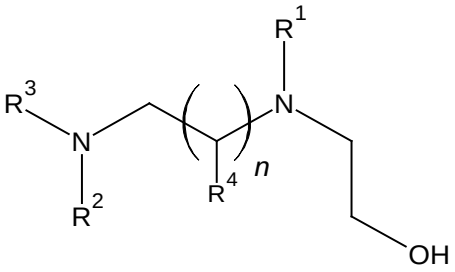
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Mono/poly-ethanolpolyamines and their short chain N-alkyl derivatives

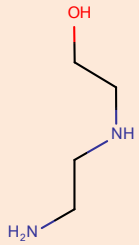
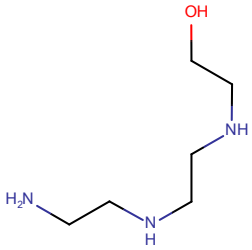
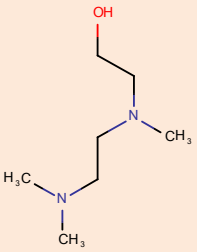
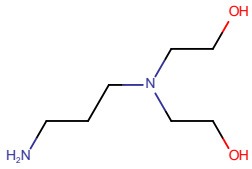
General structure:



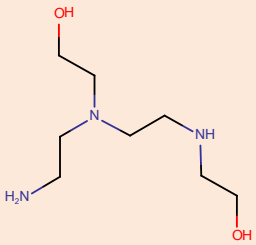
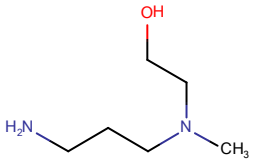
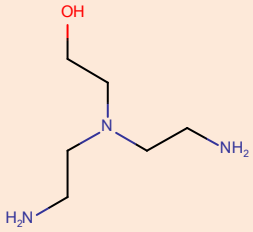
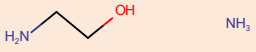
Revision history

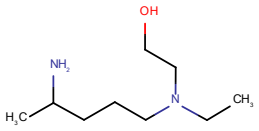
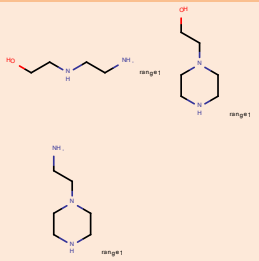
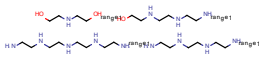
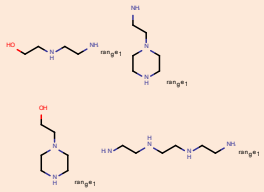
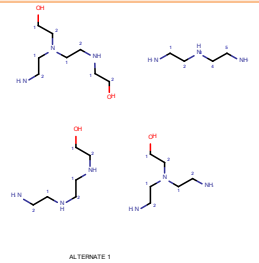
Version	*Date*	*Description*
1.0	24 April 2024	

Table 1: Substances within this group:

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
203-867-5	111-41-1	2-(2-aminoethylamino)ethanol		Full, not (publicly) available
217-811-2	1965-29-3	2-(2-(2-aminoethylamino)ethylamino)ethanol		C&L notification
218-658-4	2212-32-0	2-[[2-(dimethylamino)ethyl]methylamino]ethanol		Full, 10-100
225-642-0	4985-85-7	N-(3-aminopropyl)iminodiethanol		Full, 100-1000

[1] 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, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
254-596-4	39701-29-6	2-[(2-aminoethyl)[2-[(2-hydroxyethyl)amino]ethyl]amino]ethanol		Not registered
255-615-9	41999-70-6	2-[(3-aminopropyl)methylamino]ethanol		Full, not (publicly) available
261-141-3	58145-14-5	2-[bis(2-aminoethyl)amino]ethanol		C&L notification
272-304-3	68797-59-1	2-[[2-[(2-aminoethyl)amino]ethyl]amino]ethanol, N-(2-hydroxyethyl) derivative	No Structure	Not registered
272-729-4	68910-05-4	Ethanol, 2-amino-, reaction products with ammonia, by-products from		OSII or TII

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
274-039-9	69559-11-1	2-(4-aminopentyl(ethyl)amino)ethanol		OSII or TII
905-994-8	-	Reaction mass of 2-(2-aminoethylamino)ethanol and 2-piperazin-1-ylethanol and 2-piperazin-1-ylethylamine		OSII or TII
906-891-0	-	Ethanol, 2-amino-, reaction products with ammonia, by-products from, distn. Residues		OSII or TII
939-593-4	-	Reaction products of 1,2-dichloroethane with ammonia, 2-(2-aminoethylamino)ethanol distillation fraction		OSII or TII
945-047-6	-	Reaction mass of hydroxyethyl-DETA, DETA and dihydroxyethyl-DETA		Full, 10-100

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

Contents

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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)[2]. 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[3]. 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.

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.

[2] Working with Groups - ECHA (europa.eu)

[3] 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).

For more information on assessments of regulatory needs please consult ECHA's website[4].

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

Glossary

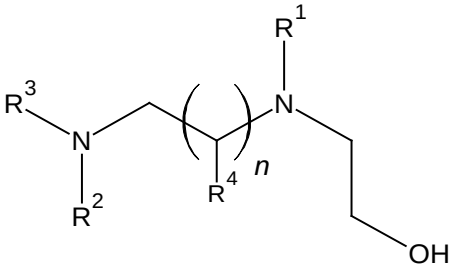
ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate 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 are available in the foreword to this document. Please read it carefully before going through the report.

ECHA has grouped together structurally similar substances based on the presence of the ethanolpolyamine moiety that have not been included in other groups. The general indicative structure is shown in the figure below. Among others, the following exclusion criteria were applied:

- No fatty aliphatic chain on the nitrogen
- No propoxylation chemistry



There are five substances with full registrations, five intermediates registrations, and four without registrations, giving a total of 14 substances.

Based on information reported in the REACH registration dossiers, all but one of the substances are used as intermediates.

Three substances have in addition to intermediate use further uses, the first being EC 203-867-5, registered for industrial use in polymer preparations. This substance also has a harmonised classification, including as Repr 1B (H360Df) and Skin Sens. 1. This substance has been assessed by EFSA for food contact materials, concluding that the use of N-(2-aminoethylamino)ethanol in manufacturing of can coatings in direct contact with food does not raise a safety concern for the substance itself if migration does not exceed 0.05 mg/kg food.

The substance EC 218-658-4 has further uses in adhesives and sealants, coatings and paints. Only industrial and professional uses are indicated, with article service life in articles covered by the Waste Electrical and Electronic Equipment (WEEE) and the End of Life Vehicles (ELV) directives.

Finally, EC 255-615-9 has, in addition to the uses already indicated for the other substances, uses in the formulation of pH-regulators/ flocculants/ precipitants/neutralisation agents, washing and cleaning products, lubricants, metal working fluids, fillers/putties/plasters. No uses of the mixtures are indicated, but it seems likely that some of the mixtures may be used by professional users or consumers.

A related risk-management options analysis (RMOA) on 'ethoxylated N-alkyltrimethylenediamines', covering 11 related substances (not included in the current ARN), has been conducted by the Irish Competent Authority in 2023[5]. Also the Swedish CA has conducted an RMOA of five UVCB-diamines in 2019 which are not covered by the current ARN[6]. Both of these analyses have

[5] https://echa.europa.eu/documents/10162/c6101595-9438-7659-0078-8bd9096ec7c9

[6] The substances covered are EC/List 292-562-0, 268-957-9, 696-364-9, 629-719-3, and 230-528-9. See https://echa.europa.eu/documents/10162/8757dea1-749c-ec1c-5ee4-ba5e427d4117

concluded that there is currently no need for further EU-level RRM on these related substances.

2 Conclusions and 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, substance name	Human Health Hazard	Environmental Hazard	Relevant uses & exposure potential	Suggested regulatory actions
203-867-5 **217-811-2** 218-658-4 **254-596-4** 255-615-9 **261-141-3** **272-304-3** 272-729-4 274-039-9 905-994-8 906-891-0 939-593-4	Known or potential hazard for reproductive toxicity Known or potential hazard for skin sensitisation except for EC 218-658-4 Known or potential hazard for respiratory sensitisation EC 272-729-4	Known or potential hazard for aquatic toxicity EC/List 225-642-0, 272-729-4, 274-039-9, 906-891-0 Inconclusive hazard for PBT/vPvB for PMT/vPvM EC 272-729-4 Inconclusive hazard for aquatic toxicity EC 203-867-5, 255-615-9	EC 272-729-4, 274-039-9, 905-994-8, 906-891-0, 939-593-4 are used as intermediates, exposure potential is considered low. EC 255-615-9 has industrial and formulation uses and EC 218-658-4 has also professional uses and article service life with some exposure potential EC 203-867-5 has industrial uses as	**First step:** No action **Potential last action:** **Currently no need for EU RRM** Justification: For the reported intermediate uses, low potential for exposure to both human health and environment is expected. For the substances with some potential for exposure: due to their registration status or existing classifications, currently no data generation is possible to clarify the hazards.

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant uses & exposure potential	Suggested regulatory actions
	Known or potential hazard for STOT RE 2 (respiratory tract) List 905-994-8 Known or potential hazard for carcinogenicity for List 906-891-0		intermediate in polymer preparations with some exposure potential EC 217-811-2, 254-596-4, 261-141-3, 272-304-3 and not exposure information	Actions may be re-considered if there is a change in the registration status and/or reported uses, when the assessment will be revisited.
945-047-6 225-642-0	Known or potential hazard for reproductive toxicity Known or potential hazard for skin sensitisation Known or potential hazard for carcinogenicity for EC 225-642-0	Inconclusive hazard for aquatic toxicity List 945-047-6 Inconclusive hazard for PBT/vPvB for PMT/vPvM EC 225-642-0, List 945-047-6	Industrial, formulation and article service life with potential for exposure	**First step:** CCH **Potential last action:** **Currently not possible to assess the regulatory needs** <u>Justification</u>: It is not possible to assess the needs for regulatory risk management for these two substances as information on hazard is not sufficient to conclude on PBT or mobility or initiate regulatory risk management for reproductive toxicity. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).

3 Justification for the no need for regulatory risk management action at EU level

Currently no need to suggest (further) regulatory risk management actions for any of the substances

Potential hazards: Reproductive toxicity has been identified for all group members and skin sensitisation for most of the group members.

All substances in the group have (potentially) the following human health hazard: **reproductive toxicity**. EC 203-867-5 has a harmonised classification as Repr. 1B H360 Df, due to induced fetal vessel abnormalities in screening reproductive toxicity studies and a developmental toxicity study. The following group members contain this substance as constituent, at concentration that meets the criteria for classification as Repr. 1B and are self-classified as such: EC/List 272-729-4, 905-994-8, 906-891-0 and 939-593-4.

For the purposes of this ARN, the hazard is extrapolated to all group members assuming that it is due to the presence of the aminoethanol moieties. This extrapolation is based on structural similarity only and therefore is tentative. For EC 218-658-4, 225-642-0 and 255-615-9, the available screening reproductive toxicity studies did not include examination of fetal vessel abnormalities and therefore did not assess the hazard identified for EC 203-867-5. The structural differences (such as the degree of substitution of the amino groups and chain length of the substituents), may result in potency differences, also impacting on detection of effects in available studies. Moreover, EC 225-642-0 contains an impurity for which there is an intention to propose CLH for Repr.1B. The impurity is present above the threshold level for classification of mixtures. The hazard identified for EC 203-867-5 is tentatively extrapolated also to these three substances.

Most of the substances in the group have the following human health hazard: **skin sensitisation**. This hazard is identified based on observed effects in several studies. This is further extrapolated to group members where there is no available experimental studies either due to members not being registered or due to waiving of the information requirement as all group members are corrosive.

No hazard of **skin sensitisation** is identified for group member EC 218-658-4. The substance has a negative OECD TG 406 study with the registered substance available in the dossier. The lack of skin sensitising properties, as compared to other group members, might be due to the difference of alkyl substituted tertiary amines in the structure.

The substance EC 272-729-4 in the group has potentially the following human health hazard: **respiratory sensitisation**. The substance is self-classified as Resp Sens 1 in the dossier. The toxicity is potentially based on a constituent/impurity with CLH for respiratory sensitisation. This hazard is not extrapolated to other group members.

No hazard of **mutagenicity** is identified for all group members. This conclusion is based on experimental studies with the registered substances. This is extrapolated to all group members based on generally similar structural features, in the absence of other data.

No systemic toxicity effects at doses that would meet the classification criteria for **STOT RE** have been observed, only the substance with List 905-994-8 in the group is self-classified as STOT RE 2 (respiratory tract), however no data is

available in the dossier and therefore this hazard is not extrapolated to other group members.

No hazard for **carcinogenicity** for the group members based on the available systemic toxicity data, except EC 225-642-0 and List 906-891-0. EC 225-642-0 and List 906-891-0 have the human health hazard of **carcinogenicity** due to presence of a constituent (EC 203-868-0) that has been classified by IARC as Cat 2B and has an intention for CLH for Carc. 2 above the threshold level for classification of mixtures.

NOTE: Although the substances as such seem not to have carcinogenic potential, the formation of carcinogenic nitrosamines cannot be excluded. Therefore, provisionally, a concern for carcinogenicity is identified that is related to the use of each substance and potential presence of nitrosating agents that can result in the formation of carcinogenic nitrosamines.

The potential of all the substances in the group to react with nitrosating agents and to form potential carcinogenic nitrosamines has not been explored further in terms of actions. A common approach needs to be developed further regarding substances with a potential to form nitrosamines as part of co-exposure with nitrosating agents, and the subsequent regulatory measures where relevant. This is a more generic topic that is of relevance also for other groups of substances.

Unlikely hazard of **ED (human health) hazard** is identified for all group members, based on no indications of effects in endocrine organ or parameters observed in the available systemic toxicity studies with EC/List 203-867-5, 218-658-4, 225-642-00, 255-615-9. This is extrapolated to all remaining group members in absence of other data.

No hazard **for STOT RE** is identified for any of the group members. The available systemic toxicity studies do not indicate effects that would meet the criteria for classification for STOT RE. This conclusion is extrapolated to all group members, in absence of other data.

All but two of the substances with full registrations in this group are unlikely PBT/vPvB or PMT/vPvM based on that they are very likely inherently biodegradable (EC 203-867-5, EC 255-615-9, EC 218-658-4) or have a low potential for bioaccumulation (EC 218-658-4).

The following OSII/TII substances have inconclusive PBT/vPvB or PMT/vPvM properties because of inconclusive data on bioaccumulation potential and mobility: EC/List 272-729-4, 274-039-9 and 906-891-0.

The substance EC 272-729-4 has a classification in registration as Aquatic Chronic 1, supported by the available data. The substances EC/List 225-642-0, 274-039-9 and 906-891-0 have self-classifications for aquatic toxicity not supported by available data as Aquatic Chronic 2, Aquatic Chronic 3 and Aquatic Chronic 3 respectively.

Unlikely hazard for ED properties is extrapolated from human health assessment.

Regulatory risk management

Based on currently available information, there is no need for (further) EU regulatory risk management for any of the substances in the group. This conclusion is in line with the conclusions of the Irish CA on related substances

(*ethoxylated N-alkyltrimethylenediamines,* 2023[7]) as well as those of the Swedish CA, also covering related substances (*UVCB-diamines,* 2019[8]).

EC/List 272-729-4, 274-039-9, 905-994-8, 906-891-0, and 939-593-4 have intermediate uses only, leading to assumed limited exposure/release potential, and thus no need for regulatory risk management. In addition, they are correctly self-classified for the hazards identified.

Therefore, no EU regulatory risk management action is currently proposed for any of the aforementioned substances due to low exposure potential. It is worth noting however that the strategy may need to be revisited and need for further regulatory action reconsidered if there is a change in the registration status or reported uses for any of these substances.

Two group members (EC 255-615-9 and EC 218-658-4) have some potential for exposure.

The substance EC 255-615-9 is self-classified as Skin Sens 1B and is indicated for industrial use and formulation, with formulation covering many potentially widespread uses (such as sealants, coatings, washing and cleaning products, lubricants, and fillers). There is also potential for Repr. 1B based on extrapolation from a similar substance. There is no information in the registration dossier on whether and by whom these formulated mixtures would be used in the EU. This situation may arise if the mixtures are only exported from the EU, but it is not possible to verify if this is the case based on the available information. No 'consumer use' is reported in the registrations. There is remaining uncertainty as it cannot be ruled out that some of the formulated products could also be accessed by the general public and not be limited only to use by professional workers. There is a concern related to skin sensitisers (potentially) present in consumer mixtures and work is ongoing on this generic issue by both Member States and ECHA which might affect the regulatory actions on substances in this group. Further, the presence of skin sensitisers must be indicated on the label of chemical products, thus prompting professionals and consumers to avoid skin contact.

The substance EC 218-658-4 is indicated for industrial and professional uses, also in products (adhesives/sealants, coatings) that may be incorporated in articles. There is also potential for Repr. 1B based on extrapolation from a similar substance.

For EC 255-615-9 and EC 218-658-4, due to current registration status and the available reproductive screening studies, it is not possible to clarify the potential reproductive hazard (fetal vessel abnormalities) with further data generation. Therefore, it is proposed that there is currently no need for EU RRM action on these two substances, either. If their registration status changes, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

The substance with EC 203-867-5 already has a harmonised classification for Repr. 1B and Skin sens. 1. The registrations indicate use in the EU as intermediate and in polymer preparations by industrial users. The currently available information on uses does not support restriction or other measures for

[7] https://echa.europa.eu/documents/10162/c6101595-9438-7659-0078-8bd9096ec7c9

[8] https://echa.europa.eu/documents/10162/8757dea1-749c-ec1c-5ee4-ba5e427d4117

this substance, as risk management in industrial and intermediate uses would already be adequate based on the harmonised classification as Repr. 1B and Skin Sens. 1, as well as Skin Corr. 1B. Regarding articles, it would seem that based on an assessment by the European Food Safety Authority (EFSA)[9], which concluded that the use of the substance is safe if migration of the substance from can coatings does not exceed 0.05 mg/kg food, no further limitations would be necessary. This conclusion related to the use of the substance in articles is based on the assumption that the substance is normally either fully transformed into other substances during material/article production or little unreacted residue remains. Based on current information about the uses of the substance, food contact materials would appear to be the most critical article use from a human exposure point of view. It should be noted that if there are uses not covered by registrations, the presence of the substance is already not allowed in mixtures intended for the general public, based on entry 30 of Annex XVII to REACH.

Currently not possible to suggest regulatory risk management actions for EC 945-047-6 and EC 225-642-0

As stated above, reproductive toxicity is tentatively extrapolated to all group members (thus including EC 945-047-6 and EC 225-642-0). The current evidence available in the registration dossiers is not sufficient to initiate regulatory risk management. The needs for regulatory risk management based on this potential hazard will be assessed following possible generation of data.

Moreover, it is not possible to assess the needs for regulatory risk management for EC 945-047-6 and EC 225-642-0 as information on hazard is not sufficient to conclude on PBT and mobility. The needs for regulatory risk management actions for these hazards will be assessed once generation of data is completed (CCH).

EC 225-642-0 is used as monomer for polymer preparations and inclusion into article with some potential for exposure.

Therefore, further assessment under CCH is proposed for EC 945-047-6 and EC 225-642-0.

[9] Scientific Opinion on the safety evaluation of the substance, N-(2-aminoethyl)ethanolamine, CAS No. 111-41-1, for use in food contact materials https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2653

Annex 1: Overview of classifications

Data extracted on 5 May 2023

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
225-642-0	4985-85-7	N-(3-aminopropyl)iminodiethanol	-	Skin Corr. 1C H314 Eye Damage 1 H318 Aquatic Chronic 2 H411
203-867-5	111-41-1	2-(2-aminoethylamino)ethanol	Index number: 603-194-00-0 Hazard Category: Skin Corr. 1B Hazard Statement: H314 Hazard Category: Repr. 1B Hazard Statement: H360Df Skin Sens. 1 Statement: H317 Category: STOT SE 3 Class: Specific Target Organ Toxicity - Single Exposure Statement: H335: C>=5%	Repr. 1B H360 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1B H317 STOT Single Exp. 3 H335, affected organs: respiratory effects, specific concentration: >=5 [intermediate (active)] Effect on or via lactation H362 [intermediate (active)] Repr. 1B H360, specific effect:May damage the unborn child. Suspected of damaging fertility. [intermediate (active)] Repr. 1B H360, specific effect:May damage fertility. Suspected of damaging the unborn child. [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)]
218-658-4	2212-32-0	2-[[2-(dimethylamino)ethyl]methylamino]ethanol	-	Skin Corr. 1C H314 Eye Damage 1 H318
255-615-9	41999-70-6	2-[(3-aminopropyl)methylamino]ethanol	-	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1B H317
945-047-6	-	Reaction mass of 2-[bis(2-aminoethyl)amino]ethanol and 2-({2-[(2-aminoethyl)amino]ethyl}amino)ethanol and N-(2-aminoethyl)ethane-1,2-diamine and 2-({2-[(2-aminoethyl)(2-hydroxyethyl)amino]ethyl}amino)ethanol	-	Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 2 H330 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: respiratory trackt
272-729-4	68910-05-4	Ethanol, 2-amino-, reaction products with ammonia, by-products from	-	STOT Single Exp. 3 H335, affected organs: Respiratory tract, specific concentration: >=5 [intermediate (inactive);intermediate (active)] Aquatic Chronic 1 H410, M-factor: 10.00 [intermediate (active);intermediate (inactive)] Resp. Sens. 1 H334 [intermediate (inactive);intermediate (active)] Effect on or via lactation H362 [intermediate (active);intermediate (inactive)] Skin Corr. 1B H314 [intermediate (inactive);intermediate (active)] Repr. 1B H360Df: May damage the unborn child. Suspected of damaging fertility. [intermediate (active)]

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
				Skin Sens. 1B H317 [intermediate (inactive);intermediate (active)] Eye Damage 1 H318 [intermediate (inactive);intermediate (active)] Acute Tox. 3 H331 [intermediate (inactive);intermediate (active)] Repr. 1B H360, specific effect:H360Df [intermediate (inactive)] Aquatic Acute 1 H400 [intermediate (active);intermediate (inactive)]
274-039-9	69559-11-1	2-(4-aminopentyl(ethyl)amino)ethanol	-	Aquatic Chronic 3 H412 [intermediate (active)] Acute Tox. 4 H332 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)]
905-994-8	-	Reaction mass of 2-(2-aminoethylamino)ethanol and 2-piperazin-1-ylethanol and 2-piperazin-1-ylethylamine	-	Skin Sens. 1 H317 [intermediate (active)] STOT Rep. Exp. 2 H373, affected organs: Respiratory tract [intermediate (active)] Repr. 1B H360, specific effect:May damage fertility. Suspected of damaging the unborn child [intermediate (active)] Effect on or via lactation H362 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)]
906-891-0	-	Reaction mass of 2,2'-iminodiethanol and 2-(2-(2-aminoethylamino)ethylamino)ethanol and 3,6,9-triazaundecamethylene diamine and trientine	-	Skin Sens. 1 H317 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] Effect on or via lactation H362 [intermediate (active)] Repr. 1B H360, specific effect:May damage fertility. Suspected of damaging the unborn child [intermediate (active)] Aquatic Chronic 3 H412 [intermediate (active)] Skin Corr. 1C H314 [intermediate (active)]
939-593-4	-	Reaction products of 1,2-dichloroethane with ammonia, 2-(2-aminoethylamino)ethanol distillation fraction	-	Repr. 1B H360, specific effect:May damage fertility. Suspected of damaging the unborn child [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] Skin Sens. 1B H317 [intermediate (active)]
217-811-2	1965-29-3	2-(2-(2-aminoethylamino)ethylamino)ethanol	-	-
261-141-3	58145-14-5	2-[bis(2-aminoethyl)amino]ethanol	-	-

(*) 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 5 May 2023

Main types of applications structured by product or article types	203-867-5	218-658-4	225-642-0	255-615-9	272-729-4	274-039-9	905-994-8	906-891-0	939-593-4	945-047-6*
Intermediate	I	I,P		I	I	I	I	I	I	
Laboratory chemicals		I,P		I,P						
Adhesives, sealants		I,P		F						
Coatings and paints, thinners, paint removers		I,P		F,I						
Polymer preparations and compounds	I	I,P	I	F						
Fillers, putties, plasters, modelling clay				F						
pH-regulators, flocculants, precipitants, neutralisation agents, etc				F						
Lubricants, greases, release products				F						
Metal working fluids				F						
Washing and cleaning products				I						
Article service life		A								

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

*Uses are not shown as they are claimed confidential by the registrant(s)

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

Data extracted on **15/05/2023**

EC / List number	RMOA	Authorisation		Restriction	CLH	Actions not under REACH / CLP*
		Candidate List	Annex XIV	Annex XVII	Annex VI (CLP)	
203-867-5				YES	YES	Cosmetics, OEL, food contact material

*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).

EC 203-867-5 is restricted under the Cosmetic Products Regulation due to its classification as Repro 1B.
The same substance has an OEL in Latvia. It has also been assessed for use in food contact materials by EFSA.

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