadecyl)oxy]ethyl]-, chloride and Ethanaminium, N,N-dimethyl-2-[(1-oxohexadecyl)oxy]-N-[2-[(1-oxooctadecyl)oxy]ethyl]-, chloride		Full, not (publicly) available
953-404-2	-	Ethanaminium, 2-hydroxy-N-(2-hydroxyethyl)-N,N-dimethyl-, diesters with C18-unsatd. fatty acids, Me sulfates		Full, not (publicly) available

Subgroup 4: compounds with two quaternary amines

ASSESSMENT OF REGULATORY NEEDS

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) <sup>1</sup>
442-730-6	35132-93-5	(2-hydroxypropyl)({6-[(2-hydroxypropyl)dimethylazaniumyl]hexyl})dimethylazanium propane-1,2-diol dihydroxide		Full, not (publicly) available
605-146-4	158451-78-6	1,6-Hexanediamine, N1,N1,N6,N6-tetramethyl-, propoxylated (>1 < 4,5 mol PO)		Full, not (publicly) available
806-726-1	-	Reaction product of 2-[[2-(dimethylamino)ethyl]methylamino]ethanol di(hexanoate) and ethyl oxirane (1:2)		Full, not (publicly) available
807-137-2	110528-94-4	1,3-Propanediaminium, 2-hydroxy-N1,N3-bis(2-hydroxyethyl)-N1,N1,N3,N3-tetramethyl-, chloride (1:2)		Full, not (publicly) available
916-222-4	-	Reaction mass of N,N'-ethylenebis[N-methyl-2-[(1-oxo-9-octadecenyl)oxy]-N-[2-[(1-oxo-9-octadecenyl)oxy]propyl]propylammonium] dimethyl disulphate and [2-[bis(2-hydroxypropyl)amino]ethyl]bis(2-hydroxypropyl)(methyl)	structure not available	Full, not (publicly) available

ASSESSMENT OF REGULATORY NEEDS

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) <sup>1</sup>
		ammonium methyl sulphate, dioleate (ester)		
947-766-0	-	Quaternary ammonium compounds, N,N,N'-tris(hydroxyethyl)-N,N'-dimethyl-N'-C16-18 (even numbered) and C18 unsatd., alkyltrimethylenedi-, bis(Me sulfates) (salts)	structure not available	Full, not (publicly) available

This table contains also group members that are only notified under the CLP Regulation, however, the list is not necessarily exhaustive.

## Contents

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2 Conclusions and proposed actions.....	21
3 Justification for the (no) need for regulatory risk management action at EU level (if hazards confirmed) .....	26
Annex 1: Overview of classifications .....	31
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**DISCLAIMER**

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## Foreword

The assessment of regulatory needs of a group of substances is an iterative, informal process to help authorities consider the most appropriate way to address an identified concern for a group of substances or a single substance and decide whether further regulatory risk management activities are necessary.

The grouping is mainly based on structural similarity and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g. OECD categories)<sup>2</sup>. These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA's grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level<sup>3</sup>. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

The outcome of these assessments are proposals for immediate (the first action) and subsequent regulatory action(s), including the foreseen ultimate regulatory action (last foreseen regulatory action) to address the identified concern(s) in case the potential hazards are confirmed. For example, further data generation through compliance check is suggested as a first action, to confirm the identified hazard.

Where hazards are confirmed, regulatory risk management actions could be considered for the whole group, for a subgroup or for individual substances within the group. The robustness of the group depends on the stage of assessment and the level of certainty this stage requires. For example, the needs for grouping under restriction may differ from the needs for grouping for the purpose of harmonised classification. Group membership is reconsidered accordingly throughout the iterative assessment of regulatory needs, for example, after further information is generated and the hazard has been clarified or when new insights on uses and risks are available.

The assessment of regulatory needs in itself does not represent a regulatory action, but rather a preparatory step to consider further possible regulatory actions at the level of individual substances or groups/subgroups of substances.

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<sup>2</sup> [Working with Groups - ECHA \(europa.eu\)](https://eucha.europa.eu)

<sup>3</sup> Regarding hazard properties the focus is for instance 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 report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).



## ASSESSMENT OF REGULATORY NEEDS

Publication of ARNs makes it easier for companies to follow the latest status of their substances of interest, anticipate potential regulatory actions and make strategic choices in their chemicals portfolio.

For more information on assessments of regulatory needs please consult ECHA's website<sup>4</sup>.

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<sup>4</sup> <https://echa.europa.eu/understanding-assessment-regulatory-needs>

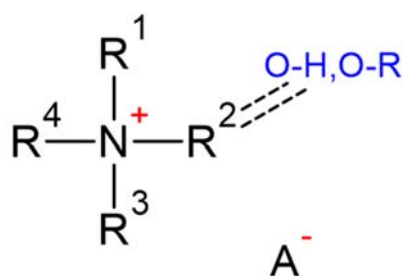
## Glossary

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
PMT/vPvM	Persistent, mobile, and toxic / very persistent and very mobile
RDT	Repeated dose toxicity
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
TPE	Testing proposal evaluation

## 1 Overview of the group

Explanations on the scope of this assessment is available in the foreword to this document. Please read it carefully before going through the report.

ECHA has grouped together structurally similar substances defined as quaternised alcohol amines and their esters of which a generic structure is represented below. The group consists of 54 substances, out of which 33 have a full registration, 4 are intermediates, 4 are non-updated NONS, 8 are not registered and 5 have ceased manufacture. Most of the registered substances are identified as mono-constituent. Some are reported as multi-constituent or UVCB-type of substances based on the presence of e.g. different alkyl chain length or different esters. The structure of the substances is based on quaternary ammonium, having at least one aliphatic or aryl substituent with an alcohol or relative ester. Typical counter anions to the quaternary amine are chloride, hydroxide, methylsulfate.



**Figure 1. Generic structure of the group**

For the purpose of the current assessment, the substances were sub-grouped into four subgroups based on their structure as reported in the table below:

Sub-group	Structural feature	Representative structure
1	Short alkyl chain	
2	Long alkyl chain or aryl group	
3	Esters	
4	Two quaternary amines	

## ASSESSMENT OF REGULATORY NEEDS

Based on information reported in the REACH registration dossiers most of the substances in subgroup 1 are mainly used as intermediates in the production of other chemicals. However, other uses, including professional and consumer uses, have been identified for specific substances, e.g. in washing and cleaning products, plant protection products or pharmaceuticals. Short alkyl chain quaternised alcohol amines in the group are structurally close analogues to short chain quaternary ammonium compounds outside this group which have potential for neurotoxicity. The toxicological information available on the substances in this group (or subgroup 1) however did not suggest neurotoxic hazards. Characteristic structural moieties (e.g. alcohol moiety) in this group may explain the unlikely neurotoxicity hazard in the group.

For substances in subgroup 2 and 3 the identified uses are associated to the surfactant properties of the substances. Main uses are in washing and cleaning products, biocidal products, fragrances, air care products, personal care products, polishes, textile and leather treatment products and surface treatment products. Professional and/or consumer uses were described for most of the uses and therefore with high potential for exposure for workers and consumers and release to the environment.

The uses described for the substances in subgroup 4 are more substance-dependent but all include professional and/or consumers uses and therefore with high potential for exposure and release to the environment. The substances are used in personal care products, adhesives/sealants, fillers and coatings.

## 2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g., strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). 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 may be updated, and conclusions and actions revisited.

**Table 1: Conclusions and proposed actions**

Subgroup name EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
<b>Subgroup 3</b> 431-530-4	Known or potential hazard for STOT RE (neurotoxicity) for reproductive toxicity for ED for skin sensitisation	Known or potential hazard for ED for aquatic toxicity  Inconclusive hazard for PBT/vPvB	No uses (substance is not registered)	<b>CLH</b> for STOT RE (neurotoxicity) for reproductive toxicity for ED  <u>Justification:</u> Inclusion of the substance to a potential group entry of harmonised classification for bromide salts
<b>Subgroup 1</b> 604-846-7 947-985-1  <b>Subgroup 2</b>	Known or potential hazards for carcinogenicity and skin sensitisation for List 916-226-6 in subgroup 2 (Carc. 1B CLH chlorotoluene impurity)  Known or potential hazard	Known or potential hazard for aquatic toxicity for all the substances in subgroup 2  Inconclusive hazard for PBT/vPvB	Substances in subgroup 1 are used as intermediates in the production of other chemicals. Substance List 947-985-1 has, in addition, many	CCH for EC/List 242-332-0, 267-382-0, 276-038-9, 306-361-3, 604-846-7, 701-357-1, 916-222-4, 916-226-6, 939-685-4, 941-174-6, 947-766-0, 951-974-7, 953-404-2  <b>Potential last action:</b>

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Subgroup name EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
242-332-0 243-008-1 244-921-8 262-380-6 265-345-3 271-760-0 274-846-6 276-038-9 288-474-7 402-610-6 417-360-3 426-210-6 608-443-7 615-231-8 701-357-1 916-226-6 947-953-7 948-061-0  <b>Subgroup 3</b>  267-382-0 306-361-3 405-660-7 418-120-0 939-685-4 941-174-6 951-974-7 953-404-2	for STOT RE 2 for subgroup 2 substances EC 276-038-9 and List 701-357-1	Inconclusive hazard for PMT/vPvM except List 615-231- 8 and 947-953-7  Inconclusive hazard for ENV ED	industrial uses identified. Low potential for exposure is expected for these two substances.  For substances in subgroup 2 and 3 the identified uses are associated to the surfactant properties of the substances. Main uses are washing and cleaning products, biocidal products, fragrances, air care products, personal care products, polishes, textile and leather treatment products and surface treatment products. Professional and/or consumer uses were described for most of the uses and therefore with high potential for exposure/release.	<p><b>Currently not possible to assess the regulatory needs</b></p> <p><u>Justification:</u>                      It is not possible to assess the needs for regulatory risk management as information on hazard is not sufficient to conclude on PBT and/or PMT. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).</p> <p>With regard to skin sensitisation, harmonised/self-classification (will) require company level risk management measures (RMM) for workers to be in place. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation.</p> <p>With regard to the classification as STOT RE 2 for substances EC 276-038-9 and List 701-357-1 in subgroup 2, CLH has already been identified as an action after data generation. Nevertheless, a harmonised classification as STOT RE 2 would not impact any known legislations based on the uses of the substances. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.</p>

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Subgroup name EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
<p><b>Subgroup 4</b></p> <p>442-730-6 605-146-4 806-726-1 807-137-2 916-222-4 947-766-0</p>			<p>For most of the substances in subgroup 4 professional and/or consumers uses are described and therefore there is high potential for exposure/release: substances List 807-137-2 and List 947-766-0 (personal care products), substance List 605-146-4 (adhesives/sealants, fillers and coatings), substance EC 442-730-6 (coatings and professional uses in inks) and substance List 947-766-0 (fillers, putties, plasters, modelling clay).</p>	
<p><b>Subgroup 1</b></p> <p>200-535-1 200-655-4</p>	<p>No hazard or unlikely hazard except EC 200-535-1 has (potentially) the</p>	<p>Known or potential hazard for aquatic toxicity</p>	<p>Most common use of the substances in subgroup 1 is as intermediate in the</p>	<p>CCH for EC/List 246-745-7, 619-057-3, 620-174-7, 931-275-3</p> <p><b>Potential last action:</b></p>

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Subgroup name EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
201-068-6 201-137-0 204-625-1 211-158-7 215-649-7 219-183-5 251-624-7 263-503-6 278-860-3 400-300-5 902-537-4  <b>Subgroup 2</b>  287-619-1 619-057-3 931-275-3  <b>Subgroup 3</b>  246-745-7 620-174-7 947-057-6	reproductive toxicity human health hazard related to methoxyethanol (EC 203-713-7) impurity with Repr. 1B H360FD CLH	EC/List 287-619-1, 619-057-3, 620-174- 7 and 931-275-3  Inconclusive hazard for PBT/vPvB and PMT/vPvM For EC/List 211-158- 7, 251-624-7, 278- 860-3 and 400-300-5	production of other chemicals. In addition, other uses were identified for some substances like, e.g. pharmaceuticals, plant protection products, fertilisers, pH regulators, washing and cleaning products, adhesive/sealants and oil and gas exploration or production. In many of those uses a high potential for exposure and release is expected. EC 211- 158-7 is registered as an intermediate while EC/List 251-624-7, 278-860-3 and 400- 300-5 are not registered  For substances in subgroup 2 and 3 the identified uses are associated to the	<p><b>Currently no need for EU RRM</b></p> <p><u>Justification:</u>                      Overall, no or unlikely hazard that would lead to concern for the reported uses.</p> <p>For aquatic toxicity: Self-classification (will) require company level risk management measures (RMM) for environment to be in place.</p> <p>According to the reported uses, low potential for exposure to both human health and environment is expected for EC/List 211-158-7, 251-624-7, 278-860-3 and 400-300-5. Actions may be reconsidered if there is a change in the registration status and/or reported uses, when the assessment will be revisited.</p> <p>For EC 200-535-1, when methoxyethanol impurity is present in quantities warranting Repr. 1B self-classification, the classification requires company level risk management measures (RMM) for workers to be in place. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management in this regard.</p>



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Subgroup name EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
			<p>surfactant properties of the substances. Main uses are in washing and cleaning products, biocidal products, personal care products and surface treatment products. High potential for exposure and release is expected.</p>	

### 3 Justification for the (no) need for regulatory risk management action at EU level (if hazards confirmed)

**Suggested regulatory risk management action for substance N,N-bis(cocoyl-2-oxypropyl)-N,N-dibutylammonium bromide (EC 431-530-4) due to ED HH and ENV, reproductive toxicity and STOT RE (neurotoxicity) hazards**

Based on ECHA's assessment of currently available hazard information, potential hazards were identified for human health and the environment. EC 431-530-4 is a bromide salt, therefore bromide ion will be systemically available and the hazards identified for bromide apply to this substances, too. ECHA has previously assessed the regulatory needs of inorganic bromide salts<sup>5</sup> and concluded that ED for human health and environment, STOT RE (thyroid), reproductive toxicity and STOT RE (neurotoxicity) hazards can be attributed to bromide anion released upon hydrolysis/metabolism. Furthermore, the substance is a known skin sensitiser.

The substance has harmonised classification as Aquatic Acute 1 and Chronic 1. Based on ECHA's screening of currently available hazard information, it is not possible to conclude on PBT/vPvB and/or PMT/vPvM properties of the substance because the substance is not registered, there is not sufficient information available to conclude on the potential persistence, bioaccumulation, and mobility. In addition, data density is too low and the structural variability is too high to extrapolate potential environmental hazards from other members of the group. As the substance is not registered data generation to clarify these properties is not possible. Actions may be re-considered if there is a change in the registration status when the assessment will be revisited.

The CLH is proposed for the substance solely to flag it for a potential CLH group entry for bromide containing substances.

**Currently not possible to suggest regulatory risk management actions for the polyol substances in subgroup 1 (List 604-846-7 and 947-985-1), all the substances in subgroup 2 (except EC/List 287-619-1, 619-057-3 and 931-275-3), all the substances in subgroup 3 (except EC/List 246-745-7, 620-174-7 and 947-057-6) and all the substances in subgroup 4**

It is not possible to assess the needs for regulatory risk management for the substances above as information on hazard is not sufficient to conclude on PBT/vPvB and/or PMT/vPvM and endocrine disruption properties for the environment. The needs for regulatory risk management actions will be assessed once generation of data is completed (compliance check).

Human health hazards are unlikely for the subgroup 1, 2, 3 and 4 substances as the currently available data does not suggest skin sensitisation, STOT RE, CMR or endocrine disrupting (ED) hazards with the exceptions indicated below. Compliance checks (CCH) are suggested on some substances to confirm the low hazards as indicated in Section 2 table.

*Subgroup 1 – compounds with short alkyl chain*

Based on ECHA's screening of currently available hazard information, it is not possible to conclude on PBT/vPvB/PMT/vPvM properties for two of the polyol

<sup>5</sup> <https://echa.europa.eu/documents/10162/6c3d613b-8fa6-9753-fec6-b801b130f9bb>

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members of subgroup 1 (List 604-846-7 and 947-985-1) because there is no sufficient information available to conclude on their potential persistence, bioaccumulation and/or mobility and toxicity (only for List 604-846-7) No relevant information is available on their endocrine disruption (ED) potential for the environment and therefore all substances in the group are considered inconclusive ED for the environment. In addition, extrapolation from other members is not possible due low data density or insufficient structural similarity in the subgroup. These two substances are not classified for aquatic toxicity however also the aquatic toxicity potential of List 604-846-7 is inconclusive due to lack of information. Based on the uses reported for these two substances there is limited potential for exposure of the environment, as List 604-846-7 is only used as an intermediate while for List 947-985-1 there are also industrial uses. A CCH is to be initiated for List 604-846-7 and the needs for regulatory risk management actions will be (re)assessed once generation of data is completed (CCH).

### *Subgroup 2 – compounds with long alkyl chain or aryl group*

Based on ECHA's screening it is not possible to conclude on PBT/vPvB/PMT/vPvM properties of nine members in subgroup 2 (EC/List 417-360-3, 948-061-0, 426-210-6, 242-332-0, 701-357-1, 615-231-8, 947-953-7, 916-226-6 and 402-610-6) and it is also not possible to conclude on PBT/vPvB properties of three substances (EC/List 276-038-9, 604-846-7, 947-985-1) in this subgroup because there is no sufficient information available to conclude on their potential persistence, bioaccumulation and/or mobility and toxicity. All registered substances in subgroup 2 are classified for environmental hazards for Acute 1 and/or Chronic 1 in some cases with M-factor 1-10. This is mainly due to high aquatic toxicity and slow degradation rate of the substances in subgroup 2. The reason for this is possibly higher molecular size (longer chain lengths) and presence of phenyl substituents in some members in subgroup 2. No relevant information is available on their ED potential for the environment and therefore all substances in the group are considered inconclusive ED for the environment. Data density and/or structural similarity are insufficient to extrapolate hazard properties from other members of the group.

EC 916-226-6 has (potentially) carcinogenicity and skin sensitisation human health hazard. The carcinogenicity self-classification is related to chlorotoluene impurity with Carc. 1B CLH while Skin Sens. 1A self-classification is applied based on positive Local Lymph Node Assay (LLNA). The substance is used only at industrial settings and self-classification requires company level risk management measures (RMM) for workers to be in place Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management in this regard.

EC 276-038-9 and 701-357-1 have (potentially) the STOT RE human health hazard. Based on a 90-day repeated dose toxicity study reporting wide range of systemic toxicity with EC 276-038-9 the classification criteria for STOT RE 2 may be warranted. EC 701-357-1 STOT RE hazard is linked to EC 276-038-9 hazard via read-across. Nevertheless, a harmonised classification as STOT RE 2 would not impact any known legislations based on the uses of the substances. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management in this regard.

For the rest of the sub-group 2 substances unlikely human health hazards as there seems no indications to support extrapolation of the hazards of EC 276-038-9 to the remaining substances.

### *Subgroup 3 – esters*

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Based on ECHA's screening of currently available hazard information, it is not possible to conclude on PBT/vPvB/PMT/vPvM properties of six members in this subgroup (EC/List 267-382-0, 306-361-3, 951-974-7, 939-685-4 and 941-174-6) and on PMT/vPvM properties of three members in this subgroup (EC/List 418-120-0, 953-404-2 and 405-660-7) because there is no sufficient information available to conclude on their potential persistence, bioaccumulation, toxicity and mobility. In addition, data density is too low and the structural variability is too high to extrapolate potential environmental hazards from other members of the subgroup.

Substance EC 405-660-7 has harmonised classification as Aquatic Chronic 2. Seven substances (EC 620-174-7, 267-382-0, 306-361-3, 953-404-2, 951-974-7, 939-685-4 and 941-174-6) in subgroup 3 are self-classified as Aquatic Chronic 3.

STOT RE, mutagenicity and reproductive toxicity hazards are unlikely for EC/List 267-382-0, 306-361-3, 953-404-2, 951-974-7, 939-685-4 and 941-174-6.

In subgroup 3 many substances have incomplete data set for aquatic toxicity and human health and therefore further data generation is suggested on some of the substances (as indicated in Table 2) to complete their environmental and human health hazard information.

### *Subgroup 4 – Two quaternary amines*

Based on ECHA's screening of currently available hazard information, it is not possible to conclude on PBT/vPvB/PMT/vPvM properties of any members in subgroup 4 (EC/List 807-137-2, 806-726-1, 605-146-4, 442-730-6, 947-766-0, 916-222-4) because there is no sufficient information available to conclude on their potential persistence, bioaccumulation, toxicity and/or mobility. No relevant information is available on their ED potential for the environment and therefore all substances in the group are considered inconclusive ED for the environment. Extrapolation of environmental hazards is not possible since the data density is too low and there is no sufficient structural similarity within the subgroup.

Subgroup 4 has two substances (947-766-0 and 916-222-4) that have environmental classification for Aquatic Acute 1 and Chronic 1 and the rest are not classified for environmental hazards.

It is also not possible to conclude on skin sensitisation properties of List 947-766-0 and 916-222-4 because of incomplete and ambiguous skin sensitisation data available. Compliance checks are proposed for the substances to confirm the low concern. Unlikely other human health hazards for the rest of the (listed subgroup 4) substances.

Based on the uses reported for the subgroup 2, 3 and 4 substances addressed above for these substances there is high potential for environmental exposure due to uses by professionals and consumers in, for example, washing and cleaning products, fragrances and air care products and surface treatment products. While it is now not possible to suggest any regulatory risk management measures CCH is to be initiated on many substances (as indicated on Table 2) and the needs for regulatory risk management actions will be assessed once generation of data is completed (CCH). For aquatic toxicity, the harmonised/self-classifications require company level risk management measures (RMM) for environment to be in place. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management on this aspect.

**Currently no need to suggest (further) regulatory risk management actions for the choline and beta-methylcholine members in subgroup 1 (EC/List 200-535-1, 200-655-4, 201-068-6, 201-137-0, 204-625-1, 211-158-7, 215-649-7, 219-183-5, 251-624-7, 263-503-6, 278-860-3, 400-**

**300-5 and 902-537-4), substances EC 287-619-1 and List 619-057-3 and 931-275-3 in subgroup 2 and substances EC 246-745-7 and List 620-174-7 and 947-057-6 in subgroup 3**

Based on currently available information, there is no need for (further) EU regulatory risk management for the choline and beta-methylcholine substances in subgroup 1 (EC/List 200-535-1, 200-655-4, 201-068-6, 201-137-0, 204-625-1, 215-649-7, 219-183-5, 263-503-6 and 902-537-4), substances EC 287-619-1 and List 619-057-3 and 931-275-3 in subgroup 2 and substances EC 246-745-7, List 620-174-7 and List 947-057-6 in subgroup 3.

Human health hazards are unlikely for these subgroup 1, 2, 3 and 4 substances as the currently available data does not suggest skin sensitisation, STOT RE, mutagenicity carcinogenicity reproductive toxicity or endocrine disrupting (ED) hazards with the exceptions indicated below. Compliance checks are suggested to confirm low hazards as indicated in Section 2 table.

*Subgroup 1 – compounds with short alkyl chain*

Based on ECHA's screening of currently available hazard information, the choline and beta-methylcholine members in this subgroup (EC/List 200-535-1, 200-655-4, 201-068-6, 201-137-0, 204-625-1, 211-158-7, 215-649-7, 219-183-5, 251-624-7, 263-503-6, 278-860-3, 400-300-5 and 902-537-4) are unlikely to have PBT/vPvB/PMT/vPvM properties because they are very likely readily biodegradable or have a low potential for bioaccumulation or have a low potential for mobility or are also unlikely to meet the T criterion and are not classified for aquatic toxicity. These conclusions are based on ready biodegradability test results, logKow, high logKoc, extrapolation from similar substances or reliable experimental data for some subgroup member(s) present in the dossiers.

Based on ECHA's screening of currently available hazard information, it is not possible to conclude on PBT/vPvB/PMT/vPvM properties for the polyol members in this subgroup (EC 211-158-7, 251-624-7, 278-860-3 and 400-300-5) because there is no sufficient information available to conclude on their potential persistence, bioaccumulation, toxicity and/or mobility as the substances are registered as intermediate (EC 211-158-7) or are not registered. In addition, evaluation of ED for the environment is not possible due to lack of information. Extrapolation from other members is not possible due low data density or insufficient structural similarity in the subgroup.

EC 200-535-1 has (potentially) the reproductive toxicity human health hazard. The hazard is related to methoxyethanol impurity with Repr. 1B H360FD harmonised classification (CLH). The hazard is not relevant to other substances in the group because the impurity is not present in the compositions. EC 215-649-7 has (potentially) the skin sensitising human health hazard. The self-classification as Skin Sens. 1 is based on OECD TG 442 D (keratinocyte activation assay) and QSAR prediction. The self-classification should trigger RMM in industrial and professional settings and correct labelling should allow safe use by consumers. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management in this regard.

Unlikely other human health hazards for the rest of the (listed subgroup 1) substances.

*Subgroup 2 – compounds with long alkyl chain or aryl group*

Based on ECHA's screening of currently available hazard information, three members in subgroup 2 (EC/List 287-619-1, 931-275-3, 619-057-3) are unlikely

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to have PBT/vPvB/PMT/vPvM properties because they are readily biodegradable and/or have a low potential for bioaccumulation and/or have a low potential for mobility and/or are unlikely to meet the T criterion. These conclusions are based on ready biodegradability test results, high logKoc and experimental data present in the dossiers. ED for the environment is considered inconclusive for all remaining substances due to lack of information. EC 287-619-1 and List 931-275-3 are self-classified as Aquatic acute 1 and chronic 2 and EC 619-057-3 as Aquatic acute and chronic 1. The self-classifications require company level risk management measures (RMM) for environment to be in place. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management on this aspect.

Unlikely human health hazards for the rest of the (listed subgroup 2) substances.

### *Subgroup 3 – esters*

Based on ECHA's screening of currently available hazard information, three members in this (sub)group (EC/List 620-174-7, 246-745-7 and 947-057-6) are unlikely to have PBT/vPvB/PMT/vPvM properties because they are readily biodegradable and/or have a low potential for bioaccumulation and/or have a low potential for mobility and/or are unlikely to meet the T criterion. These conclusions are based on ready biodegradability test results, logKow, high logKoc and experimental data present in the dossiers. ED for the environment is considered inconclusive for all remaining substances due to lack of information. List 620-174-7 is self-classified as Aquatic chronic 3. The self-classification require company level risk management measures (RMM) for environment to be in place. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management on this aspect.

Human health hazards are unlikely for the rest of the (listed subgroup 3) substances.

## Annex 1: Overview of classifications

Data extracted on 25 May 2023

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
200-535-1	62-49-7	choline	-	STOT Single Exp. 1 H370, affected organs: Optic nerve (nervus opticus), central nervous system Skin Corr. 1 H314 Flam. Liquid 2 H225 Repr. 1B H360, specific effect:H360FD May damage fertility. May damage the unborn child. Eye Damage 1 H318
200-655-4	67-48-1	choline chloride	-	-
201-068-6	77-91-8	choline dihydrogen citrate	-	Skin Irrit. 2 H315 Skin Sens. 1 H317
201-137-0	78-73-9	choline hydrogen carbonate	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT Single Exp. 3 H335, affected organs: Respiratory tract
204-625-1	123-41-1	choline hydroxide	-	Skin Corr. 1A H314 Eye Damage 1 H318
211-158-7	631-41-4	tetrakis(2-hydroxyethyl)ammonium hydroxide	-	Skin Corr. 1A H314 Eye Damage 1 H318
215-649-7	1336-80-7	Ferrencholine	-	Eye Irrit. 2 H319 Skin Sens. 1 H317
219-183-5	2382-43-6	(2-hydroxypropyl)trimethylammonium chloride	-	-
242-332-0	18448-65-2	bis(hydroxyethyl)methylolammonium chloride	-	Acute Tox. 4 H302 Skin Irrit. 2 H315

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EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
				Eye Irrit. 2 H319 Aquatic Acute 1 H400
243-008-1	19379-90-9	benzoxonium chloride	-	STOT Single Exp. 3 H335 Skin Irrit. 2 H315 Acute Tox. 4 H302 Eye Irrit. 2 H319
244-921-8	22340-01-8	dodecylbis(2-hydroxyethyl)methylammonium chloride	-	-
246-745-7	25234-60-0	2-lauroyloxyethyltrimethylammonium chloride	-	-
251-624-7	33667-48-0	tris(2-hydroxyethyl)methylammonium hydroxide	-	-
263-503-6	62314-25-4	(2-hydroxypropyl)trimethylammonium formate	-	Skin Corr. 1C H314 Eye Damage 1 H318
265-345-3	65059-91-8	benzylododecylbis(2-hydroxypropyl)ammonium chloride	-	-
267-382-0	67846-68-8	dimethylbis[2-[(1-oxooctadecyl)oxy]ethyl]ammonium chloride	-	Aquatic Chronic 3 H412
274-846-6	70750-47-9	Quaternary ammonium compounds, coco alkylbis(hydroxyethyl)methyl, chlorides	-	-
276-038-9	71808-53-2	Quaternary ammonium compounds, C12-18-alkylbis(hydroxyethyl)methyl, chlorides	-	Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318 Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 2 H411
278-860-3	78182-00-0	(2-hydroxyethyl)(3-hydroxypropyl)dimethylammonium chloride	-	-
287-619-1	85563-48-0	hexadecyl(2-hydroxyethyl)dimethylammonium dihydrogen phosphate	-	Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 2 H411
288-474-7	85736-63-6	Quaternary ammonium compounds, C12-18-alkyl(hydroxyethyl)dimethyl, chlorides	-	-



ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
306-361-3	97158-31-1	dimethylbis[2-[(1-oxohexadecyl)oxy]ethyl]ammonium chloride	-	Aquatic Chronic 3 H412
402-610-6	113694-52-3	benzyl-2-hydroxydodecyldimethylammonium benzoate	Index number: 612-095-00-1 Acute Tox. 4 H302 (Minimum classification) Skin Corr. 1B H314 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	Aquatic Chronic 1 H410 Acute Tox. 4 H302 Skin Corr. 1B H314
405-660-7	220609-41-6	N,N,N-trimethyl-2,3-bis(stearoyloxy)propylammonium chloride	Index number: 017-018-X Aquatic Chronic 2 H411	
417-360-3	-	C8-10 alkyl dimethyl hydroxyethyl ammoniumchloride (chain < C8: <3%, chain = C8: 15%-70%, chain = C10: 30%-85%, chain > C10: <3%)	-	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Irrit. 2 H315
426-210-6	120086-58-0	(Z)-13-docosenyl-N,N-bis(2-hydroxyethyl)-N-methyl-ammonium chloride	Index number: 017-017-00-4 Skin Corr. 1B H314 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	-
431-530-4	1380226-29-8	N,N-bis(cocoyl-2-oxypropyl)-N,N-dibutylammonium bromide	Index number: 612-230-00-4 Skin Corr. 1A H314 Skin sens. 1 H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	
442-730-6	-	(2-hydroxypropyl)({6-[(2-hydroxypropyl)dimethylazaniumyl]hexyl})dimethylazanium propane-1,2-diol dihydroxide	-	Acute Tox. 4 H302 Skin Corr. 1C H314 Eye Damage 1 H318
604-846-7	152390-17-5	N, N-bis-(2-hydroxyethyl) dimethyl ammonium methane sulfonate	-	-
605-146-4	158451-78-6	1,6-Hexanediamine, N1,N1,N6,N6-tetramethyl-, propoxylated (>1 < 4,5 mol PO)	-	Skin Corr. 1 H314 Eye Damage 1 H318
615-231-8	70983-58-3	Poly(oxy-1,2-ethanediyl), $\alpha,\alpha'$ -(iminodi-2,1-ethanediyl)bis[.omega.-hydroxy-, N-[3-(C10-16-alkyloxy)propyl] derivs., di-Et sulfate-quaternized	-	Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Damage 1 H318

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
				Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410
619-057-3	94667-33-1	Poly(oxy-1,2-ethanediyl), α-[2-(dicylmethylammonio)ethyl]-.omega.-hydroxy-, propanoate (salt) (Bardap 26)	-	Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318 Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410
620-174-7	1079184-43-2	Ethanaminium, 2-hydroxy-N-(2-hydroxyethyl)-N,N-dimethyl-, esters with C16-18 and C18-unsatd. fatty acids, chlorides	-	Aquatic Chronic 3 H412
701-357-1	-	Quaternary ammonium compounds, C12-14 (even numbered) alkyl(hydroxyethyl)dimethyl, C12 alkylbis(hydroxyethyl)methyl, chlorides and amines, C12-14 (even numbered) alkyl dimethyl, chlorides	-	Acute Tox. 3 H301 Skin Corr. 1C H314 Eye Damage 1 H318 Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410
806-726-1	-	Reaction product of 2-[[2-(dimethylamino)ethyl]methylamino]ethanol di(hexanoate) and ethyl oxirane (1:2)	-	Skin Corr. 1B H314 Eye Damage 1 H318
807-137-2	110528-94-4	1,3-Propanediaminium, 2-hydroxy-N1,N3-bis(2-hydroxyethyl)-N1,N1,N3,N3-tetramethyl-, chloride (1:2)	-	-
902-537-4	-	Reaction mass of tetrahydroxysilane and choline chloride and calcium chloride and water	-	Met. Corr. 1 H290 Skin Corr. 1B H314 Eye Damage 1 H318
916-222-4	-	Reaction mass of N,N'-ethylenebis[N-methyl-2-[(1-oxo-9-octadecenyl)oxy]-N-[2-[(1-oxo-9-octadecenyl)oxy]propyl]propylammonium] dimethyl disulphate and [2-[bis(2-hydroxypropyl)amino]ethyl]bis(2-hydroxypropyl)(methyl)ammonium methyl sulphate, dioleate (ester)	-	Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Acute 1 H400 Aquatic Chronic 1 H410

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
916-226-6	-	Reaction mass of benzyldodecylbis(2-hydroxypropyl)ammonium chloride and benzylbis(2-hydroxypropyl)tetradecylammonium chloride	-	Carc. 1B H350 Acute Tox. 4 H302 Acute Tox. 2 H330 Skin Irrit. 2 H315 Eye Damage 1 H318 Skin Sens. 1A H317 STOT Single Exp. 3 H335, affected organs: respiratory tract Aquatic Chronic 1 H410
931-275-3	-	Quaternary ammonium compounds, C12-14-alkyl(hydroxyethyl)dimethyl, chlorides	-	Acute Tox. 4 H302 Skin Corr. 1C H314 STOT Rep. Exp. 2 H373 Aquatic Acute 1 H400 Aquatic Chronic 2 H411
939-685-4	-	1-Propanaminium, 2-hydroxy-N-(2-hydroxypropyl)-N,N-dimethyl-, esters with fatty acids, C18 unsatd., Me sulfates (salts)	-	Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Chronic 3 H412
941-174-6	-	1-Propanaminium, 2-hydroxy-N-(2-hydroxypropyl)-N,N-dimethyl-, esters with fatty acids, C16-18 (even numbered) and C18 unsatd., Me sulfates (salts)	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Chronic 3 H412
947-057-6	-	Reaction mass of 2-hydroxy-3-[(1-oxodocosyl)oxy]propyltrimethylammonium chloride and 2-methylpentane-2,4-diol	-	-
947-766-0	-	Quaternary ammonium compounds, N,N,N'-tris(hydroxyethyl)-N,N'-dimethyl-N'-C16-18 (even numbered) and C18 unsatd., alkyltrimethylenedi-, bis(Me sulfates) (salts)	-	Acute Tox. 4 H302 Eye Irrit. 2 H319 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
947-953-7	-	Reaction mass of Reaction product of 1-chloro-3-{[1-chloro-3-(dodecyloxy)propan-2-yl]oxy}propan-2-ol with methyl diethanolamine and [3-(dodecyloxy)-2-hydroxypropyl]bis(2-hydroxyethyl)methylammonium chloride	-	Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
947-985-1	-	Reaction mass of 2-hydroxy-N-(2-(2-hydroxyethoxy)ethyl)-N-(2-hydroxyethyl)-N-methylethan-	-	Acute Tox. 4 H302 Acute Tox. 4 H312

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
		1-amininium hydroxide and 2-hydroxy-N,N-bis(2-hydroxyethyl)-N-methylethanaminium hydroxide		Skin Corr. 1B H314 Eye Damage 1 H318
<b>948-061-0</b>	-	Quaternary ammonium compounds, C14-18 (even numbered) and C18 unsaturated-alkyl-hydroxyethyl-dimethyl, chlorides		Skin Corr. 1C H314 Eye Damage 1 H318 Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410
<b>951-974-7</b>	-	Reaction mass of Ethanaminium, 2-hydroxy-N,N-dimethyl-N-[2-[(1-oxooctadecyl)oxy]ethyl]-, chloride and Ethanaminium, N,N-dimethyl-2-[(1-oxohexadecyl)oxy]-N-[2-[(1-oxooctadecyl)oxy]ethyl]-, chloride		Aquatic Chronic 3 H412
<b>953-404-2</b>	-	Ethanaminium, 2-hydroxy-N-(2-hydroxyethyl)-N,N-dimethyl-, diesters with C18-unsatd. fatty acids, Me sulfates		Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Chronic 3 H412

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

Data extracted on 25 May 2023

Table 2. Overview of main uses for substances in subgroup 1

Main types of applications structured by product or article types	EC 200-535-1	EC 200-655-4	EC 201-068-6	EC 201-137-0	EC 204-625-1	EC 215-649-7	List 902-537-4	EC 219-183-5	EC 263-503-6	EC 211-158-7	EC 278-860-3	EC 400-300-5	List 604-846-7	List 947-985-1
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents		F, I, P		F, I	F, I									F
PC 12: Fertilisers		F, I, P					F, I, P							
PC 27: Plant protection products		F, I, P		F	F									
PC 35: Washing and cleaning products		F, I, P, C, A			F, I				I					I
PC 29: Pharmaceuticals		F		F, I	F	I								
PC 15: Non-metal-surface treatment products				F, I	F, I									
PC 24: Lubricants, greases, release products					I									F
PC 25: Metal working fluids														F
PC 17: Hydraulic fluids				F, I										

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	EC 200-535-1	EC 200-655-4	EC 201-068-6	EC 201-137-0	EC 204-625-1	EC 215-649-7	List 902-537-4	EC 219-183-5	EC 263-503-6	EC 211-158-7	EC 278-860-3	EC 400-300-5	List 604-846-7	List 947-985-1
PC 32: Polymer preparations and compounds		F							F, I, P, A				I	F
PC 1: Adhesives, sealants									F, I, P					F
PC 9b: Fillers, putties, plasters, modelling clay									F					F
PC 9a: Coatings and paints, thinners, paint removes									F, I, P					F
PC 14: Metal surface treatment products				F, I	F, I									
PC 38: Welding and soldering products, flux products				F, I	F, I									
PC 21: Laboratory chemicals	I	F, I, P	I	F, I	F, I	I	F, I	I	F, I			I	I	F, I
PC 19: Intermediate	I	I	I	I	F, I	I		I	I	I	I		I	I
PC x1: Food and feed additives		F												
PC 41: Oil and gas exploration or production products		I, P		I, P										

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life

ASSESSMENT OF REGULATORY NEEDS

Table 3. Overview of main uses for substances in subgroup 2

Main types of applications structured by product or article types	EC 242-332-0	EC 276-038-9	EC 287-619-1	EC 417-360-3	List 615-231-8	List 619-057-3	List 701-357-1	List 931-275-3	List 947-953-7	List 948-061-0	EC 271-760-0
PC 27: Plant protection products		F, P, C									
PC 35: Washing and cleaning products	I, P			C		F, I, P, C	F, I, P, C	F, I, P, C			
PC 8: Biocidal products (e.g. disinfectants, pest control)						F, I, P, C	F, I, P				
PC 28: Perfumes, fragrances										F, C	
PC 3: Air care products							F				
PC 39: Cosmetics, personal care products			F, C	C						F, C	
PC 31: Polishes and wax blends						P, C	F				
PC 15: Non-metal-surface treatment products					F, I				I		
PC 34: Textile dyes, and impregnating products								P			
PC 23: Leather treatment products						C					
PC 14: Metal surface treatment products						I,					
PC 21: Laboratory chemicals	F, I				F, I	F, I	F, I	F, I	F, I	F	I

## ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	EC 242-332-0	EC 276-038-9	EC 287-619-1	EC 417-360-3	List 615-231-8	List 619-057-3	List 701-357-1	List 931-275-3	List 947-953-7	List 948-061-0	EC 271-760-0
<b>PC 19: Intermediate</b>											

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life



ASSESSMENT OF REGULATORY NEEDS

Table 4. Overview of main uses for substances in subgroup 3

Main types of applications structured by product or article types	EC 267-382-0	EC 306-361-3	List 620-174-7	List 951-974-7	List 953-404-2	List 939-685-4	List 941-174-6	EC 246-745-7	EC 405-660-7	List 947-057-6
PC 35: Washing and cleaning products			F, P, C	F	F, P, C	F, I, P, C	C		I, P, C	
PC 8: Biocidal products (e.g. disinfectants, pest control)			F							
PC 39: Cosmetics, personal care products	F, C	F, P, C	(P), C	F, C		F, C	C			F, P, C
PC 31: Polishes and wax blends						F, C				
PC 15: Non-metal-surface treatment products								I, P, C		
PC 32: Polymer preparations and compounds								A		
PC 34: Textile dyes, and impregnating products			P, C				C			
PC 21: Laboratory chemicals		F	F	F	F	F, I		F, I	I	F
PC 19: Intermediate										

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life

ASSESSMENT OF REGULATORY NEEDS

Table 5. Overview of main uses for substances in subgroup 4

Main types of applications structured by product or article types	EC 442-730-6	List 605-146-4	List 807-137-2	List 916-222-4	List 947-766-0
PC 39: Cosmetics, personal care products			I, C	I, C	
PC 1: Adhesives, sealants		C			
PC 9b: Fillers, putties, plasters, modelling clay		(F), (I), (P), C, (A)			(F), (I), (P), (A)
PC 9a: Coatings and paints, thinners, paint removes	F, P, C	(F), (I), (P), C, (A)			
PC 18: Ink and toners	F, P				
PC 21: Laboratory chemicals	F, I	F, I	I	I	F
PC 19: Intermediate					

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life

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

Data extracted on 8 June 2023

EC/List No	RMOA, ARN	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
200-535-1						PPP
200-655-4						
400-300-5						Claimed NONS, inactive
402-610-6					YES	Claimed NONS, inactive
405-660-7					YES	Claimed NONS, inactive
417-360-3					YES	Claimed NONS
426-210-6					YES	
431-530-4					YES	
442-730-6						Claimed NONS
619-057-3						BPR

\*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, 40 and 75).

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