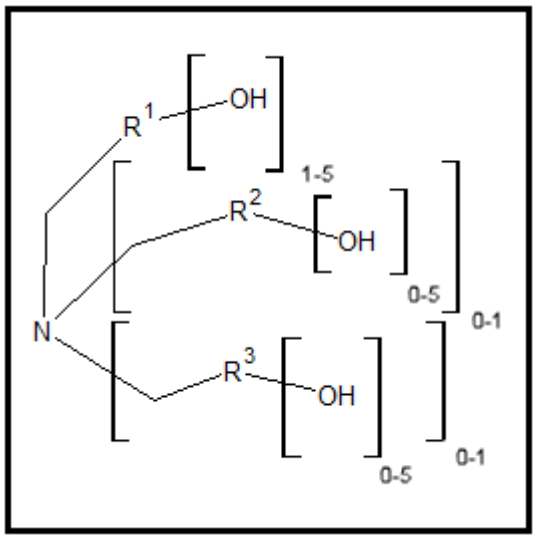
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 16 September 2022

Group Name: Polyol amines

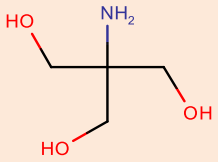
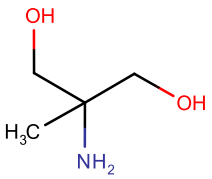
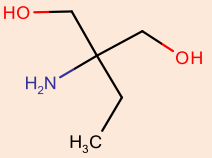
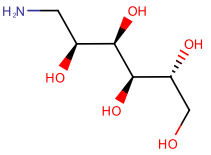
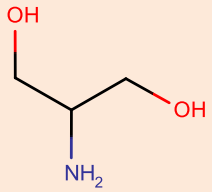
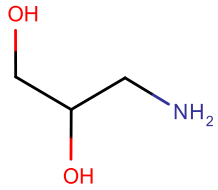
Generic structure:



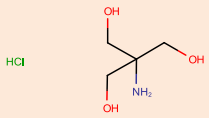
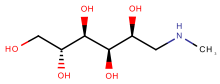
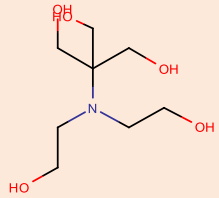
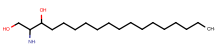
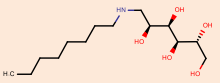
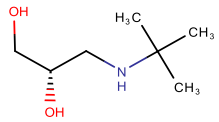
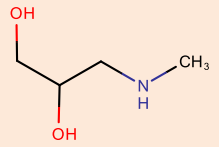
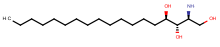
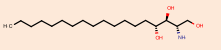
Revision history

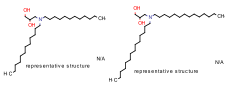
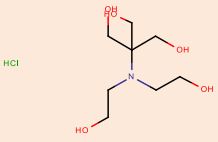
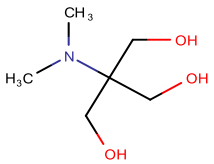
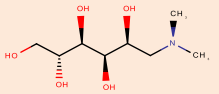
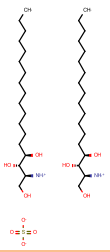
Version	*Date*	*Description*
1.0	24 October 2022	

Substances within this group:

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
201-064-4	77-86-1	Trometamol		Full, >1000
204-100-7	115-69-5	2-amino-2-methylpropane-1,3-diol		Full, not (publicly) available
204-101-2	115-70-8	2-amino-2-ethylpropanediol		Full, not (publicly) available
207-677-3	488-43-7	1-amino-1-deoxy-D-glucitol		OSII or TII
208-584-0	534-03-2	2-aminopropane-1,3-diol		Full, not (publicly) available
210-475-8	616-30-8	3-aminopropane-1,2-diol		OSII or TII

[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 [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
214-684-5	1185-53-1	2-amino-2-(hydroxymethyl) propane-1,3-diol hydrochloride		Full, 10-100
228-506-9	6284-40-8	Meglumine		Full, 10-100
230-237-7	6976-37-0	2-[bis(2-hydroxyethyl)amino]-2-(hydroxymethyl) propane-1,3-diol		Full, 10-100
236-933-7	13552-09-5	2-aminooctadecane-1,3-diol		OSII or TII
245-582-9	23323-37-7	1-deoxy-1-(octylamino)-D-glucitol		OSII or TII
250-125-1	30315-46-9	(S)-3-(tert-butylamino)propane-1,2-diol		OSII or TII
254-809-0	40137-22-2	3-(methylamino)propane-1,2-diol		OSII or TII
439-210-6	554-62-1	(2S,3S,4R)-2-aminooctadecane-1,3,4-triol		Full, not (publicly) available
445-560-0	-	Phytosphingosine HCl		NONS

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
482-000-4	-	3-(dicocoalkylamino)-1,2-propanediol		Full, not (publicly) available
695-696-1	124763-51-5	2-[bis(2-hydroxyethyl)amino]-2-(hydroxymethyl)-1,3-propanediol hydrochloride		Full, not (publicly) available
810-179-4	1112-24-9	1,3-Propanediol, 2-(dimethylamino)-2-(hydroxymethyl)-		OSII or TII
810-394-3	76326-99-3	D-Glucitol, 1-deoxy-1-(dimethylamino)-		Full, not (publicly) available
917-270-9	29790-50-9	1,3,4-Octadecanetriol, 2-amino-, sulfate (2:1) (salt), D-ribo- (8CI)		OSII or TII

This table does not contain group members that are only notified under the CLP Regulation. However, the list is not necessarily exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

Contents

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. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

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

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

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

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

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

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

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

Glossary

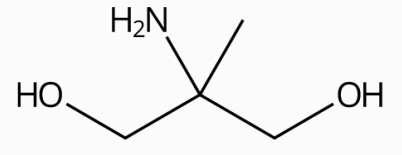
ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
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
UVCB	Substances of Unknown or Variable composition, Complex reaction products or Biological materials

1 Overview of the group

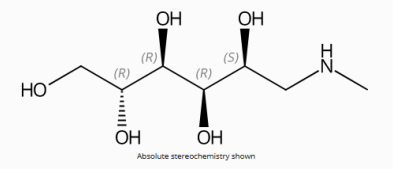
ECHA has grouped together structurally similar substances based on the presence of the multiple hydroxyl groups in the substituents of a monoamine moiety.

Example structures:

Simple polyol amines

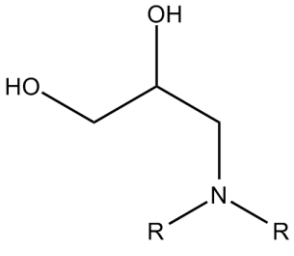


Diol primary amine



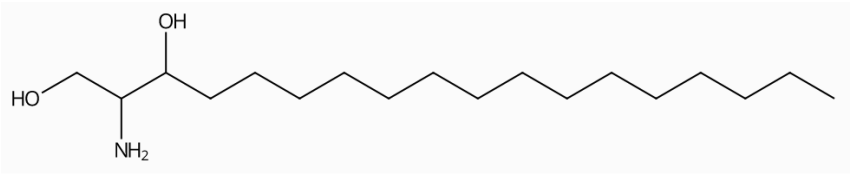
Polyol secondary amine

UVCB



where R=$C_{8\text{-}18(even)}$,$C_{18(unsaturated)}$

Sphingoid base



The group consists of 20 substances of which 11 full registrations, 8 intermediates and 1 NONS.

Most of the substances are well-defined mono-constituent polyol amines and sphingoid bases (19), one is a UVCB substance. Sphingoid bases are backbones of Sphingolipids which are building blocks of biological membranes.

Based on information reported in the REACH registration dossiers, the substances are used both as intermediates in industrial settings and by professionals and consumers in many different applications, e.g. lubricants & greases, perfumes, fragrances, cosmetics, personal care products and pharmaceuticals, , coatings and paints, thinners, paint removes, ink & toners, textile dyes & impregnating products and leather treatment products. Therefore, there is potential for exposure for workers and release to the environment for many of the substances in the group.

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 no need for regulatory risk management action at EU level

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

Based on ECHA's assessment of currently available hazard information, several potential hazards were identified for human health. The available information indicates potential for skin sensitization due to adverse findings with EC 482-000-4. Furthermore, the available information indicates potential for corrosive to the eye/potentially irritating to the eye, due to findings with EC 204-101-2, EC 208-584-0, EC 204-100-7, EC 482-000-4, EC 230-237-7, EC 439-210-6, EC 695-696-1 and EC 228-506-9, which are all substances in this group.

Based on ECHA's assessment of currently available hazard information, no potential CMR or ED hazards were identified for human health. These conclusions are based on overall negative observations stemming from *in vitro* and *in vivo* assays with the group members. The decision on unlikely mutagenicity and carcinogenicity is made with respectively medium (read-across but only few data gaps) and high (conclusion largely based on mutagenicity data) uncertainty. Unlikely ED was concluded with high uncertainty due to low data density and extensive read-across. Of note, there is some similarity with the substances of GMT 115 (n-alkyl diethanolamines), wherein reproductive toxicity is flagged as a potential hazard for human health. The number of reproductive and developmental toxicity studies with substances from GMT 332 is currently limited to screening studies with EC 204-100-7, EC 204-101-2, EC 201-064-4, EC 810-394-3, EC 230-237-7, and a PNDT study with EC 208-584-0. Several adverse effects were observed with EC 208-584-0 (PNDT, abnormal skeletal ossifications at high doses) and EC 810-394-3 (OECD TG 421, increased T4 levels in pups). It was concluded that the observed effects are not sufficiently severe that they would warrant classification. In the study with

EC 230-237-7, an increase in post-implantation loss (substantial and above historical controls) was observed, which is an adverse effect that may warrant repr. 2. However based on the negative outcome of the other group members we conclude overall unlikely repr. for the group, but with a high level of uncertainty (in part due to read-across and existing data gaps). The outcome of the ongoing data generation (PNDT 1st species requested with the registered Substances EC 204-101-2 and EC 201-064-4) may alter the overall conclusion of likelihood of the reproductive/developmental toxicity hazard.

The substance EC 482-000-4 is a UVCB (substance of unknown or variable composition, complex reaction products or biological materials). It is self-classified as Skin Sens 1 and Aquatic Chronic 3, and is also a potential PBT/vPvB. The substance is used by industrial and professional workers as a lubricating agent in lubricants and greases, heat transfer and hydraulic fluids and laboratory chemicals. Therefore, there is potential for exposure for workers and release to the environment. Based on the current registration status of EC 482-000-4, it is not possible to clarify the potential PBT/vPvB hazard of that substance via compliance check (CCH). Generating further information on PBT/vPvB properties via Substance evaluation may also be challenging due to the overall low exposure/release potential of this substance and the consequent potential difficultie in supporting a possible EU wide risk.

The substance EC 439-210-6 (Sphingoin base) has no human health hazards but it is self classified as Aquatic Acute 1 and Aquatic Chronic 1. The substance is used in industrial settings as an intermediate. Also, professional and consumer use in perfumes, fragrances, cosmetics, personal care products and pharmaceuticals have been registered. Therefore, there is potential for exposure for workers and consumers and release to the environment. For industrial and professional uses, sufficient and consistent self-classification by registrants should allow adequate risk management measures to be in place according to workplace legislation to ensure safe use.

For the substances EC 236-933-7, EC 445-560-0 and EC 917-270-9 (Sphingoin bases) there is not data available yet and classifications do not exist. Based on structural similarity with EC 439-210-6 it is concluded that health hazards are unlikely but all of them are potentially toxic for the aquatic environment. EC 236-933-7 and EC 917-270-9 have intermediate registrations (OSII/TII) only so no significant exposure or release is expected for the substances. EC 445-560-0 is used as a cosmetic additive and there is potential for exposure and release to the environment, however, the substance has a low tonnage, claimed NONS (Notified new substances) registration so the overall exposure/release potential is low. Due to intermediate/ low tonnage registrations it is not possible to further clarify the potential hazards of the substances. If the registration status changes, data generation and potentially follow up actions will be re-considered when the assessment will be revisited. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management on the substances EC 482-000-4, EC 439-210-623, EC 236-933-7, EC 445-560-0 and EC 917-270-9.

Based on ECHA's assessment of currently available hazard information, no potential hazards were identified for human health or the environment for the remaining substances. For substances EC 250-125-1, EC 254-809-0, EC 810-179-4, EC 207-677-3 and EC 245-582-9 there is no data available but the same conclusion is reached based on structural similarity.

EC 250-125-1, EC 254-809-0, EC 810-179-4, EC 207-677-3 and EC 245-582-9 have only intermediate registrations (OSII/TII) so no significant exposure or release is expected for the substances.

EC 208-584-0 and EC 210-475-8 are used in industrial settings as intermediate/ precursor in pharmaceutical products so the potential for exposure and release is expected to be low.

EC 204-100-7, EC 204-101-2, EC 201-064-4, EC 214-684-5, EC 695-696-1, EC 230-237-7, EC 810-394-3, EC 228-506-9 have professional and/or consumer use in perfumes, fragrances, cosmetics, personal care products and pharmaceuticals, lubricants & greases, coatings and paints, thinners, paint removes, ink & toners, textile dyes & impregnating products and leather treatment products. Therefore, there is potential for exposure for workers and consumers and release to the environment. Article service life is not reported in registrations, however, the product categories registered (and listed above) indicate that they may occur in articles (coated articles, textile and leather articles, printed articles etc).

Overall, based on current information, there is no or unlikely hazard that would lead to concern for the reported uses and therefore no EU RRM is suggested for the substances 204-100-7, 204-101-2, 201-064-4, 214-684-5, 695-696-1, 230-237-7, 810-394-3, 228-506-9, 208-584-0, 210-475-8, 250-125-1, 254-809-0, 810-179-4, 207-677-3, 245-582-9.

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
482-000-4	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity, PBT/vPvB	Industrial and professional use in lubricants and greases, heat transfer and hydraulic fluids, laboratory chemical, potential for exposure for workers and release to the environemnt	**Currently no need for EU RRM** <u>Justification:</u> For industrial and professional uses, sufficient and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation. and ensure safe use for environment. Based on the current registration status, PBT/vPvB hazard cannot be clarified. Actions (including data generation) will be re-	**No action**

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				considered when the assessment will be revisited if the registration status and/or uses change.	
439-210-6	No hazard or unlikely hazard. As an exception to the other substances in the group, EC 230-237-7 has a known or potential hazard for reproductive toxicity.	Known or potential hazard for aquatic toxicity	Intermediate use in industrial settings. Professional and consumer use in fragrances, cosmetics and pharmaceuticlas. Potential for exposure for workers and consumers and release to the environment.	**Currently no need for EU RRM** <u>Justification:</u> Harmonised/self classification followed by implementation of necessary RRMs should be sufficient to ensure safe use for environment.	**No action**
236-933-7 **445-560-0** **917-270-9**			Intermediate use in industrial settings, low potential for exposure for workers and release to the environment for EC 236-933-7, EC 917-290-9, EC 250-125-1, EC 254-809-0, EC 810-179-4, EC 207-677-3, EC 245-582-9, EC 208-584-0, EC 210-475-8	**Currently no need for EU RRM** <u>Justification:</u> Due to intermediate registration/ NONS low tonnage, no data generation is possible to clarify the hazard currently.	**No action**
204-100-7 **204-101-2**		No hazard or unlikely hazard	Professional and/or consumer use in perfumes& fragrances,	**Currently no need for EU RRM**	**First step:** No action

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
201-064-4 **214-684-5** **695-696-1** **230-237-7** **810-394-3** **228-506-9** **208-584-0** **210-475-8** **250-125-1** **254-809-0** **810-179-4** **207-677-3** **245-582-9**			cosmetics& personal care products and pharmaceuticals, lubricants& greases, coatings& paints, thinners, paint removes, ink& toners, textile dyes& impregnating products, leather treatment products, potential for exposure& release for workers and consumers, potential for exposure & release from articles for EC 204-100-7, EC 204-101-2, EC 201-064-4, EC 214-684-5, EC 695-696-1, EC 230-237-7, EC 810-394-3, EC 228-506-9 EC 445-560-0 is used as cosmetic additive. Potential for exposure for workers and consumers and release to the environment.	<u>Justification:</u> Overall, based on current information, no or unlikely hazard that would lead to concern for the reported uses.	

Annex 1: Overview of classifications

Data extracted on 31/05/2022

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
204-100-7	115-69-5	2-amino-2-methylpropane-1,3-diol (AMPD)	-	Eye Damage 1 H318
208-584-0	534-03-2	2-aminopropane-1,3-diol (ADP)	-	Eye Damage 1 H318
204-101-2	115-70-8	2-amino-2-ethylpropanediol (AEPD)	-	Eye Damage 1 H318
201-064-4	77-86-1	trometamol	-	-
210-475-8	616-30-8	3-aminopropane-1,2-diol	-	Skin Corr. 1C H314 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)]
214-684-5	1185-53-1	2-amino-2-(hydroxymethyl)propane-1,3-diol hydrochloride	-	-
695-696-1	124763-51-5	1,3-dihydroxy-N,N-bis(2-hydroxyethyl)-2-(hydroxymethyl)propan-2-aminium chloride	-	Eye Irrit. 2 H319
230-237-7	6976-37-0	2-[bis(2-hydroxyethyl)amino]-2-(hydroxymethyl)propane-1,3-diol	-	Eye Damage 1 H318
810-394-3	76326-99-3	1-deoxy-1-(dimethylamino)-D-glucitol	-	-
228-506-9	6284-40-8	meglumine	-	-
250-125-1	30315-46-9	(S)-3-(tert-butylamino)propane-1,2-diol	-	-
254-809-0	40137-22-2	3-(methylamino)propane-1,2-diol	-	Skin Corr. 1C H314 [intermediate (active)]
810-179-4	1112-24-9	2-(dimethylamino)-2-(hydroxymethyl)propane-1,3-diol	-	Eye Irrit. 2A H319 [intermediate (active)]
207-677-3	488-43-7	1-amino-1-deoxy-D-glucitol	-	Eye Irrit. 2 H319 [intermediate (active)]
245-582-9	23323-37-7	1-deoxy-1-(octylamino)-D-glucitol	-	-

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
439-210-6	554-62-1	(2S,3S,4R)-2-aminooctadecane-1,3,4-triol	-	Eye Damage 1 H318 Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410, M-factor: 10.00 Aquatic Chronic 1 H410
236-933-7	13552-09-5	2-aminooctadecane-1,3-diol	-	Eye Irrit. 2 H319 [intermediate (active)]
445-560-0	-	445-560-0	-	-
917-270-9	29790-50-9	bis[(2S,3S,4R)-1,3,4-trihydroxyoctadecan-2-aminium] sulfate	-	Eye Irrit. 2 H319 [intermediate (active)]
482-000-4	897393-64-5	3-(dicocoalkylamino)-1,2-propanediol	-	Skin Sens. 1 H317 Aquatic Chronic 3 H412

(*) 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 31 May 2022.

EC number	201-064-4	204-100-7	204-101-2	207-677-3	208-584-0	210-475-8	214-684-5	228-506-9	230-237-7	236-933-7	245-582-9	250-125-1	254-809-0	439-210-6	482-000-4	695-696-1	810-179-4	810-394-3	917-270-9
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	F, I, **P**, **C**						F, I, **P**	I, **P**	F, I, **P**							I, **P**			
PC 28: Perfumes, fragrances	F, **C**	F, **C**												F, **P**, **C**					
PC 39: Cosmetics, personal care products	F, I, **P**, **C**	F, **C**						F, I						F, **P**, **C**				F, **C**	
PC 29: Pharmaceuticals	F, I					I		F, I	F, I, **P**	I		I	I	F, **C**					
PC 31: Polishes and wax blends	**C**		**C**																
PC 24: Lubricants, greases, release products	**C**		I, **P**, **C**												I, **P**				

EC number	201-064-4	204-100-7	204-101-2	207-677-3	208-584-0	210-475-8	214-684-5	228-506-9	230-237-7	236-933-7	245-582-9	250-125-1	254-809-0	439-210-6	482-000-4	695-696-1	810-179-4	810-394-3	917-270-9
PC 25: Metal working fluids			I, **P**												I				
PC 16: Heat transfer fluids															I, **P**				
PC 17: Hydraulic fluids															I, **P**				
PC 32: Polymer preparations and compounds	F, I								F										
PC 1: Adhesives, sealants	**C**		**C**																
PC 9c: Finger paint			**C**																
PC 9b: Fillers, putties, plasters, modelling clay	**C**		**C**					I											
PC 9a: Coatings and paints, thinners, paint removes	F, I, **P**, **C**		I, **P**, **C**					F, I										F, I, **P**, **C**	
PC 18: Ink and toners	**C**		**C**																

EC number	201-064-4	204-100-7	204-101-2	207-677-3	208-584-0	210-475-8	214-684-5	228-506-9	230-237-7	236-933-7	245-582-9	250-125-1	254-809-0	439-210-6	482-000-4	695-696-1	810-179-4	810-394-3	917-270-9
PC 34: Textile dyes, and impregnating products	**C**		**C**																
PC 23: Leather treatment products	**C**		**C**																
PC 21: Laboratory chemicals	F, I, **P**, **C**						F, I, **P**	F, I, **P**	F, I, **P**	I					I	F, I, **P**			
PC 19: Intermediate	F, I		I	I	I	I		I		I	I	I	I	I					I
PC 40: Extraction agents	F, I																		
PC 30: Photo-chemicals	F, I																		
PC x1: Food and feed additives	F																		

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

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

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