

## Assessment of regulatory needs

**Authority: European Chemicals Agency (ECHA)**

**Date: 11 January 2022**

**Group Name: Aralkylamines**

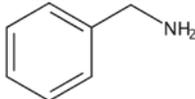
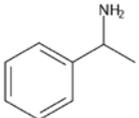
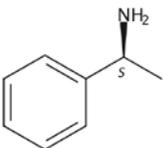
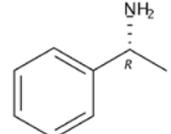
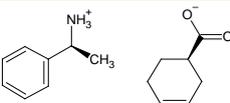
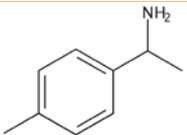
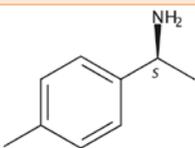
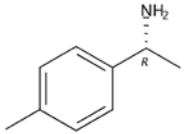
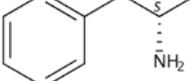
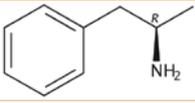
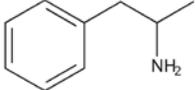
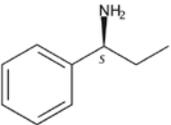
### General structure:

The general structure of the substances from the group corresponds to amines connected to a phenyl moiety via a carbon bridge and without heteroatom. The substances include diverse chemical structures (e.g., 1-4 amine moieties, primary/secondary/tertiary amines, 1-3 phenyl groups...).

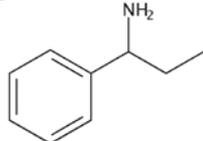
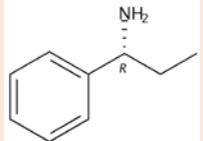
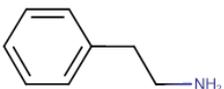
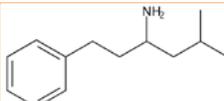
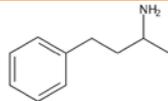
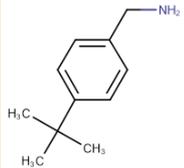
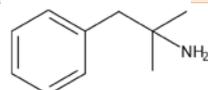
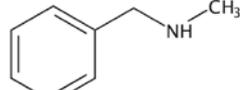
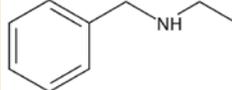
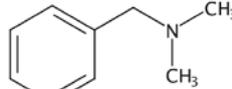
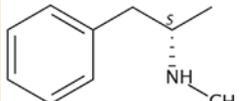
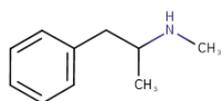
### Revision history

<i>Version</i>	<i>Date</i>	<i>Description</i>
1	19/05/2022	

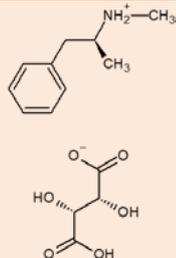
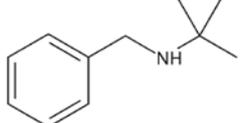
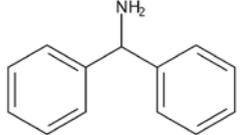
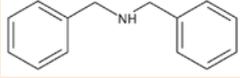
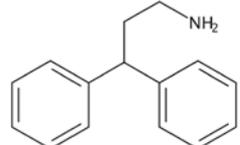
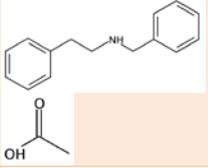
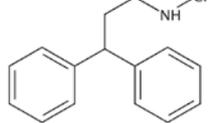
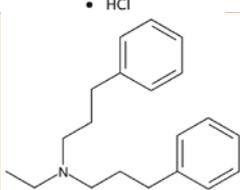
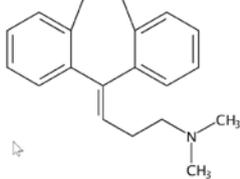
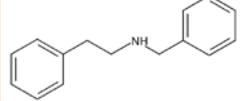
## Substances within this group:

EC/List number	CAS number	Substance name	Chemical structures	Registration status
<b>Subgroup 1 (n=19, counting duplicates substances as one): primary monoamines with one alkylphenyl group (includes amphetamine and its stereoisomers):</b>				
202-854-1	100-46-9	benzylamine		Full, 10-100
210-545-8 (202-706-6*)	618-36-0	DL- $\alpha$ -methylbenzylamine		Full, not (publicly) available
220-098-0	2627-86-3	L- $\alpha$ -methylbenzylamine		Full, not (publicly) available
223-423-4	3886-69-9	D- $\alpha$ -methylbenzylamine		Full, not (publicly) available
814-700-6	67976-81-2	(1R)cyclohex-3-enecarboxylic acid (1S)-1-phenylethylamine		OSII or TII
443-160-0 [1] 937-697-4 [2] (624-212-3*)[3]	[1]: 586-70-9	[1]: 1-(4-methylphenyl)ethan-1-amine [2]: 1-(p-tolyl)ethanamine [3]: 1-(4-Methylphenyl)ethylamine		[1]: OSII or TII [2]: Cease manufacture
623-635-0	27298-98-2	Benzenemethanamine, .alpha.,4-dimethyl-, (.alpha.S)-		OSII or TII
624-182-1	4187-38-6	Benzenemethanamine, .alpha.,4-dimethyl-, (.alpha.R)-		OSII or TII
200-112-1	51-64-9	Dexamphetamine		OSII or TII
205-850-8	156-34-3	Levamphetamine		OSII or TII
206-096-2	300-62-9	amphetamine		OSII or TII
455-040-5 (609-485-9*)	3789-59-1	Benzenemethanamine, .alpha.-ethyl-, (S)-		OSII or TII

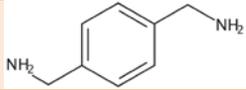
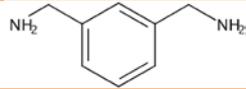
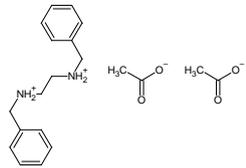
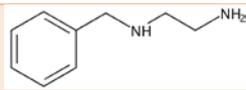
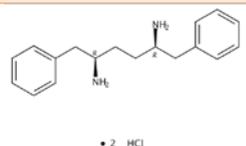
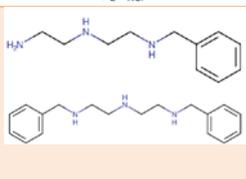
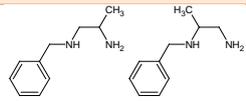
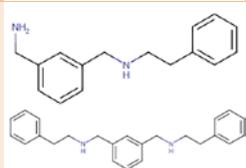
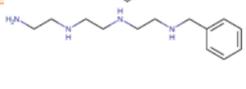
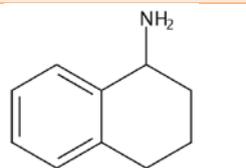
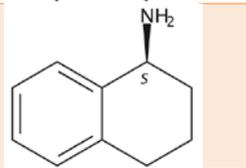
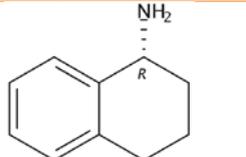
## ASSESSMENT OF REGULATORY NEEDS

608-356-4	2941-20-0	Benzenemethanamine, .alpha.-ethyl-		OSII or TII
608-544-6	3082-64-2	Benzenemethanamine, .alpha.-ethyl-, (.alpha.R)-		OSII or TII
200-574-4	64-04-0	Phenethylamine		OSII or TII
229-007-9	6396-93-6	3-methyl-1-phenethylbutylamine		OSII or TII
244-942-2	22374-89-6	1-methyl-3-phenylpropylamine		Full, not (publicly) available
254-681-6	39895-55-1	4-tert-butylbenzylamine		OSII or TII
204-522-1	122-09-8	Phentermine		OSII or TII
<b>Subgroup 2 (n=7, counting duplicates substances as one): secondary and tertiary monoamines with one alkylphenyl group, including one amine salt (includes metamphatamine and the corresponding racemate)</b>				
203-133-4	103-67-3	benzyl(methyl)amine		OSII or TII
238-265-1	14321-27-8	N-ethylbenzylamine		OSII or TII
203-149-1	103-83-3	benzyl(dimethyl)amine		Full, >1000
208-668-7	537-46-2	methamphetamine		OSII or TII
231-559-0 [1] 225-433-4 [2]	[1]: 7632-10-2 [2]: 4846-07-5	[1]: N,α-dimethylphenethylamine [2]: (±)-N,α-dimethylphenethylamine		[1]: OSII or TII [2]: OSII or TII

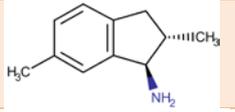
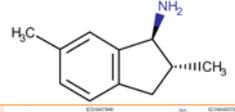
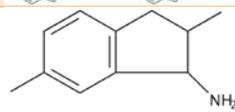
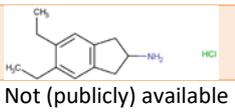
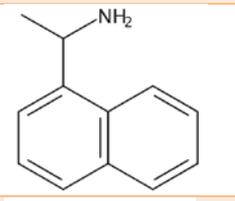
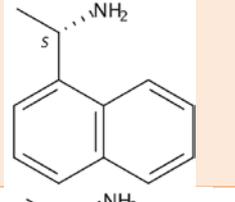
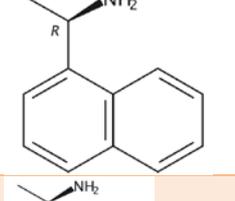
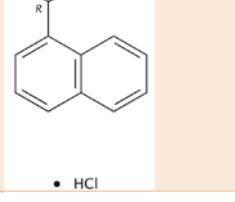
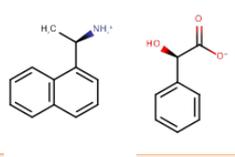
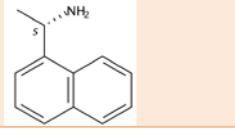
ASSESSMENT OF REGULATORY NEEDS

298-036-7	93777-08-3	(R)-methyl( $\alpha$ -methylphenethyl)ammonium [R-(R*,R*)]-hydrogen tartrate		OSII or TII
222-179-6	3378-72-1	N-(tert-butyl)benzylamine		OSII or TII
<b>Subgroup 3 (n=8): primary, secondary and tertiary monoamines with two phenyl groups, including two amine salts</b>				
202-032-2	91-00-9	Benzhydramine		OSII or TII
203-117-7	103-49-1	dibenzylamine		Full, not (publicly) available
226-984-3	5586-73-2	3-3-diphenylpropylamine		OSII or TII
302-174-6	94094-72-1	N-benzylphenethylammonium diacetate		OSII or TII
608-414-9	29768-15-8	3,3-diphenylpropyl methyl ammonium chloride		OSII or TII
205-763-5	150-59-4	alverine		OSII or TII
200-041-6	50-48-6	amitriptyline		OSII or TII
222-882-8	3647-71-0	N-benzylphenethylamine		OSII or TII
<b>Subgroup 4 (n=2): 1,3- and 1,4-phenylenedimethanamines</b>				

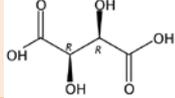
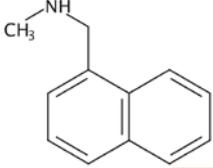
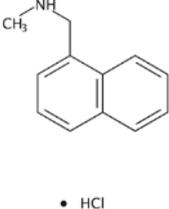
ASSESSMENT OF REGULATORY NEEDS

208-719-3	539-48-0	p-phenylenebis(methylamine)		Full, not (publicly) available
216-032-5	1477-55-0	m-phenylenebis(methylamine)		Full, >1000
<b>Subgroup 5 (n=7): di-, tri-, tetraamines with primary and secondary amine groups and 1-3 phenyl groups, including two amine salts</b>				
204-572-4	122-75-8	N,N'-dibenzylethylenediammonium di(acetate)		OSII or TII
223-984-5	4152-09-4	N-benzylethylenediamine		Full, not (publicly) available
700-856-1	1247119-31-8	(2R,5R)-1,6-Diphenylhexane-2,5-diamine dihydrochloride		OSII or TII
846-447-2	1219458-07-7	Reaction products of benzaldehyde and N-(2-aminoethyl)ethane-1,2-diamine and N,N'-bis(2-aminoethyl)ethane-1,2-diamine, hydrogenated		Full, not (publicly) available
942-655-3	1802727-84-9	Reaction mass of N1-benzylpropane-1,2-diamine and N2-benzylpropane-1,2-diamine		Full, not (publicly) available
445-790-1	404362-22-7	1,3-Benzenedimethanamine, N-(2-phenylethyl) derivs.		Full, not (publicly) available
244-734-1*	22029-44-3	N-(2-aminoethyl)-N'-[2-(benzylamino)ethyl]ethylenediamine		Not registered
<b>Subgroup 6 (n=9): alkyl aminoindanes, including two amine salts / stereoisomers of 1,2,3,4-tetrahydronaphthalene-1-amine</b>				
218-712-7	2217-40-5	1,2,3,4-tetrahydro-1-naphthylamine		OSII or TII
629-348-7	23357-52-0	1-Naphthalenamine, 1,2,3,4-tetrahydro-, (1S)-		OSII or TII
628-771-4	23357-46-2	1-Naphthalenamine, 1,2,3,4-tetrahydro-, (1R)-		OSII or TII

ASSESSMENT OF REGULATORY NEEDS

700-140-9	752984-24-0	(1R,2S)-2,6-dimethyl-2,3-dihydro-1H-inden-1-amine		OSII or TII
700-575-4	1351564-23-2	trans-2,6-dimethylindan-1-amine		OSII or TII
940-806-8		Reductive amination products of 2,6-dimethylindan-1-one and ammonia and hydrogen		OSII or TII
937-760-6	1225478-65-8	2,6-dimethylindan-1-amine		OSII or TII
455-940-8		5,6-diethylindan-2-aminium chloride		OSII or TII
Not (publicly) available	-	-	Not (publicly) available	Not registered
<b>Subgroup 7 (n=8): alkylnaphthyl monoamines (primary and secondary amine groups and one naphthyl group, including two amine salts)</b>				
610-076-2	42882-31-5	1-Naphthalenemethanamine, a-methyl-		OSII or TII
436-100-1		(1S)-1-NAPHTHYLETHYLAMINE		OSII or TII
223-425-5	3886-70-2	R-(+)-1-(1-naphthyl)ethylamine		OSII or TII
617-358-4	82572-04-1	(1R)-1-Naphthylethylamine Hydrochloride		OSII or TII
600-816-2	1073144-62-3	(R)-1-(1-Naphthyl)ethylamine (R)-Mandelate		OSII or TII
600-817-8	1073145-07-9	(S)-(-)-1-(1-Naphthyl)ethylamine (2R,3R)-2,3-dihydroxybutanedioic salt		OSII or TII

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<b>238-497-3</b>	14489-75-9	N-methylnaphthalene-1-methylamine		OSII or TII
<b>613-801-0</b>	65473-13-4	1-Naphthalenemethanamine, N-methyl-, hydrochloride (1:1)		OSII or TII

\*: not registered

This table also contains group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA will make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

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## Foreword

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

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

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

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

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

For more information on Assessment of regulatory needs please consult ECHA website<sup>1</sup>.

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<sup>1</sup> <https://echa.europa.eu/understanding-assessment-regulatory-needs>

## Glossary

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

## 1 Overview of the group

ECHA has grouped together structurally similar amine substances based on the presence of both aryl and alkyl moieties and phenyl moieties connected to the amine group via a carbon bridge. The group "aralkylamines" includes 60 amine (or amine salt) substances. The group includes substances with quite diverse chemical structures, e.g. primary/secondary/tertiary amines, with 1-4 amine groups, and 1-3 phenyl groups. The alkyl groups are linear or branched. Most of the substances in the group are well-defined mono-constituent or multi-constituent substances. The structures of the substances are presented in the above table (see front pages of this document), divided into the following subgroups:

- Subgroup 1: primary monoamines with one alkylphenyl group (includes amphetamine and its stereoisomers)
- Subgroup 2: secondary and tertiary monoamines with one alkylphenyl group, including one amine salt (includes metamphetamine and the corresponding racemate)
- Subgroup 3: primary, secondary and tertiary monoamines with two phenyl groups, including two amine salts
- Subgroup 4: 1,3- and 1,4-phenylenedimethanamines
- Subgroup 5: di-, tri-, tetraamines with primary and secondary amine groups and 1-3 phenyl groups, including two amine salts
- Subgroup 6: alkyl aminoindanes, including also amine salts / stereoisomers of 1,2,3,4-tetrahydronaphthalene-1-amine
- Subgroup 7: alkylnaphthyl monoamines (primary and secondary amine groups and one naphthyl group, including two amine salts)

The majority of the substances are registered as intermediates where use under strictly controlled conditions is expected. Of the 13 fully registered substances, 6 have widespread use by professional workers or article service life reported - mainly for use in polymer preparations and compounds (including rubber and plastic article production), use in adhesives and sealants, and use in coatings and paints. There is a potential for exposure for workers in the industrial and professional setting as well as potential for releases to the environment. In addition, there is a potential for exposure for consumers and the environment resulting from the reported/suspected article service life. The remaining fully registered substances are used at industrial sites as intermediates (precursors) in the synthesis of chemicals (particularly pharmaceuticals) or as laboratory chemicals. Although there are some uncertainties as to whether all reported uses are indeed intermediate, the provided information is generally consistent and therefore, although potential for exposure cannot be excluded, it is considered unlikely.

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

For the purpose of the hazard assessment, the substances were divided into 7 subgroups based on commonalities in structural moieties (mainly presence of phenyl moiety connected to an amino moiety via a carbon bridge). There is a significant degree of structural variability amongst group members, not only across the different subgroups but also within. The hazard conclusions are based on limited available information on representative substances within each subgroup and some degree of extrapolation to other (sub)group members for specific endpoints assuming similar properties due to presence of common functional groups only. In addition, in most cases it is not possible to assume potential interchangeability of substances based on their structure and function/uses.

Therefore, the regulatory hypothesis is developed based on the potential for exposure and the subgrouping was not considered essential in the regulatory actions proposed.

Many substances in the group might have the potential to react with nitrosating agents and to form potential carcinogenic nitrosamines. This has not been explored further in terms of actions in this assessment. A common approach needs to be developed further regarding substances with 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 to other groups of substances.

**Based on currently available information, there is a need for (further) EU regulatory risk management – namely restriction** due to potential PBT/vPvB and skin sensitisation properties combined with potential for exposure/releases to the environment for two members in the group (EC 445-790-1, List No. 846-447-2).

Both substances have potential PBT/vPvB properties, aquatic toxicity, and are potent skin sensitisers (self-classified as Skin Sens. 1A); additionally, EC 445-790-1 has a self-classification for STOT RE 2 (skeletal muscle, heart, small intestine). They are used in the industrial and professional settings (particularly construction) in adhesives, sealants and coatings. Activities associated with high potential for exposure such as spraying, dipping, pouring have been reported therefore, the potential for release to the environment and exposure to workers is likely in both settings. Furthermore, the reported technical functions indicate that residual amounts of the substance may remain in the coating/adhesive after application into/onto articles. Therefore, article service life is potentially relevant and consequently potential for exposure to the general public and releases to the environment from the use of articles cannot be excluded.

Restriction is considered as the most appropriate regulatory risk management option to minimise releases of these substances to the environment and limit exposure; however, as a first step, both substances will require data generation via compliance check in order to substantiate hazard confirmation.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via SVHC identification and inclusion on the Candidate List as PBT/vPvB.

SVHC identification will trigger (i) supply chain communication and (ii) substances in articles requirements.

Confirmation of the hazard properties via SVHC identification is not considered sufficient to minimise potential releases of the substances in the environment. A

restriction is seen as the most appropriate option as potential for exposure is expected from professional uses, article service and industrial uses.

Professional use is typically widespread with relatively low levels of operational controls and risk management measures. Widespread professional uses are typically non-contained and non-automated leading to releases to the environment. Furthermore, potential for exposure and releases to the environment from articles cannot be excluded.

Therefore, a restriction of the substances as such or in mixtures (concentration limit in mixtures) used by professional workers and industrial workers is suggested after SVHC identification, with the aim to minimise as much as possible the releases to the environment. Moreover, restricting substances used in articles is also proposed.

The use of PBT and vPvB substances by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability<sup>2</sup>.

It is suggested to cover possibly also industrial uses as part of the restriction. However, the need for authorisation might be considered for industrial uses excluded from the scope of the restriction as it may not be proportionate to restrict all uses.

To address the potent skin sensitisation properties and possible consumer (via article use) and worker exposure, CLH for Skin Sens. 1A would be suggested for both substances. The restriction targeting PBT/vPvB properties (as described above) should lead to a minimisation of environmental releases and thereby also ensure limited exposure to humans, particularly consumers that may be exposed to the substances via use of articles. Harmonised classification as Skin Sens. 1A should in addition ensure that adequate risk management measures are triggered according to workplace legislation to limit exposure and offer adequate protection for professional and industrial workers.

**Based on currently available information, there is a need for (further) EU regulatory risk management – namely CLH** due to potential potent skin sensitisation properties and potential for worker exposure (List No. 942-655-3).

Similarly, to the substances above, this member has potential PBT/vPvB properties, aquatic toxicity, and is self-classified as Skin Sens. 1A; it also has similar applications with a potential for exposure to industrial and professional workers. However, based on currently available registration information, the required data for PBT/vPvB confirmation cannot be requested under compliance check and data generation under substance evaluation is also unlikely. It may be possible to extrapolate findings on PBT/vPvB from data requested for the structurally similar substances however this will be further clarified and considered once the studies have been provided.

A harmonised classification as Skin Sens. 1A is proposed for this substance in order to trigger company level risk management measures under OSH legislation and to ensure adequate protection of professional and industrial workers. In case there are relevant updates to the registration in the future, it is suggested to align with the regulatory strategy foreseen for the other similar substances detailed in the previous section: data generation (CCH or SEV), followed by SVHC identification and restriction.

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<sup>2</sup> European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

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

Potential hazards have been identified for all of these substances however vary between members. Most substances have potential skin sensitisation properties, aquatic toxicity, suspected reproductive toxicity (expected to be category Repr. 2 based on similarity to amphetamine and methamphetamine) and a couple (EC 298-036-7, EC 231-559-0) are self-classified as Carc. 2. Additionally, EC 223-984-5 has potential PBT/vPvB properties. A detailed breakdown of hazards per substance is shown in the regulatory strategy table below.

The majority of the substances in the group (47 out of 62) are registered under Article 17/18 where use is expected to occur under strictly controlled conditions. Due to the strict risk management measures expected to be already in place, the potential for exposure is not considered likely for any of these substances.

In addition, there are 6 fully registered substances (EC 202-854-1, EC 210-545-8, EC 220-098-0, EC 223-423-4, EC 244-942-2, EC 203-117-7) where the reported uses are mainly as intermediates in the synthesis of chemicals such as pharmaceuticals and/or as laboratory chemicals. Exposure and release potential from those uses is also considered unlikely - most registrants report use under controlled conditions or provide use descriptors suggesting unlikelihood of exposure. As an exception, substance EC 202-854-1 has in addition reported industrial and professional use in polymer preparation and compounds; however there are inconsistencies in the provided information and therefore uncertainties as to whether this may also be referring to use as intermediate (or monomer).

Substance EC 208-719-3 is a monomer in an imported polymer; exposure and release of the residual monomer from the polymer matrix is considered unlikely, however cannot be confirmed due to the lack of information. For substance EC 223-984-5 the provided use information is poor, only the formulation life cycle stage (and manufacturing) is reported. Release and exposure are considered unlikely however there are uncertainties due to the lack of information.

Despite the potential hazards, no EU regulatory risk management action is currently proposed for any of the aforementioned substances due to low exposure potential and the unlikelihood of regrettable substitution. It is worth noting however that the strategy may need to be revised 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 of the remaining substances (EC 244-734-1, EC/List No. not (publicly) available) are not registered and it is therefore not possible to request data generation. It is also not possible to assume that either substance could be a potential substitute for another registered substance in the group. No further EU RRM is currently proposed for either substance; however, the strategy may need to be revised and data requested if the substances are registered in the future.

Substance EC 203-149-1 is mainly used industrially in polymer preparations and compounds, in adhesives and sealants and in coatings. It is also present in articles such as fabrics, textiles and in mechanical appliances however according to the reported environmental release category, release from the article is not intended. Exposure potential for industrial workers and for the general public (via articles) cannot be excluded. The substance has a potential reproductive toxicity hazard due to structural similarity to methamphetamine that is self-classified as Repr. 2. The classification category for this substance is also expected to be Repr. 2 as it is based only on structural similarity with methamphetamine whereas available data on the substance itself (PNDT in rodents) does not raise concern for developmental toxicity. No further regulatory action is currently proposed for this substance - for industrial uses, sufficient and consistent self-classification by registrants should

trigger adequate risk management measures according to workplace legislation. Data generation is currently ongoing to further clarify the repro potential and may require a revision of the strategy, particularly if the results rather indicate Repr. 1B classification.

The remaining substance (EC 216-032-5) is mainly used by industrial and professional workers in adhesives, sealants and coatings and potentially remains (likely in residual amounts) following application into/onto articles. Potential for release/exposure is expected from industrial and professional uses; potential for release/exposure from articles cannot be excluded. The substance is hazardous to the aquatic environment, is self-classified as Skin Sens. 1B and is expected to be Repr. 2 based on structural similarity to methamphetamine. A compliance check will be opened for this substance in order to clarify the human health and environmental hazards. For industrial and professional workers, sufficient and consistent self-classification by registrants should trigger adequate risk management measures according to workplace legislation. It is expected that the registrant(s) will update the registration dossier and classify accordingly following data generation. Therefore, no further EU RRM is currently proposed however the strategy may need to be revised once the hazards are clarified.

### 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.

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
<b>SG 5</b> 445-790-1 846-447-2	Known or likely hazard for (potent) skin sensitisation  Known or likely hazard for STOT RE for EC 445-790-1	Known or potential hazard for aquatic toxicity and PBT/vPvB	Widespread uses with potential for release and exposure including use in polymer preparations (F,I,P,A); adhesives, sealants (F,I,P,A); coatings (F,I,P,A)	<b>Need for EU RRM: Restriction</b>	<ol style="list-style-type: none"> <li>For PBT/vPvB properties:</li> <li>CCH</li> <li>potentially followed by SVHC identification</li> <li>potentially followed by Restriction for use in articles, professional uses and potentially industrial uses</li> </ol> For potent skin sensitisation: <ol style="list-style-type: none"> <li>CLH</li> </ol>

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<p><b>SG 5</b> 942-655-3</p>				<p><b>Need for EU RRM:</b> <b>CLH</b></p>	<p>CLH</p>
<p><b>SG 1</b> (202-706-6) 814-700-6 443-160-0 (937-697-4) (624-212-3) 623-635-0 624-182-1 200-112-1 205-850-8 206-096-2 455-040-5 609-485-9 608-356-4 608-544-6 200-574-4 229-007-9 254-681-6 204-522-1</p>	<p>Known or likely hazard for skin sensitisation, reproductive toxicity and STOT RE</p>	<p>Known or likely hazard for aquatic toxicity</p>	<p>Unlikely release and exposure potential – registered under Article17/18</p>	<p><b>Currently no need for EU RRM</b></p>	<p>No action <i>CCH for EC 244-942-2, 203-149-1, 208-719-3, 216-032-5</i></p>

ASSESSMENT OF REGULATORY NEEDS

202-854-1 210-545-8 220-098-0 223-423-4 244-942-2			Unlikely release and exposure potential – only intermediate uses reported		
<b>SG 2</b> 203-133-4 238-265-1 208-668-7 (231-559-0) 225-433-4 298-036-7 222-179-6 203-149-1	Known or likely hazard for reproductive toxicity and STOT RE  Known or likely hazard for carcinogenicity for EC 298-036-7 and 231-559-0	Known or likely hazard for aquatic toxicity	Unlikely release and exposure potential – registered under Article17/18  Widespread uses with potential for release and exposure including use in polymer preparations (F,I,A); adhesives, sealants (F,I,A); coatings (F,I,A)		
<b>SG 3</b> 202-032-2 226-984-3 302-174-6 608-414-9	Known or likely hazard for reproductive toxicity	Known or likely hazard for aquatic toxicity	Unlikely release and exposure potential – registered under Article17/18		

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205-763-5 200-041-6 222-882-8	Known or likely hazard for STOT RE	Inconclusive hazard for PBT/vPvB			
203-117-7			Unlikely release and exposure potential – only intermediate uses reported		
<b>SG 4</b> 208-719-3	Known or likely hazard for skin sensitisation, reproductive toxicity and STOT RE	Known or likely hazard for aquatic toxicity	Monomer in an imported polymer; release and exposure are unlikely		
216-032-5			Widespread uses with potential for release and exposure including use in polymer preparations (F,I,P,A); adhesives, sealants (F,I,P,A); coatings (F,I,P,A)		
<b>SG 5</b> 204-572-4 700-856-1	Known or likely hazard for skin sensitisation and STOT RE	Known or likely hazard for aquatic toxicity and PBT/vPvB	Unlikely release and exposure potential – registered under Article17/18		
223-984-5			Only used in formulation; release and exposure are unlikely (with some uncertainties)		

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244-734-1			Not registered		
<b>SG 6</b> 218-712-7 629-348-7 628-771-4 700-140-9 700-575-4 940-806-8 937-760-6 455-940-8	Inconclusive hazard for carcinogenicity, ED, reproductive toxicity and STOT RE  Known or likely hazard for skin sensitisation for 455-940-8	Known or likely hazard for aquatic toxicity  Inconclusive hazard for PBT/vPvB and ED	Unlikely release and exposure potential – registered under Article17/18		
Not (publicly) available			Not registered		
<b>SG 7</b> 610-076-2 436-100-1 223-425-5 617-358-4 600-816-2 600-817-8 238-497-3 613-801-0	Known or likely hazard for skin sensitisation except for 238-497-3  Known or likely hazard for STOT RE  Inconclusive hazard for carcinogenicity, ED and reproductive toxicity	Known or likely hazard for aquatic toxicity  Inconclusive hazard for PBT/vPvB and ED	Unlikely release and exposure potential – registered under Article17/18		

## Annex 1: Overview of classifications

Data extracted on 22 April 2021

EC/List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
200-041-6	amitriptyline	<i>Not included in Annex VI</i>	Acute Tox. 3 H301 [int. (act.)] Acute Tox. 3 H311 [int. (act.)] Aquatic Chronic 1 H410 [int. (act.)] Repr. 2 H361 [int. (act.)] Acute Tox. 3 H331 [int. (act.)] Eye Damage 1 H318 [int. (act.)]	Acute Tox. 4 H302[1 out of 3]
200-112-1	dexamphetamine	<i>Not included in Annex VI</i>	Skin Corr. 1C H314 [int. (act.)] Flam. Liquid 3 H226 [int. (act.)] Acute Tox. 2 H300 [int. (act.)]	Acute Tox. 3 H301[1 out of 2] Acute Tox. 3 H311[1 out of 2] Acute Tox. 2 H330[1 out of 2] Skin Corr. 1B H314[1 out of 2]
200-574-4	phenethylamine	<i>Not included in Annex VI</i>	Acute Tox. 3 H301 [int. (act.)] Eye Damage 1 H318 [int. (act.)] Skin Corr. 1B H314 [int. (act.)] Met. Corr. 1 H290 [int. (act.)] Skin Corr. 1A H314 [int. (act.)]	Acute Tox. 4 H312[12 out of 28] Acute Tox. 4 H302[15 out of 28] Acute Tox. 4 H332[11 out of 28] STOT Single Exp. 3 H335, affected organs: respiratory organ[1 out of 28]
202-032-2	benzhydramine	<i>Not included in Annex VI</i>	STOT Single Exp. 3 H335, affected organs: Respiratory tract [int. (act.)] Eye Irrit. 2 H319 [int. (act.)] Skin Irrit. 2 H315 [int. (act.)] Acute Tox. 4 H302 [int. (act.)]	Acute Tox. 2 H330[1 out of 7] Acute Tox. 3 H301[1 out of 7] Eye Damage 1 H318[1 out of 7] Skin Corr. 1B H314[1 out of 7] STOT Single Exp. 3 H335, affected organs: [1 out of 7] Eye Irrit. 2A H319[1 out of 7] Acute Tox. 3 H311[1 out of 7]
202-706-6	1-phenylethylamine	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314	-	-
202-854-1	Benzylamine	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314 Eye Damage 1 H318	-
203-117-7	Dibenzylamine	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318 Aquatic Chronic 1 H410 Skin Corr. 1C H314 [int. (act.)] Aquatic Chronic 2 H411 [int. (act.)] Aquatic Acute 2 H401 [int. (act.)]	Skin Irrit. 2 H315[4 out of 17] Aquatic Chronic 3 H412[4 out of 17] STOT Single Exp. 3 H335, affected organs: [1 out of 17] Eye Irrit. 2 H319[4 out of 17]
203-133-4	Benzyl(methyl)amine	<i>Not included in Annex VI</i>	Skin Corr. 1B H314 [int. (act.)] Acute Tox. 4 H302 [int. (act.)]	Flam. Liquid 3 H226[4 out of 21] Met. Corr. 1 H290[2 out of 21] Eye Damage 1 H318[6 out of 21] Acute Tox. 3 H311[1 out of 21] Acute Tox. 4 H332[4 out of 21] Skin Corr. 1C H314[3 out of 21]

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				21] STOT Single Exp. 3 H335, affected organs: dýchacie orgány[1 out of 21] Skin Sens. 1B H317[1 out of 21] STOT Single Exp. 3 H335, affected organs: Respiratory tract[1 out of 21] Acute Tox. 3 H301[4 out of 21] Resp. Sens. 1 H334[3 out of 21] Skin Corr. 1 H314[1 out of 21] STOT Single Exp. 3 H335, affected organs: respiratory[1 out of 21] Skin Irrit. 2 H315[1 out of 21] Skin Sens. 1 H317[3 out of 21] Eye Irrit. 2 H319[1 out of 21] Acute Tox. 4 H312[7 out of 21]
203-149-1	Benzylidimethylamine	Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 4 H332 Skin Corr. 1B H314 Aquatic Chronic 3 H412	Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 3 H331 Acute Tox. 4 H332 Skin Corr. 1B H314 Aquatic Chronic 2 H411 Aquatic Chronic 3 H412	Acute Tox. 3 H301[1 out of 70] Acute Tox. 3 H311[1 out of 70] Met. Corr. 1 H290[1 out of 70] Aquatic Chronic 1 H410[1 out of 70] Acute Tox. 4 H331[1 out of 70] Eye Damage 1 H318[3 out of 70] STOT Rep. Exp. 2 H373, affected organs: Respiratory system, Kidney[2 out of 70]
204-522-1	Phentermine	<i>Not included in Annex VI</i>	Acute Tox. 3 H311 [int. (act.)] Acute Tox. 3 H301 [int. (act.)] Skin Irrit. 2 H315 [int. (act.)] Acute Tox. 4 H332 [int. (act.)] Eye Irrit. 2 H319 [int. (act.)]	-
204-572-4	N,N'-dibenzylethylenediamine di(acetate)	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 [int. (act.)]	-
205-763-5	alverine	<i>Not included in Annex VI</i>	-	-
205-850-8	levamfetamine	<i>Not included in Annex VI</i>	Acute Tox. 3 H301 [int. (act.)] Acute Tox. 3 H311 [int. (act.)]	-
206-096-2	amphetamine	<i>Not included in Annex VI</i>	Flam. Liquid 2 H225 [int. (act.)] Acute Tox. 1 H300 [int. (act.)]	Acute Tox. 2 H300[1 out of 1] Flam. Liquid 3 H226[1 out of 1]
208-668-7	methamphetamine	<i>Not included in Annex VI</i>	Acute Tox. 3 H301 [int. (act.)]	-
208-719-3	p-phenylenediamine(methylamine)	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1 H317 Aquatic Chronic 3 H412	Skin Corr. 1C H314[1 out of 5]
210-545-8	DL- $\alpha$ -methylbenzylamine	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314	Acute Tox. 3 H311[1 out of 8] Eye Damage 1 H318[2 out of 8]
216-032-5	m-phenylenediamine	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 Acute Tox. 4 H332 Skin Corr. 1B H314	STOT Single Exp. 1 H370, affected organs: Respiratory system.[1 out of 99]

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	s(methylamine)		Eye Damage 1 H318 Skin Sens. 1B H317 Aquatic Chronic 3 H412	Acute Tox. 2 H330[6 out of 99] STOT Single Exp. 1 H370, affected organs: lungs[1 out of 99] STOT Single Exp. 1 H370, affected organs: respiratory system[2 out of 99] Carc. 2 H351[1 out of 99] Acute Tox. 3 H331[35 out of 99] Skin Sens. 1 H317[74 out of 99] Acute Tox. 4 H312[10 out of 99] STOT Single Exp. 2 H371, affected organs: [1 out of 99] Skin Corr. 1C H314[2 out of 99] STOT Rep. Exp. 2 H373, affected organs: Liver, Kidney, Lung[2 out of 99] STOT Single Exp. 3 H335, affected organs: [1 out of 99] Skin Corr. 1 H314[3 out of 99] Eye Irrit. 2 H319[1 out of 99] STOT Single Exp. 1 H370, affected organs: Respiratory System[1 out of 99] Skin Corr. 1A H314[15 out of 99]
218-712-7	1,2,3,4-tetrahydro-1-naphthylamine	<i>Not included in Annex VI</i>	Skin Corr. 1C H314 [int. (act.)] Eye Damage 1 H318 [int. (act.)] Acute Tox. 4 H302 [int. (act.)] Aquatic Acute 3 H402 [int. (act.)] Aquatic Chronic 3 H412 [int. (act.)]	Eye Irrit. 2 H319[3 out of 6] STOT Single Exp. 3 H335, affected organs: [2 out of 6] STOT Single Exp. 3 H335, affected organs: Respiratory tract[1 out of 6] Skin Irrit. 2 H315[4 out of 6] Eye Irrit. 2A H319[1 out of 6]
220-098-0	L- $\alpha$ -methylbenzylamine	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314 Acute Tox. 3 H311 [int. (act.)]	Skin Corr. 1C H314[1 out of 16] Eye Irrit. 2 H319[1 out of 16] Acute Tox. 3 H331[1 out of 16] Acute Tox. 3 H301[1 out of 16] Eye Damage 1 H318[3 out of 16]
222-179-6	N-(tert-butyl)benzylamine	<i>Not included in Annex VI</i>	Flam. Liquid 3 H226 [int. (act.)] Skin Corr. 1 H314 [int. (act.)] Acute Tox. 4 H302 [int. (act.)]	Eye Damage 1 H318[2 out of 9] Acute Tox. 3 H301[1 out of 9] Flam. Liquid 2 H225[1 out of 9] Skin Corr. 1B H314[4 out of 9] Skin Corr. 1C H314[2 out of 9] Acute Tox. 4 H312[1 out of 9]
222-882-8	N-benzylphenethylamine	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 [int. (act.)] Skin Corr. 1C H314 [int. (act.)] Eye Damage 1 H318 [int. (act.)] Aquatic Chronic 2 H411 [int. (act.)]	STOT Single Exp. 3 H335, affected organs: Respiratory tract[1 out of 3] Skin Irrit. 2 H315[2 out of 3] Eye Irrit. 2 H319[1 out of 3] Eye Irrit. 2A H319[1 out of 3] STOT Single Exp. 3 H335, affected organs: [1 out of 3]
223-423-4	D- $\alpha$ -methylbenzylamine	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314	Eye Damage 1 H318[3 out of 16] Acute Tox. 3 H311[3 out of 16]

ASSESSMENT OF REGULATORY NEEDS

				16] STOT Single Exp. 3 H335[1 out of 16]
223-425-5	R-(+)-1-(1-naphthyl)ethylamine	<i>Not included in Annex VI</i>	STOT Single Exp. 3 H335, affected organs: Respiratory [int. (act.)] Eye Irrit. 2 H318 [int. (act.)] Skin Irrit. 2 H315 [int. (act.)] Skin Sens. 1A H317 [int. (act.)] Acute Tox. 4 H302 [int. (act.)] Acute Tox. 4 H312 [int. (act.)]	STOT Single Exp. 3 H335, affected organs: Respiratory tract[1 out of 9] Acute Tox. 3 H301[1 out of 9] Aquatic Chronic 2 H411[1 out of 9] Eye Irrit. 2 H319[5 out of 9] Skin Corr. 1B H314[1 out of 9] STOT Single Exp. 3 H335, affected organs: [3 out of 9] Eye Damage 1 H318[1 out of 9]
223-984-5	N-benzylethylethylenediamine	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1A H317 Aquatic Chronic 3 H412	Skin Sens. 1 H317[1 out of 8] Skin Corr. 1C H314[1 out of 8]
225-433-4	(±)-N,N-dimethylethylenediamine	<i>Not included in Annex VI</i>	Eye Irrit. 2 H319 [int. (act.)]	-
226-984-3	3,3-diphenylpropylamine	<i>Not included in Annex VI</i>	-	Skin Irrit. 2 H315[4 out of 6] Eye Irrit. 2A H319[1 out of 6] STOT Single Exp. 3 H335, affected organs: Respiratory tract[1 out of 6] STOT Single Exp. 3 H335, affected organs: [2 out of 6] Eye Irrit. 2 H319[3 out of 6]
229-007-9	3-methyl-1-phenethylbutylamine	<i>Not included in Annex VI</i>	Skin Corr. 1B H314 [int. (act.)] Acute Tox. 4 H302 [int. (act.)]	-
231-559-0	N,N-dimethylethylenediamine	<i>Not included in Annex VI</i>	Repr. 2 H361, specific effect: Suspected of damaging the unborn child [int. (act.)] Carc. 2 H351 [int. (act.)] Acute Tox. 3 H301 [int. (act.)] STOT Single Exp. 3 H336, affected organs: Nervous system [int. (act.)]	-
238-265-1	N-ethylbenzylamine	<i>Not included in Annex VI</i>	Skin Corr. 1B H314 [int. (act.)]	Eye Damage 1 H318[1 out of 7] Acute Tox. 3 H301[1 out of 7] Skin Corr. 1C H314[1 out of 7] Aquatic Chronic 3 H412[1 out of 7]
238-497-3	N-methylnaphthalene-1-methylamine	<i>Not included in Annex VI</i>	Aquatic Acute 2 H401 [int. (act.)] Aquatic Chronic 2 H411 [int. (act.)] Eye Irrit. 2 H319 [int. (act.)] Acute Tox. 3 H301 [int. (act.)] Eye Irrit. 2A H319 [int. (act.)] STOT Single Exp. 3 H335, affected organs: respiratory tract [int. (act.)] Skin Irrit. 2 H315 [int. (act.)]	Aquatic Chronic 3 H412[1 out of 5] Skin Corr. 1C H314[1 out of 5] STOT Single Exp. 3 H335[1 out of 5] Acute Tox. 4 H302[1 out of 5]
244-734-1	N-(2-aminoethyl)-N'-[2-(benzylamino)ethyl]ethylenediamine	<i>Not included in Annex VI</i>	-	-
244-942-2	1-methyl-3-phenylpropylamine	<i>Not included in Annex VI</i>	Skin Corr. 1 H314 Eye Damage 1 H318 Skin Sens. 1 H317	STOT Single Exp. 3 H335, affected organs: Respiratory tract[1 out of 7] Acute Tox. 3 H311[1 out of 7]

## ASSESSMENT OF REGULATORY NEEDS

			Aquatic Chronic 3 H412 Skin Corr. 1B H314 [int. (act.)]	Skin Corr. 1C H314[1 out of 7] Acute Tox. 4 H302[3 out of 7] Acute Tox. 3 H301[1 out of 7] Skin Corr. 1A H314[1 out of 7]
254-681-6	4-tert-butylbenzylamine	<i>Not included in Annex VI</i>	Eye Damage 1 H318 [int. (act.)] Skin Corr. 1B H314 [int. (act.)] Aquatic Chronic 3 H412 [int. (act.)]	Skin Corr. 1C H314[1 out of 5] Eye Irrit. 2 H319[1 out of 5]
298-036-7	(R)-methyl(α-methylphenethyl)ammonium [R-(R*,R*)]-hydrogen tartrate	<i>Not included in Annex VI</i>	Carc. 2 H351 [int. (act.)] Repr. 2 H361 [int. (act.)] Acute Tox. 3 H301 [int. (act.)]	-
302-174-6	N-benzylphenethylammonium diacetate	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 [int. (act.)] Skin Irrit. 2 H315 [int. (act.)] Eye Irrit. 2 H319 [int. (act.)]	Eye Damage 1 H318[1 out of 1] STOT Single Exp. 3 H335, affected organs: respiratory track[1 out of 1]
436-100-1	(1S)-1-NAPHTHYLETHYLAMINE	<i>Not included in Annex VI</i>	STOT Single Exp. 3 H335, affected organs: Respiratory [int. (act.)] Eye Irrit. 2 H318 [int. (act.)] Acute Tox. 4 H302 [int. (act.)] Skin Irrit. 2 H315 [int. (act.)] Acute Tox. 4 H312 [int. (act.)] Skin Sens. 1A H317 [int. (act.)]	-
443-160-0	1-(4-methylphenyl)ethan-1-amine	<i>Not included in Annex VI</i>	Skin Corr. 1C H314 [int. (act.)] Acute Tox. 3 H331 [int. (act.)] Acute Tox. 4 H302 [int. (act.)] Aquatic Chronic 2 H411 [int. (act.)]	Skin Irrit. 2 H315[1 out of 5] Skin Corr. 1B H314[1 out of 5] Skin Sens. 1 H317[1 out of 5] Eye Damage 1 H318[3 out of 5] STOT Single Exp. 3 H335, affected organs: [1 out of 5] Flam. Liquid 4 H227[1 out of 5]
445-790-1	1,3-Benzenedimethanamine, N-(2-phenylethyl) derivs.	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1A H317 STOT Rep. Exp. 2 H373, affected organs: skeletal muscle, heart, small intestines Aquatic Acute 1 H400 Aquatic Chronic 1 H410	Skin Sens. 1 H317[1 out of 1] Skin Corr. 1A H314[1 out of 1] STOT Rep. Exp. 2 H373[1 out of 1]
455-040-5	Benzenemethanamine, .alpha.-ethyl-, (S)-	<i>Not included in Annex VI</i>	Eye Damage 1 H318 [int. (act.)] Skin Corr. 1A H314 [int. (act.)] Aquatic Chronic 2 H411 [int. (act.)] Aquatic Acute 2 H401 [int. (act.)] Acute Tox. 3 H301 [int. (act.)]	Met. Corr. 1 H290[1 out of 5] Acute Tox. 4 H302[2 out of 5] Skin Corr. 1B H314[4 out of 5] Flam. Liquid 4 H227[1 out of 5]
455-940-8	5,6-diethylindan-2-aminium chloride	<i>Not included in Annex VI</i>	Eye Damage 1 H318 [int. (act.)] Aquatic Chronic 2 H411 [int. (act.)] Skin Sens. 1 H317 [int. (act.)] Acute Tox. 4 H302 [int. (act.)] Aquatic Acute 2 H401 [int. (act.)]	-
600-816-2	(R)-1-(1-Naphthyl)ethylamine (R)-Mandelate	<i>Not included in Annex VI</i>	-	-
600-817-8	(S)-(-)-1-(1-Naphthyl)ethylamine	<i>Not included in Annex VI</i>	-	-

ASSESSMENT OF REGULATORY NEEDS

	(2R,3R)-2,3-dihydroxybutanedioic salt			
608-356-4	Benzenemetanamine, .alpha.-ethyl-	<i>Not included in Annex VI</i>	Acute Tox. 3 H301 [int. (act.)] Aquatic Chronic 2 H411 [int. (act.)] Skin Corr. 1A H314 [int. (act.)] Aquatic Acute 2 H401 [int. (act.)] Eye Irrit. 2 H319 [int. (act.)]	Skin Corr. 1B H314[3 out of 3] Eye Damage 1 H318[1 out of 3] Acute Tox. 4 H302[2 out of 3]
608-414-9	3,3-diphenylpropyl methyl ammonium chloride	<i>Not included in Annex VI</i>	STOT Single Exp. 3 H335, affected organs: High respiratory tract [int. (act.)] Eye Irrit. 2 H319 [int. (act.)]	-
608-544-6	Benzenemetanamine, .alpha.-ethyl-, (.alpha.R)-	<i>Not included in Annex VI</i>	Acute Tox. 3 H301 [int. (act.)] Skin Corr. 1A H314 [int. (act.)] Eye Irrit. 2 H319 [int. (act.)] Aquatic Chronic 2 H411 [int. (act.)] Aquatic Acute 2 H401 [int. (act.)]	Eye Damage 1 H318[1 out of 5] Acute Tox. 4 H302[3 out of 5] Skin Corr. 1B H314[4 out of 5]
609-485-9	(S)-(-)-1-Phenylpropylamine	<i>Not included in Annex VI</i>	-	-
610-076-2	1-Naphthalene methanamine, a-methyl-	<i>Not included in Annex VI</i>	Skin Sens. 1A H317 [int. (act.)] Eye Irrit. 2 H318 [int. (act.)] Skin Irrit. 2 H315 [int. (act.)] Acute Tox. 4 H302 [int. (act.)] Acute Tox. 4 H312 [int. (act.)] STOT Single Exp. 3 H335, affected organs: Respiratory [int. (act.)]	STOT Single Exp. 3 H335, affected organs: RESPIRATORY[1 out of 5] Acute Tox. 3 H301[1 out of 5] Eye Damage 1 H318[1 out of 5] STOT Single Exp. 3 H335, affected organs: [1 out of 5] Skin Corr. 1B H314[1 out of 5] Eye Irrit. 2 H319[3 out of 5] Aquatic Chronic 2 H411[1 out of 5]
613-801-0	N-methyl-1-(1-naphthyl)methanamine hydrochloride (1:1)	<i>Not included in Annex VI</i>	-	STOT Single Exp. 3 H335, affected organs: Respiratory tract[1 out of 9] Eye Irrit. 2 H319[6 out of 9] Eye Irrit. 2A H319[1 out of 9] STOT Single Exp. 3 H335, affected organs: respiratory system[1 out of 9] STOT Single Exp. 3 H335, affected organs: dýchacie orgány, pečeň[1 out of 9] STOT Single Exp. 3 H335, affected organs: Vías respiratorias[1 out of 9] STOT Single Exp. 3 H335, affected organs: [2 out of 9] Skin Irrit. 2 H315[7 out of 9] Repr. 2 H361[1 out of 9]
617-358-4	(1R)-1-Naphthylethylamine Hydrochloride	<i>Not included in Annex VI</i>	Eye Irrit. 2 H319 [int. (act.)] Acute Tox. 4 H302 [int. (act.)] Skin Irrit. 2 H315 [int. (act.)] STOT Single Exp. 3 H335, affected organs: Respiratory [int. (act.)]	Aquatic Acute 1 H400[1 out of 4] STOT Single Exp. 3 H335, affected organs: lungs[1 out of 4] STOT Single Exp. 3 H335, affected organs: [1 out of 4] STOT Single Exp. 3 H335, affected organs: Respiratory system[2 out of 4]
Not (publicly) available	-	<i>Not included in Annex VI</i>	-	-

## ASSESSMENT OF REGULATORY NEEDS

623-635-0	Benzenemet hanamine, .alpha.,4- dimethyl- ,(.alpha.S)-	<i>Not included in Annex VI</i>	Eye Damage 1 H318 [int. (act.)] Acute Tox. 4 H302 [int. (act.)] Skin Corr. 1B H314 [int. (act.)] Skin Sens. 1A H317 [int. (act.)]	Acute Tox. 4 H312[2 out of 5] Acute Tox. 4 H332[2 out of 5] Skin Sens. 1 H317[1 out of 5] Skin Corr. 1C H314[1 out of 5]
624-182-1	Benzenemet hanamine, .alpha.,4- dimethyl- ,(.alpha.R)-	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 [int. (act.)] Skin Sens. 1A H317 [int. (act.)] Eye Damage 1 H318 [int. (act.)] Skin Corr. 1B H314 [int. (act.)]	Skin Corr. 1C H314[1 out of 4] Skin Sens. 1 H317[1 out of 4] Acute Tox. 4 H332[1 out of 4] Acute Tox. 4 H312[1 out of 4]
624-212-3	1-(4- Methylpheny l)ethylamine	<i>Not included in Annex VI</i>	-	-
628-771-4	1- Naphthalena mine, 1,2,3,4- tetrahydro- ,(1R)-	<i>Not included in Annex VI</i>	Skin Corr. 1C H314 [int. (act.)] Aquatic Chronic 3 H412 [int. (act.)] Aquatic Acute 3 H402 [int. (act.)] Acute Tox. 4 H302 [int. (act.)] Eye Damage 1 H318 [int. (act.)]	Aquatic Chronic 2 H411[1 out of 4] Eye Irrit. 2 H319[2 out of 4] STOT Single Exp. 3 H335, affected organs: [1 out of 4] Skin Irrit. 2 H315[2 out of 4]
629-348-7	1- Naphthalena mine, 1,2,3,4- tetrahydro- ,(1S)-	<i>Not included in Annex VI</i>	Aquatic Chronic 3 H412 [int. (act.)] Skin Corr. 1C H314 [int. (act.)] Eye Damage 1 H318 [int. (act.)] Acute Tox. 4 H302 [int. (act.)] Aquatic Acute 3 H402 [int. (act.)]	Eye Irrit. 2 H319[1 out of 7] Aquatic Chronic 2 H411[3 out of 7] Skin Corr. 1B H314[3 out of 7] Skin Irrit. 2 H315[1 out of 7]
700-140-9	(1R,2S)- 2,6- dimethyl- 2,3-dihydro- 1H-inden-1- amine	<i>Not included in Annex VI</i>	Eye Damage 1 H318 [int. (act.)] Acute Tox. 4 H302 [int. (act.)] Aquatic Chronic 3 H412 [int. (act.)] Skin Corr. 1B H314 [int. (act.)] Skin Corr. 1C H314 [int. (act.)]	-
700-575-4	trans-2,6- dimethylind an-1-amine	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 [int. (act.)] Skin Corr. 1B H314 [int. (act.)] Aquatic Chronic 3 H412 [int. (act.)]	-
700-856-1	(2R,5R)- 1,6- Diphenylhex ane-2,5- diamine dihydrochlor ide	<i>Not included in Annex VI</i>	-	-
814-700-6	(1R)cyclohe x-3- enecarboxyli c acid (1S)- 1- phenylethyla mine	<i>Not included in Annex VI</i>	-	-
846-447-2	Reaction products of benzaldehyd e and N-(2- aminoethyl) ethane-1,2- diamine and N,N'-bis(2- aminoethyl) ethane-1,2- diamine, hydrogenate d	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318 Aquatic Chronic 2 H411	-
937-697-4	1-(p- tolyl)ethana mine	<i>Not included in Annex VI</i>	Eye Damage 1 H318 [intermediate (inactive)] Acute Tox. 4 H302 [intermediate (inactive)] Skin Corr. 1B H314 [intermediate (inactive)] Skin Sens. 1A H317 [intermediate (inactive)]	-

## ASSESSMENT OF REGULATORY NEEDS

937-760-6	2,6-dimethylindan-1-amine	<i>Not included in Annex VI</i>	Aquatic Chronic 3 H412 [int. (act.)] Skin Corr. 1B H314 [int. (act.)] Acute Tox. 4 H302 [int. (act.)] Eye Damage 1 H318 [int. (act.)]	-
940-806-8	Reductive amination products of 2,6-dimethylindan-1-one and ammonia and hydrogen	<i>Not included in Annex VI</i>	Eye Damage 1 H318 [int. (act.)] Aquatic Chronic 3 H412 [int. (act.)] Skin Corr. 1B H314 [int. (act.)] Acute Tox. 4 H302 [int. (act.)]	-
942-655-3	Reaction mass of N1-benzylpropane-1,2-diamine and N2-benzylpropane-1,2-diamine	<i>Not included in Annex VI</i>	Acute Tox. 4 H302 Skin Corr. 1C H314 Eye Damage 1 H318 Skin Sens. 1A H317 Aquatic Chronic 2 H411	-

(\*) 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 26 May 2021

Main types of applications structured by product or article types	Subgroup 1					Subgroup 2	Subgroup 3	Subgroup 4		Subgroup 5			
	202-854-1	210-545-8	220-098-0	223-423-4	244-942-2	203-149-1	203-117-7	208-719-3*	216-032-5	445-790-1	223-984-5	846-447-2	942-655-3
PC 32: Polymer preparations and compounds	F,I,P					F,I,(A)			I,(A)		F		I
PC 1: Adhesives, sealants						F,I,A			F,I,P,(A)	I,P,(A)		F,I,P,(A)	F,I,P,(A)
PC 9b: Fillers, putties, plasters, modelling clay									F,I,P,(A)			F,I,P,(A)	
PC 9a: Coatings and paints, thinners, paint removes	I					F,I,A			F,I,P,(A)	F,I,P,(A)		F,I,P,(A)	F,I,P,(A)
PC 21: Laboratory chemicals	I,P	I	I		I	I							
PC 19: Intermediate (synthesis of chemicals e.g. pharmaceuticals)	I	I	I	I	I		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.

\* Justification for not providing use info: "The substance is a monomer within an imported polymer, and hence there is no identified use in the neat form within EU."

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

Data extracted on 12 May 2021

EC/List number	RMOA	Authorisation		Restriction*		CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)		
200-041-6							
200-112-1							
200-574-4							
202-032-2							
202-706-6		Not registered				YES	
202-854-1						YES	
203-117-7							
203-133-4							
203-149-1						YES	
204-522-1							
204-572-4							
205-763-5							
205-850-8							
206-096-2							
208-668-7							
208-719-3							
210-545-8						YES	
216-032-5							
218-712-7							
220-098-0							
222-179-6							
222-882-8							
223-423-4							
223-425-5							
223-984-5							
225-433-4							
226-984-3							
229-007-9							
231-559-0							
238-265-1							
238-497-3							
244-734-1		Not registered					
244-942-2							
254-681-6							
298-036-7							
302-174-6							
436-100-1							
443-160-0							
445-790-1							
455-040-5							
455-940-8							
600-816-2							
600-817-8							
608-356-4							
608-414-9							
608-544-6							
609-485-9		Not registered					
623-635-0							
613-801-0							
617-358-4							

## ASSESSMENT OF REGULATORY NEEDS

EC/List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
Not (publicly) available		Not registered				
623-635-0						
624-182-1						
624-212-3		Not registered				
628-771-4						
629-348-7						
700-140-9						
700-575-4						
700-856-1						
814-700-6						
846-447-2						
937-697-4						
937-760-6						
940-806-8						
942-655-3						

\*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).

