Assessment of regulatory needs

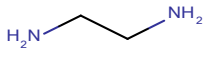
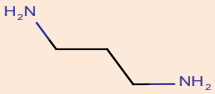
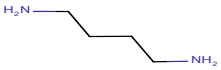
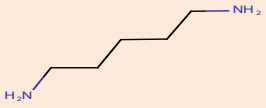
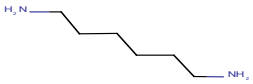
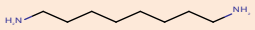
Authority: European Chemicals Agency (ECHA)

Group Name: Primary aliphatic diamines and their salts

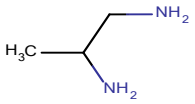
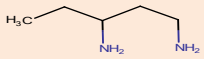
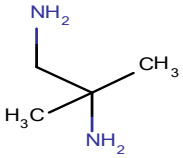
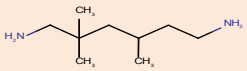
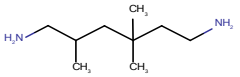
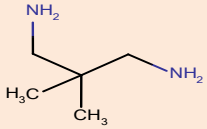
Revision history

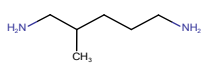
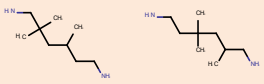
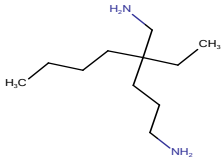
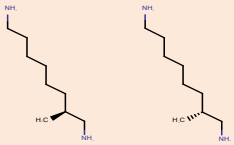
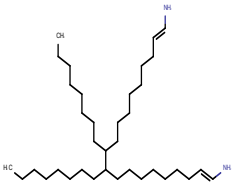
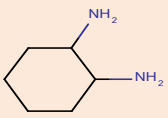
Version	*Date*	*Description*
1.0	13 January 2023	

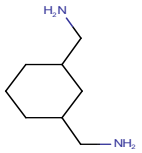
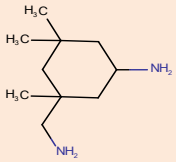
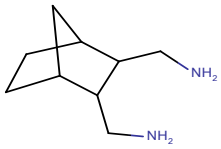
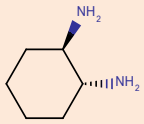
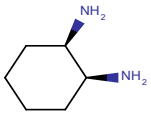
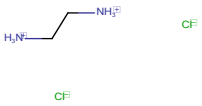
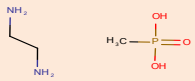
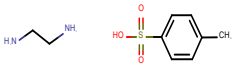
Substances within this group:

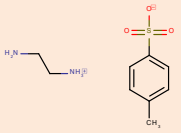
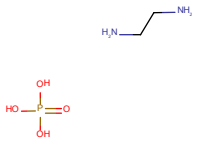
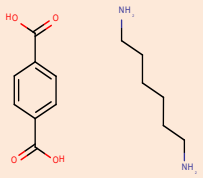
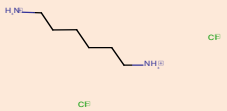
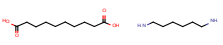
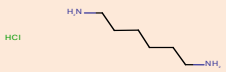
EC / List number	CAS number	Substance name	Chemical structures	Registration type (full / OSII / TII / NONS), highest tonnage band among all the registrations (t / y)[1]
Subgroup 1 (n=9): Linear aliphatic primary diamines				
203-468-6	107-15-3	Ethylenediamine		Full, >1000
203-702-7	109-76-2	Trimethylenediamine		Full, not (publicly) available
203-782-3	110-60-1	Tetramethylenediamine		Full, not (publicly) available
207-329-0	462-94-2	Pentamethylenediamine		Full, >1000
204-679-6	124-09-4	Hexamethylenediamine		Full, >1000
206-764-3	373-44-4	Octamethylenediamine		Full, not (publicly) available
211-470-3	646-24-2	Nonamethylenediamine		Full, not (publicly) available

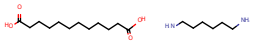
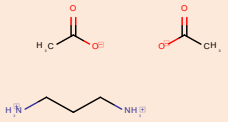
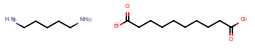
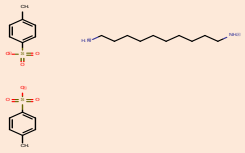
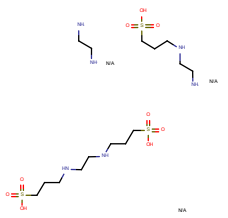
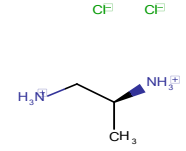
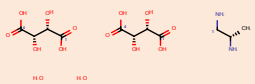
[1] Note that the total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

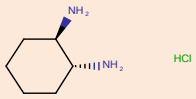
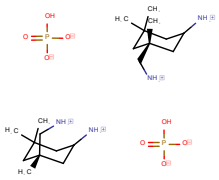
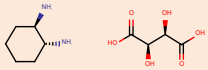
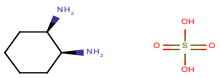
EC / List number	CAS number	Substance name	Chemical structures	Registration type (full / OSII / TII / NONS), highest tonnage band among all the registrations (t / y)[1]
211-471-9	646-25-3	Decamethylenediamine		Full, 100-1000
220-489-6	2783-17-7	Dodecamethylenediamine		Full, not (publicly) available
Subgroup 2 (n=11+1 outlier): Branched aliphatic primary diamines				
201-155-9	78-90-0	Propylenediamine		Full, not (publicly) available
425-690-4		1,3-pentanediamine		NONS
212-374-4	811-93-8	2-methylpropylenediamine		OSII or TII
221-792-6	3236-53-1	2,2,4-trimethylhexane-1,6-diamine		C&L notification
221-793-1	3236-54-2	2,4,4-trimethylhexane-1,6-diamine		Not registered
230-819-0	7328-91-8	2,2-dimethylpropane-1,3-diamine		OSII or TII

EC / List number	CAS number	Substance name	Chemical structures	Registration type (full / OSII / TII / NONS), highest tonnage band among all the registrations (t / y)[1]
239-556-6	15520-10-2	2-methylpentane-1,5-diamine		Full, >1000
247-063-2	25513-64-8	2,2,4(or 2,4,4)-trimethylhexane-1,6-diamine		Full, not (publicly) available
412-700-7		2-butyl-2-ethyl-1,5-diaminopentane		NONS
700-111-0	148528-05-6	2-Methyloctane-1,8-diamine		Full, not (publicly) available
273-282-8	68955-56-6	Amines, C36-alkylenedi-		Full, not (publicly) available
247-134-8	25620-58-0	trimethylhexane-1,6-diamine	No Structure	C&L notifications
Subgroup 3 (n=6): Cyclic primary diamines				
211-776-7	694-83-7	cyclohex-1,2-ylenediamine		Full, 100-1000

EC / List number	CAS number	Substance name	Chemical structures	Registration type (full / OSII / TII / NONS), highest tonnage band among all the registrations (t / y)[1]
219-941-5	2579-20-6	1,3-Cyclohexanedimethanamine		Full, not (publicly) available
220-666-8	2855-13-2	3-aminomethyl-3,5,5-trimethylcyclohexylamine		Full, >1000
260-280-7	56602-77-8	bicyclo[2.2.1]heptanebis(methylamine)		Full, not (publicly) available
601-163-6	1121-22-8	601-163-6		OSII or TII
604-372-0	1436-59-5	604-372-0		OSII or TII
Subgroup 4 (n=14+1 outlier): Linear aliphatic primary diamines salts				
206-369-6	333-18-6	ethylenediammonium dichloride		C&L notifications
483-300-8	99580-93-5	ethane-1,2-bis(aminium) methylphosphonate		Full, not (publicly) available
230-728-6	7294-10-2	ethylenediamine p-toluenesulphonate		OSII or TII

EC / List number	CAS number	Substance name	Chemical structures	Registration type (full / OSII / TII / NONS), highest tonnage band among all the registrations (t / y)[1]
810-688-1	14034-59-4	810-688-1		OSII or TII
238-914-9	14852-17-6	ethylenediamine, salt with phosphoric acid		Full, not (publicly) available
700-230-8	3160-86-9	[No public or meaningful name is available]		OSII or TII
222-037-3	3323-53-3	adipic acid, compound with hexane-1,6-diamine (1:1)		Full, >1000
227-977-8	6055-52-3	hexamethylenediammonium dichloride		C&L notifications
229-177-4	6422-99-7	sebacic acid, compound with hexane-1,6-diamine (1:1)		OSII or TII
245-053-2	22527-59-9	hexamethylenediamine hydrochloride		C&L notifications

EC / List number	CAS number	Substance name	Chemical structures	Registration type (full / OSII / TII / NONS), highest tonnage band among all the registrations (t / y)[1]
236-143-2	13188-60-8	dodecanedioic acid, compound with hexane-1,6-diamine (1:1)		OSII or TII
807-720-1	69112-70-5	propane-1,3-diaminium diacetate		Full, not (publicly) available
811-236-6	799768-48-2	pentane-1,5-diaminium sebacate		OSII or TII
855-905-0	1326716-46-4	decane-1,10-bis(aminium) bis(4-methylbenzenesulfonate)		Full, not (publicly) available
700-580-1		Reaction mass of 3-[(2-aminoethyl)ammonio]propane-1-sulfonate and 3,3'-(ethane-1,2-diyldiammonio)dipropane-1-sulfonate and ethane-1,2-diamine		Full, not (publicly) available
Subgroup 5 (n=2): Branched aliphatic primary diamines salts				
606-377-3	19777-66-3	(2S)-propane-1,2-diamine dihydrochloride		OSII or TII
924-425-4		S-1,2-Diaminopropane (2S, 3S)-2,3-dihydroxybutanedioic acid salt		OSII or TII

EC / List number	CAS number	Substance name	Chemical structures	Registration type (full / OSII / TII / NONS), highest tonnage band among all the registrations (t / y)[1]
Subgroup 6 (n=4): Cyclic primary diamines salts				
600-815-7	1073144-49-6	(±)-trans-cyclohexane-1,2-diamine hydrochloride		OSII or TII
411-830-1	114765-88-7	A mixture of: cis-(5-ammonium-1,3,3-trimethyl)-cyclohexanemethylammonium phosphate (1:1); trans-(5-ammonium-1,3,3-trimethyl)-cyclohexanemethylammonium phosphate (1:1)		NONS
609-759-8	39961-95-0	(1R,2R)-cyclohexane-1,2-diamine (2R,3R)-2,3-dihydroxybutanedioic acid		OSII or TII
613-794-4	65433-80-9	(1R,2S)-cyclohexane-1,2-diamine; sulfuric acid		OSII or TII

This table contains also group members that are not registered (yet) but have a C&L notification under the CLP Regulation. However, the list is currently non-exhaustive. Once further regulatory risk management action on one or more registered substances is being considered, ECHA may make an extensive search for related C&L notified substances to be included in the group and develop a regulatory strategy for them.

Contents

DISCLAIMER

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

Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult the ECHA website[2].

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

Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the two primary amine groups moiety shown in the figure below:

$H_2N\text{-}C\text{-}(C)_n\text{-}NH_2$ $n \geq 1$

Carbons in the above formula can be in the form of a cyclic structure.

The group of "**Primary aliphatic diamines and their salts**" consists of 48 substances: 24 have a full registration, 15 are only registered as transported or on-site isolated intermediates, 1 is an unclaimed and 2 are inactive NONS, and 6 are non-registered substances. Out of 42 registered substances, 33 are mono-constituent, 8 multi-constituent and 1 UVCB.

Based on chemical structure similarities, we have identified 6 subgroups. The following sub-grouping is referred to for parts of the hazard assessment:

- subgroup 1: Linear aliphatic primary diamines (9 substances);
- subgroup 2: Branched aliphatic primary diamines (11 substances + 1 outlier);
- subgroup 3: Cyclic primary diamines (6 substances);
- subgroup 4: Linear aliphatic primary diamines salts (14 substances + 1 outlier);
- subgroup 5: Branched aliphatic primary diamines salts (2 substances);
- subgroup 6: Cyclic primary diamines salts (4 substances).

The structural feature that determines the above sub-grouping is the structure of the alkyl chain to which two primary amine groups are bound. The alkyl chain can be linear, branched or cyclic and for each type of alkyl chain a sub-group was created. Additionally, some of the group members are in the form of salts, therefore the additional sub-groups for primary aliphatic diamines salts have been identified.

The sub-grouping described above is not followed in the section on regulatory risk management actions below, as the actions recommended are based mainly on human health hazard/ respiratory sensitisation for which the sub-grouping is of limited value. However, the sub-grouping is relevant for corrosivity and for environmental hazards[3].

Based on information reported in the REACH registration dossiers, the main use applications for most of the substances in the sub-groups 1-4, in addition to the use as intermediates, are polymer preparations, adhesives and sealants, coatings, paints and paint removers, fillers, putties, and plasters. Overall, for most of the substances within these sub-groups widespread, professional uses have been reported and thus potential for human exposure and environmental release can be expected to be high.

All the substances in the sub-group 5 (Branched aliphatic primary diamines salts) and sub-group 6 (Cyclic primary diamines salts) are either manufactured for the use as intermediates or used as intermediates in industrial setting only.

Within the whole group, consumer uses have only been reported explicitly for 3 substances (ECs 220-489-6, 273-282-8 and 483-300-8) and article service life for

[3] Based on structural features and structural similarity, most substances in sub-groups 1-3 are skin corrosives and are classified Skin Corr to one degree or other and substances in sub-groups 4, 5 and 6 are not skin corrosive. All substances in sub-groups 2, 3 and 6 screen as persistent, but they are not bioaccumulative and not mobile.

4 substances: ECs 204-679-6 (textiles), 483-300-8 and 273-282-8 (plastic articles), and 239-556-6 (in glue for parts of an article). Due to the nature of some of the other substances used as adhesives, sealants, coatings, paints and thinners (ECs 220-489-6, 219-941-5, 260-280-7, 211-776-7, 220-666-8 and 203-468-6) ECHA suspects these substances also to be included in articles.

There is a harmonised classification for ethylenediamine (EDA, EC 203-468-6) as a respiratory sensitiser category 1. This substance has been added in 2018 to the Candidate List due to its respiratory sensitising properties. In addition, ECs 201-155-9 and 220-666-8 have harmonised classifications, among other hazards as skin corrosion and for the latter substance as skin sensitisation, but no harmonised classification as respiratory sensitisation for these substances. For ECs 201-155-9, 211-776-7, 220-666-8 and 239-556-6 data generation is ongoing to investigate their potential toxicity for reproduction. The approval of EC 203-782-3 as an active Substances for Plant Protection Products has expired by 31/08/2019.

The substances ECs 220-666-8, 204-679-6, 203-782-3, 203-468-6, 247-063-2 and 211-471-9 are included in the Union list of authorised substances for the manufacture of plastic layers in plastic materials and articles under the Plastic Food Contact Materials Regulation 10/2011/EU. Therefore, it is assumed that these substances are also included in articles.

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

2 Justification for the need for regulatory risk management action at EU level

For three substances restriction is recommended in this assessment, but below they are discussed separately due to different hazard endpoints. When a restriction is to be prepared, these substances might be addressed together.

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction possibly combined with

authorisation for respiratory sensitisation hazard due to the potential for exposure of workers and consumers for ECs 203-468-6 (ethylenediamine) and 700-580-1.

Both substances have widespread uses, where exposure is expected to occur. Industrial and professional workers are using EC 203-468-6 e.g. in coatings and paints, thinners, paint removers, adhesive and sealants, fillers, putters and modelling clays (article service life cannot be ruled out from these uses but are not reported in the registration dossiers) and EC 700-580-1 in polymer preparation and compounds.

Based on ECHA's assessment of currently available hazard information, potential hazards were identified for human health. There is a harmonised classification for ethylenediamine (EC 203-468-6) as a respiratory sensitiser category 1 and as a skin sensitiser category 1, and the substance is included on the Candidate list since 2018 due to respiratory sensitising property. ECHA's draft recommendation for inclusion of this substance in the Authorisation list has been under consultation until 2 May 2022. Based on the feedback received in this consultation and the MSC opinion expected to be adopted in February 2023, ECHA will probably include this substance in its final recommendation by April 2023. The registrants have self-classified EC 700-580-1 as a respiratory sensitiser because it contains EC 203-468-6 at up to 13 %.

EC 203-468-6 is self-classified as aquatic chronic 3. There are no acute effects in Daphnia or algal effects at 100 mg/l in EC 700-580-1. Based on ECHA's assessment, EC 700-580-1 screens as persistent, but it is not bioaccumulative and not mobile.

EC 203-468-6 is a known asthmagen, asthmatic reactions were elicited in sensitised individuals below levels of respiratory irritation based on observations in workers. In order to avoid additional cases of respiratory sensitisation among professional workers from the use of these substances, restriction should be considered.

The following professional uses e.g. coatings and paints, thinners, paint removers, adhesive and sealants, fillers, putters and modelling clays (EC 203-468-6) and polymer preparation and compounds (EC 700-580-1) are expected to be widespread (at many sites and by many users) and may generate aerosols, vapours or dust. Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by the occupational safety and health (OSH) legislation.

Therefore, a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals** is suggested.

The choice of the restriction for professional uses over other regulatory management options (e.g. authorisation) is in line with the policy recently proposed by the European Commission under the Chemical Strategy for Sustainability[4] that expresses the need to extend the level of protection granted under REACH to consumers also to professional users.

If EC 203-468-6 will nevertheless be included after its recommendation in the authorisation list under Annex XIV REACH the conclusion will need to be revisited.

Moreover, restricting certain industrial uses may be considered as well. Moreover, restriction of the substances in articles used by professionals or consumers (suspected for EC 203-468-6) could be considered in the context of the restriction. However, considering the focus on respiratory sensitisation, the potential for

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

exposure from articles can generally be expected to be limited, however exposure from sanding paints and coatings for instance may generate relevant concentrations in air.

For industrial and professional uses that are out of the scope of the restriction it is suggested to consider **authorisation**. Once the scope of a potential future restriction is clear it is suggested that the need for authorisation in addition to restriction is re-evaluated. EC 203-468-6 is already on the Candidate List and currently recommended to be included in the Authorisation List. EC 700-580-1 has this candidate list substance as a constituent up to 13 %, thus a first step is the identification of EC 700-580-1 as an SVHC. This would require to identify the substance as being of equivalent level of concern to CMR substances which has not been done in the context of this work.

An EU-wide exposure limit for workers under OSH or REACH as an alternative risk management option to authorisation for industrial uses was also considered, especially for high tonnage substances (widely) used by workers. The authorisation also better promotes substitution than an OEL/DNEL would (as the restriction does for professional and consumer uses). Moreover, according to the Annex XV dossier for SVHC identification for EC 203-468-6, the EU has not derived an Indicative Occupational Exposure Limit Value (IOELV) or a Binding Occupational Exposure Limit Value (BOEL) for ethylenediamine (EC 203-468-6), although a number of Member States (Austria, Belgium, Denmark, Finland, France, Ireland, Spain and Sweden) have adopted an occupational exposure limit (OEL) of 10 ppm (25 mg/m^3). The observed effects of occupational asthma reported in the case studies occurred at a level ten times lower than the current Occupational Exposure Limit (OEL) of 10 ppm (8h TWA) adopted in many EU countries.[5] The same document states that "*On the basis of the available data for EDA it was not possible to derive a no effect level. The available data do not allow either elucidation of dose-response relationships or identification of the thresholds for induction of the sensitive state or provocation of an asthmatic response.*" Therefore, for the time being, even though a clear decision between the two regulatory options for uses at industrial sites is not possible, authorisation is suggested as the next regulatory risk management option following restriction.

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for skin sensitisation hazard due to exposure of professional workers for EC 220-666-8.

Industrial and professional workers are using EC 220-666-8 e.g. in coatings and paints, thinners, paint removers, adhesive and sealants, fillers, putters and modelling clays. Article service life cannot be ruled out from some of these uses, even though not reported in the registration dossiers.

Based on ECHA's assessment of currently available hazard information, the substance EC 220-666-8 is a very potent skin sensitiser with harmonised classification of Skin Sens. 1A and a specific concentration limit (SCL) of >0.001 %.

The following professional uses, such as the uses in coatings and paints, thinners, paint removers etc. are expected to be widespread (at many sites and by many users). Therefore, **a restriction of the substance as such or in mixtures (concentration limit in mixtures**) used by professionals is suggested.

[5] https://echa.europa.eu/documents/10162/f0a61fa4-64d1-2d19-35ed-d98134aec10d

There is a potential EU wide risk of getting sensitised from handling the substance as such or in mixtures. Professional use is widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures, professional users may be self-employed and therefore not covered by the occupational safety and health (OSH) legislation for workers, therefore a specific restriction on mixtures used by professionals is suggested. Moreover, **restricting substances in articles** used by professionals or consumers should be considered in the context of the restriction of professional uses as potential exposure from articles needs further investigation first.

For industrial uses, sufficient and consistent harmonised classification by registrants should trigger adequate risk management measures according to workplace legislation.

No hazard was confirmed for reproductive toxicity (pending further confirmation with ongoing data generation) for EC 220-666-8. However, there is no specific concern for reproductive toxicity, thus it is proposed not to await new data before any restriction proposal. EC 220-666-8 has a harmonised classification for aquatic chronic 3. The substance is unlikely to fulfil the PBT screening criteria. The needs for regulatory risk management actions will be re-assessed once generation of data is completed (CCH).

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for reproductive toxicity due to exposure of professional workers for EC 211-776-7.

The substance EC 211-776-7 has industrial and professional uses as coatings and paints, thinners, paint removers. In addition it has industrial uses in polymer preparations, textile dyes and leather treatment. Article service life cannot be ruled out from some of these uses, even though not reported in the registration dossiers.

Based on ECHA's assessment of currently available hazard information, the substance EC 211-776-7, has potential hazard for reproductive toxicity (pending further confirmation with ongoing data generation).

The first step of the regulatory risk management action proposed for EC 211-776-7, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Repro. cat 1B.

CLH i) will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place and ii) is needed or highly recommended for further regulatory processes under REACH.

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

The following professional uses, i.e. uses as coatings and paints, thinners, paint removers are expected to be widespread (at many sites and by many users). Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation.

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

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

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

Moreover, **restricting substances in articles** used by professionals or consumers should be considered in the context of the restriction of professional uses as potential exposure from articles needs further investigation first.

It is proposed to cover possibly industrial uses for which exposure is likely as part of the restriction for EC 211-776-7.

Based on currently available information, there is a need for (further) EU regulatory risk management – CLH and **EU-wide exposure limit** for workers under OSH or REACH for repeated dose toxicity (STOT RE, respiratory tract) for EC 219-941-5 in the group.

EC 219-941-5 is used as adhesives, sealants, fillers, putties, plasters, modelling clay, coatings and paints, thinners and paint removers by industrial and professional workers with potential exposure. Article service life cannot be ruled out from these uses.

Based on ECHA's assessment of currently available hazard information, there is no indication of respiratory sensitising property for this substance, but based on information reported in the registration dossier there is data supporting its classification for STOT RE 1 (lungs or larynx). Currently no STOT RE self-classification is applied and the effects may warrant low specific concentration limit (SCL), thus the substance is proposed for CLH. Having harmonised classification would support the companies to take appropriate risk reduction measures, as the effect is seen in very low concentrations. No EU OEL has been established for this substance under the OSH legislation. EU-wide exposure limit would be a good regulatory tool to control/reduce inhalation exposure at the workplace. The uses reported indicate that there are many workers using the substance and it is proposed in addition to CLH to derive such limit value for workers under OSH or REACH.

Based on information reported in the registration dossiers, the substance is not expected to be toxic to reproduction and is unlikely to be PBT as it does not screen for B. The CCH is proposed to be opened and the needs for regulatory risk management actions will be re-assessed once remaining uncertainties on these hazards have been clarified.

Based on currently available information, it is not possible to assess the need for regulatory risk management as information on hazard is not sufficient to conclude on PBT/vPvB and reproduction toxicity for EC 273-282-8.

Based on ECHA's assessment of currently available hazard information, the substance EC 273-282-8 screens as being persistent, is self-classified as aquatic chronic category 1, and meets the T criterion due to effects on algae. Information on long-term toxicity for fish is missing. The substance is not expected to be mobile in the environment because of strong adsorption of the cationic form to particles.

EC 273-282-8 is a poorly water soluble surfactant. No relevant information is therefore available to assess the bioaccumulation potential. Thus CCH is proposed

for the substance to clarify long term fish toxicity, persistency and bioaccumulation potential.

As regards human health hazards of EC 273-282-8, registrants have classified this substance for skin irritation and eye damage. No evidence of skin sensitisation was observed based on the submitted read-across data and in the absence of a structural alert therefore respiratory sensitisation is not expected. More information is needed to conclude on the other properties, like reproduction toxicity. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).

Based on currently available information, there is no need for (further) EU regulatory risk management for all other substances in the group.

ECHA distinguishes the following grounds for suggesting no need for further EU RRM action:

Substances with self-classified or suspected respiratory sensitisation for which current use profile does not warrant EU action at this stage:

Based on ECHA's assessment of currently available hazard information, several substances have potential respiratory sensitisation. However, their current use profile does not warrant actions at this stage. EC 203-702-7 is self-classified as respiratory sensitiser (a close structural analogue of EC 203-468-6), in addition it is self-classified due to its skin sensitisation potential. The substance is reported to be used only as an intermediate. ECs 230-728-6, 238-914-9, and 810-688-1 are salts of ethylenediamine (203-468-6) and 807-720-1 is a salt of trimethylenediamine (203-702-7) and on this basis are suspected as respiratory sensitisers , of which ECs 238-914-9, and 810-688-1 are classified by registrants as skin sensitisers 1/1B. The substances are used in industry in polymer preparation and/or as an intermediate, EC 810-688-1 also in pharmaceutical industry.

EC 238-914-9 is recommended for CCH to confirm low hazard for human health endpoints (other than respiratory sensitisation).

In case there are changes in the registration status, uses and/or tonnages, the assessment will be revisited.

Substances where there is uncertainty of the respiratory sensitisation hazard and company level risk management measures are suggested:

Based on ECHA's assessment of currently available hazard information, for several substances their potential to cause respiratory sensitisation cannot be concluded: ECs 201-155-9, 203-782-3, 204-679-6, 206-764-3*, 207-329-0, 211-470-3*, 211-471-9, 212-374-4*, 220-489-6, 229-177-4, 236-143-2, 260-280-7, 483-300-8, 600-815-7, 601-163-6* 604-372-0*, 606-377-3, 609-759-8, 613-794-4, 700-230-8, 811-236-6 and 924-425-4. The registered substances have a high pH and are skin corrosives to one or other degree and this has been used in the majority of cases to correctly apply a waiver for the information requirement for a skin sensitisation test. In cases were animal skin sensitation tests are available these show both positive and negative results without clear pattern across the group(s). Nonetheless a proportion of the substances are skin sensitisers (marked with *). Substances with mainly intermediate uses and lower information requirements are not classified as skin corrosives in line with the available data. No data are available for skin sensitisation and none are classified for this property. For EC 483-300-8 the substance does not show skin sensitising potential based on a negative result in a Local Lymph Node Assay (LLNA) which may indicate that the substance would

not be a respiratory sensitiser. The substance is not corrosive. Industrial and professional uses of flame retardant in polymer preparation are reported. Article service life (plastics) and consumer use (in polymer preparation) is also reported for this use of the substance, but as the respiratory sensitising hazard is not unambiguous, no further actions are proposed.

In respect of the substances in the above paragraph, (Q)SARs did not show any respiratory sensitisation alerts (whereas they did for ethylenediamine moieties – see above). This respiratory sensitisation property is usually confirmed based on human data and typically few data from reports of human observations are reported in the registrations.No compliance checks are proposed to address skin sensitisation as generally the waivers have been correctly applied, the substances are classified for skin sensitisation or it is not a standard information requirement. A number of other properties of these substances result in classifications which indicate hazards following airborne or dermal exposures for some of the substances (e.g. Flam. Liquid, Acute Tox (inhalation), Acute Tox (dermal), STOT SE (respiratory tract)). However, it cannot be assessed whether the expected exposure control measures would control for the potential induction of respiratory sensitisation.

It is proposed for the companies to be aware of uncertainty related to the respiratory sensitisation. ECHA recommends the industry to monitor the workers health with possible early signals of respiratory sensitisation.

Some of the above substances are also used by professionals and EC 220-489-6 is used also by consumers as adhesive and sealants (article service life may also be possible due to these uses), thus there remains open, how e.g. self-employed workers and consumers would be able to tackle this uncertainty.

For three of the substances (ECs 201-155-9, 207-329-0 and 211-470-3) ‘no hazard’ cannot yet be confirmed and CCH is suggested to be opened for ECs 207-329-0 and 201-155-9. The needs for regulatory risk management actions will be re-assessed once generation of data is completed (CCH).

For other registered substances with inconclusive hazard for respiratory sensitisation (ECs 600-815-7, 606-377-3, 609-759-8, 613-794-4, 811-236-6 and 924-425-4) all the reported uses show low potential for exposure and/or releases.

Substances with absence of concern that would lead to regulatory measures:

For 5 substances (ECs 230-819-0, 239-556-6, 222-037-3, 700-111-0 and 855-905-0) this screening indicates they do not pose respiratory sensitisation hazard on the basis of negative results in animal skin sensitisation results and absence of structural alerts. For one of these substances, ‘no hazard’ cannot yet be confirmed for reproductive toxicity (pending further confirmation with ongoing data generation for EC 239-556-6). It is proposed to open the CCH for another substance (EC 700-111-0) for reproductive tests. However, for ECs 239-556-6 and 700-111-0, the reprotoxic hazard is expected to be unlikely.

Of the NONs (unclaimed/inactive), i.e. ECs 411-830-1, 412-700-7 and 425-690-4, all have low concern for human health. One substance (EC 411-830-1) is suspected as aquatic chronic 3. Uses of these substances have low potential for exposure and/or releases.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
203-468-6 700-580-1	Known or potential hazard for respiratory sensitisation and for skin sensitisation	No hazard or unlikely hazard	Widespread industrial and professional uses for 203-468-6: Coatings and paints, thinners, paint removers; adhesive and sealants; fillers, putters, modelling clays, etc., article service life cannot be ruled out for these uses but has not been reported in the registration dossiers; for 700-580-1: Polymer preparation and compounds.	**Need for EU RRM: Restriction in combination with authorisation** <u>Justification:</u> Respiratory sensitisers: important to substitute to the safer alternatives in industrial sites. It is generally difficult for consumers and professional users to control exposure, as uses are mainly non-contained and non-automated. It is proposed that restricting the	**First step:** SVHC identification for 700-580-1 **Next steps (if hazard confirmed):** Restriction in combination with authorisation

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				substance in articles used by professionals or consumers should be considered in the context of the restriction, as potential exposure from articles needs further investigation first.	
220-666-8	Known or potential hazard for skin sensitisation (EC 220-666-8)	Known or potential hazard for aquatic toxicity (EC 220-666-8)	EC 220-666-8: Widespread industrial and professional uses: Coatings and paints, thinners, paint removers; adhesive and sealants; fillers, putters, modelling clays, etc. Article service life cannot be ruled out.	**Need for EU RRM: Restriction** <u>Justification:</u> The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over	Restriction

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. Restricting substances in articles used by professionals or consumers should be considered in the context of the restriction of professional uses as potential exposure from articles needs further investigation first. It is recommended not to await the pending data generation for reprotoxicity (unlikely to be toxic to reproduction).	

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
211-776-7	Known or potential hazard for reproductive toxicity (EC 211-776-7)	No hazard or unlikely hazard	EC 211-776-7: Industrial and professional uses as coatings and paints, thinners, paint removers. In addition the substance has industrial uses in polymer preparations, textile dyes and leather treatment. Article service life cannot be ruled out from some of these uses.	**Need for EU RRM: Restriction** <u>Justification:</u> The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. restricting substances in articles used by	**First step:** CCH ongoing **Next steps (if hazard confirmed:** CLH Restriction

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				professionals or consumers should be considered in the context of the restriction of professional uses as potential exposure from articles needs further investigation first. Possibly industrial uses for which exposure is likely to be considered as part of the restriction. It is recommended not to await the pending data generation for reprotoxicity (unlikely to be toxic to reproduction).	
219-941-5	Known or potential hazard for STOT RE (respiratory tract)	No hazard or unlikely hazard	Substance is used as adhesives, sealants, fillers, putties, plasters, modelling clay, coatings and	**Need for EU RRM: CLH, OEL** <u>Justification:</u>	**First step:** CCH CLH for STOT RE **Next step:**

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			paints, thinners and paint removers by industrial and professional workers with potential exposure. Article service life cannot be ruled out but has not been reported in the registration dossiers.	Having harmonised classification for STOT RE would support the companies to take appropriate risk reduction measures, as the effect is seen in very low concentrations. EU-wide exposure limit would be a good regulatory tool to control/reduce inhalation exposure at the workplace. The uses reported indicate that there are many workers using the substance and it is proposed in addition to CLH to derive such limit value for workers under OSH or REACH.	OEL
273-282-8	Inconclusive hazard for reproductive toxicity	Known or potential hazard for aquatic toxicity	273-282-2: Widespread industrial,	**No hypothesis yet** <u>Justification:</u>	CCH

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
		Inconclusive hazard for bioaccumulation	professional and consumer uses as adhesive and sealants, coatings and paints, thinners, paint removers, consumer uses of ink and toners. Article service life reported from the polymer preparation.	It is proposed to await the outcome of the CCH whether the substances are toxic to reproduction (unlikely) and/or fulfils the PBT criteria.	
203-702-7 230-728-6 238-914-9 807-720-1 810-688-1	Known or potential hazard for respiratory sensitisation Known or potential hazard for skin sensitisation (203-702-7, 238-914-9 and 810-688-1)	No hazard or unlikely hazard	Substances are used in industry in polymer preparation (238-914-9) or as intermediate (230-728-6, 203-702-7 and 810-688-1 (the latter used also in pharmaceuticals). 807-720-1 is used in formulation (laboratory use).	**Currently no need for EU RRM** <u>Justification:</u> Currently no widespread uses reported. Risk management measures currently in place are regarded sufficient, provided that respiratory sensitisation is correctly self-classified. In case there are changes in the	CCH (238-914-9)

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				registration status, uses and/or tonnages, the assessment will be revisited.	
201-155-9 203-782-3 204-679-6 206-764-3 207-329-0 211-470-3 211-471-9 212-374-4 220-489-6 229-177-4 236-143-2 247-063-2	Known or potential hazard for skin sensitisation (206-764-3, 211-470-3, 212-374-4, 247-063-2, 601-163-6, 604-372-0) Inconclusive hazard for respiratory sensitisation	No hazard or unlikely hazard	Widespread industrial and professional uses for 260-280-7 in polymer preparations and compounds, coatings and paints, thinners, paint removers, adhesive and sealants and fillers, putters, modelling clays; the substance 204-679-6 has article service life in textiles, dyes and impregnating products and widespread uses (I, P) in coatings and paints, thinners, paint removers; the substance 220-489-6 is used in formulation and by professionals and consumers	**Currently no need for EU RRM** <u>Justification:</u> There is uncertainty of respiratory sensitisation property. It is proposed for the companies to be aware of this uncertainty, and to monitor the workers health with possible early signals of respiratory sensitisation.	CCH for 201-155-9, and 207-329-0

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
260-280-7 483-300-8 600-815-7 601-163-6 604-372-0 606-377-3 609-759-8 613-794-4 700-230-8 811-236-6 924-425-4			(adhesives, sealants); the substance 483-300-8 has widespread uses, i.e. industrial, professional uses of flame retardant in polymer preparation and it has an article service life (plastics) and a consumer use as polymer preparation; the rest of the substances is either used as intermediate only and/or industrial uses only have been reported.		
<u>Registered substances</u> 222-037-3 230-819-0 239-556-6	Known or potential hazard for skin sensitisation (230-819-0 and 700-111-0)	Known or potential hazard for aquatic toxicity (411-830-1)	239-556-6: Industrial use in adhesives, sealants (article service life reported) and industrial and professional uses in coatings and paints, thinners, paint removers.	**Currently no need for EU RRM** <u>Justification:</u> No such hazards that would lead to the need for regulatory management.	CCH for 700-111-0

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
700-111-0 855-905-0 <u>NONS (unclaimed/inactive):</u> 411-830-1 412-700-7 425-690-4 <u>Not registered/C&L notified substances:</u> 206-369-6 221-792-6 221-793-1 227-977-8 245-053-2 247-134-8			Other registered substances are used in industrial settings in polymer preparation, in laboratory and/or in non-metal-surface treatment. Some substances have only intermediate use.		

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

Data extracted on 4 May 2021.

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations
203-468-6	107-15-3	Ethylenediamine	Flam. Liq. 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H31 Skin Sens. 1 H317 Resp. Sens. 1 H334	Resp. Sens. 1 H334 [intermediate (active)] Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 3 H311 Acute Tox. 4 H332 Skin Corr. 1B H314 Resp. Sens. 1B H334 Skin Sens. 1B H317 Aquatic Chronic 3 H412
203-702-7	109-76-2	Trimethylenediamine	Not included in Annex VI	Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 2 H310 Skin Corr. 1B H314 Eye Damage 1 H318 Resp. Sens. 1B H334 Skin Sens. 1B H317
203-782-3	110-60-1	Tetramethylenediamine	Not included in Annex VI	Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 3 H311 Acute Tox. 2 H330 Skin Corr. 1B H314 Eye Damage 1 H318
207-329-0	462-94-2	Pentamethylenediamine	Not included in Annex VI	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314 Eye Damage 1 H318 Flam. Liquid 4 H227 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratory tract [intermediate (active)]
204-679-6	124-09-4	Hexamethylenediamine	Not included in Annex VI	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314 STOT Single Exp. 3 H335, affected organs: Upper respiratory tract
206-764-3	373-44-4	Octamethylenediamine	Not included in Annex VI	Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1 H317
211-470-3	646-24-2	Nonamethylenediamine	Not included in Annex VI	Acute Tox. 4 H302 Skin Corr. 1A H314 Skin Sens. 1 H317 Aquatic Chronic 4 H413
211-471-9	646-25-3	Decamethylenediamine	Not included in Annex VI	Acute Tox. 4 H302 Skin Corr. 1B H314

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations
220-489-6	2783-17-7	Dodecamethylenediamine	Not included in Annex VI	Acute Tox. 4 H302 Acute Tox. 3 H331 Skin Corr. 1 H314 Eye Damage 1 H318 Aquatic Acute 1 H400
201-155-9	78-90-0	Propylenediamine	Skin Corr. 1A H314 Flam. Liq. 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H312	Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 3 H311 Skin Corr. 1A H314 Eye Damage 1 H318
425-690-4		1,3-pentanediamine	Not included in Annex VI	
212-374-4	811-93-8	2-methylpropylenediamine	Not included in Annex VI	Flam. Liquid 3 H226 [intermediate (active)] Skin Corr. 1 H314 [intermediate (active)] Aquatic Chronic 3 H412 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Skin Sens. 1B H317 [intermediate (active)]
221-792-6	3236-53-1	2,2,4-trimethylhexane-1,6-diamine	Not included in Annex VI	-
221-793-1	3236-54-2	2,4,4-trimethylhexane-1,6-diamine	Not included in Annex VI	-
230-819-0	7328-91-8	2,2-dimethylpropane-1,3-diamine	Not included in Annex VI	Skin Sens. 1B H317 [intermediate (active)] Acute Tox. 4 H312 [intermediate (active)] Skin Corr. 1A H314 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Flam. Liquid 2 H225 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)]
239-556-6	15520-10-2	2-methylpentane-1,5-diamine	Not included in Annex VI	Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 4 H332 Skin Corr. 1A H314 Eye Damage 1 H318 STOT Single Exp. 3 H335, affected organs: upper respiratory tract (clinical signs as well as microscopically lesions observed in nose, trachea, and larynx)
247-063-2	25513-64-8	2,2,4(or 2,4,4)-trimethylhexane-1,6-diamine	Not included in Annex VI	Acute Tox. 4 H302 Skin Corr. 1A H314 Eye Damage 1 H318 Skin Sens. 1A H317

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations
412-700-7		2-butyl-2-ethyl-1,5-diaminopentane	Not included in Annex VI	-
700-111-0	148528-05-6	2-Methyloctane-1,8-diamine	Not included in Annex VI	Acute Tox. 4 H302 Skin Corr. 1A H314 Skin Sens. 1 H317 Aquatic Chronic 3 H412
273-282-8	68955-56-6	Amines, C36-alkylenedi-	Not included in Annex VI	Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410
247-134-8	25620-58-0	trimethylhexane-1,6-diamine	Not included in Annex VI	-
211-776-7	694-83-7	cyclohex-1,2-ylenediamine	Not included in Annex VI	Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 4 H332 Skin Corr. 1A H314 Eye Damage 1 H318 STOT Single Exp. 3 H335, affected organs: upper respiratory tract (clinical signs as well as microscopically lesions observed in nose, trachea, and larynx)
219-941-5	2579-20-6	1,3-Cyclohexanedimethanamine	Not included in Annex VI	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1A H314 Eye Damage 1 H318 Aquatic Chronic 3 H412
220-666-8	2855-13-2	3-aminomethyl-3,5,5-trimethylcyclohexylamine	Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Dam. 1 H318 Skin Sens. 1A H317	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1A H317 Skin Sens. 1 H317 Aquatic Chronic 3 H412
260-280-7	56602-77-8	bicyclo[2.2.1]heptanebis(methylamine)	Not included in Annex VI	Acute Tox. 4 H302 Skin Corr. 1C H314 Eye Damage 1 H318 Aquatic Chronic 3 H412
601-163-6	1121-22-8	601-163-6	Not included in Annex VI	Eye Damage 1 H318 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)]
604-372-0	1436-59-5	604-372-0	Not included in Annex VI	Eye Damage 1 H318 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)]
206-369-6	333-18-6	ethylenediammonium dichloride	Not included in Annex VI	-

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations
483-300-8	99580-93-5	ethane-1,2-bis(aminium) methylphosphonate	Not included in Annex VI	Aquatic Chronic 3 H412
230-728-6	7294-10-2	ethylenediamine p-toluenesulphonate	Not included in Annex VI	Flam. Solid 2 H228 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)]
810-688-1	14034-59-4	810-688-1	Not included in Annex VI	Acute Tox. 4 H302 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Skin Sens. 1B H317 [intermediate (active)]
238-914-9	14852-17-6	ethylenediamine, salt with phosphoric acid	Not included in Annex VI	Skin Sens. 1 H317
700-230-8	3160-86-9	[No public or meaningful name is available]	Not included in Annex VI	-
222-037-3	3323-53-3	adipic acid, compound with hexane-1,6-diamine (1:1)	Not included in Annex VI	-
227-977-8	6055-52-3	hexamethylenediammonium dichloride	Not included in Annex VI	-
229-177-4	6422-99-7	sebacic acid, compound with hexane-1,6-diamine (1:1)	Not included in Annex VI	-
245-053-2	22527-59-9	hexamethylenediamine hydrochloride	Not included in Annex VI	-
236-143-2	13188-60-8	dodecanedioic acid, compound with hexane-1,6-diamine (1:1)	Not included in Annex VI	-
807-720-1	69112-70-5	propane-1,3-diaminium diacetate	Not included in Annex VI	-
811-236-6	799768-48-2	pentane-1,5-diaminium sebacate	Not included in Annex VI	-
855-905-0	1326716-46-4	decane-1,10-bis(aminium) bis(4-methylbenzenesulfonate)	Not included in Annex VI	Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Chronic 3 H412
700-580-1		Reaction mass of 3-[(2-aminoethyl)ammonio]propane-1-	Not included in Annex VI	Resp. Sens. 1 H334 Skin Sens. 1 H317

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations
		sulfonate and 3,3'-(ethane-1,2-diyldiammonio)dipropane-1-sulfonate and ethane-1,2-diamine		
606-377-3	19777-66-3	(2S)-propane-1,2-diamine dihydrochloride	Not included in Annex VI	Skin Irrit. 2 H315 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: lungs [intermediate (active)] Skin Mild Irrit. 3 H315 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: Respiratory system [intermediate (active)]
924-425-4		S-1,2-Diaminopropane (2S, 3S)-2,3-dihydroxybutanedioic acid salt		STOT Single Exp. 3 H335, affected organs: respiratory tract [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)]
600-815-7	1073144-49-6	(±)-trans-cyclohexane-1,2-diamine hydrochloride	Not included in Annex VI	-
411-830-1	114765-88-7	A mixture of: cis-(5-ammonium-1,3,3-trimethyl)-cyclohexanemethylammonium phosphate (1:1); trans-(5-ammonium-1,3,3-trimethyl)-cyclohexanemethylammonium phosphate (1:1)	Not included in Annex VI	-
609-759-8	39961-95-0	(1R,2R)-cyclohexane-1,2-diamine (2R,3R)-2,3-dihydroxybutanedioic acid	Not included in Annex VI	Eye Irrit. 2 H319 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: Respiratory [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)]
613-794-4	65433-80-9	(1R,2S)-cyclohexane-1,2-diamine; sulfuric acid	Not included in Annex VI	-

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

Data extracted on 4 May 2021.

Main types of applications structured by product or article types	EC/ List 201-155-9	EC/ List 203-468-6	EC/ List 203-782-3	EC/ List 204-679-6	EC/ List 207-329-0	EC/ List 211-470-3	EC/ List 211-776-7	EC/ List 219-941-5	EC/ List 220-489-6	EC/ List 220-666-8	EC/ List 239-556-6	EC/ List 247-063-2	EC/ List 260-280-7	EC/ List 273-282-8	EC/ List 483-300-8	EC/ List 700-111-0	EC/ List 700-580-1	EC/ List 807-720-1	EC/ List 810-688-1	EC/ List 811-236-6	EC/ List 855-905-0
Products such as ph-regulators, flocculants, precipitants, neutralisation agents		I, P		F, I			I														
Water treatment chemicals		P																			
Fertilisers			I																		
Pharmaceuticals	I																		I		
Non-metal-surface treatment products																					F, I
Heat transfer fluids		I																			
Hydraulic fluids		I																			
Fuels	I	F, I																			
Polymer		F, I	I	F, I	F, I	I	I	I		I, P,	I	I, P,	F, I,	F, A	F, I,	I	I, P	F		I	

Main types of applications structured by product or article types	EC/ List 201-155-9	EC/ List 203-468-6	EC/ List 203-782-3	EC/ List 204-679-6	EC/ List 207-329-0	EC/ List 211-470-3	EC/ List 211-776-7	EC/ List 219-941-5	EC/ List 220-489-6	EC/ List 220-666-8	EC/ List 239-556-6	EC/ List 247-063-2	EC/ List 260-280-7	EC/ List 273-282-8	EC/ List 483-300-8	EC/ List 700-111-0	EC/ List 700-580-1	EC/ List 807-720-1	EC/ List 810-688-1	EC/ List 811-236-6	EC/ List 855-905-0
preparations and compounds										A		A	P, A		P, C, A						
Adhesives, sealants		I, P, A						F, I, P, A	F, P, C, A	F, I, P, A	F, I, A	P, A	F, I, P, A	F, I, P, C							
Fillers, putties, plasters, modelling clay		P, A						F, I, P, A		F, I, P, A		P, A	F, I, P, A								
Coatings and paints, thinners, paint removes		I, P, A		I, P, A			F, I, P, A	F, I, P, A		F, I, P, A	F, I, P	F, I, P, A	F, I, P, A	F, I, P, C							
Ink and toners														F, C							
Textile dyes, and impregnating products				F, I, A	F		I														
Leather treatment products							I														
Laboratory chemicals	I	I, P								I, P		I, P	I					F		I	
Intermediate	I	F, I, P	I	F, I	I		I	I	I	I, P	I	I, P		I					I	I	

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

ECs 211-471-9, 222-037-3 and 236-143-2 have industrial uses as polymer preparations and compounds and as intermediates. EC 238-914-9 has only formulation and industrial uses as polymer preparations and compounds.

ECs 203-702-7, 206-764-3, 212-374-4, 229-177-4, 230-728-6, 230-819-0, 601-163-6, 604-372-0, 606-377-3, 600-815-7, 609-759-8, 613-794-4, 700-230-8 and 924-425-4 are reported to be used only as intermediates.

ECs 206-369-6, 221-792-6, 221-793-1, 227-977-8, 245-053-2, 247-134-8, 411-830-1, 412-700-7 and 425-690-4 are not registered or NONS (no upgrade, inactive or not claimed).

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

Data extracted on 11 June 2021.

EC / List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
201-155-9					YES	
203-468-6	YES	YES			YES	OEL (MS)
204-679-6						OEL (MS)
211-776-7						OEL (MS)
220-666-8					YES	
203-782-3						

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

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

Note that some substances are reviewed by other EU agencies.