Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

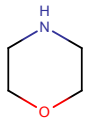
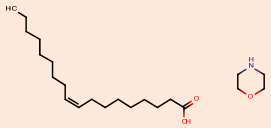
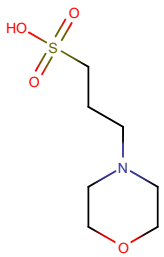
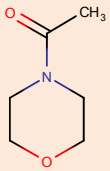
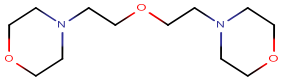
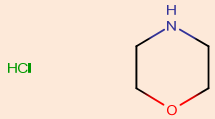
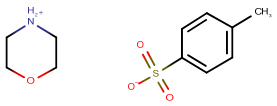
Group Name: Morpholine derivatives

General structure: -

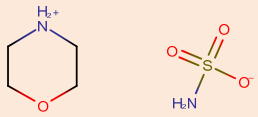
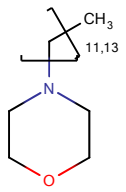
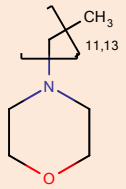
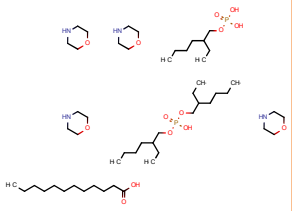
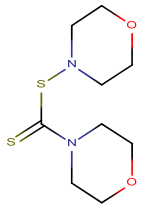
Revision history

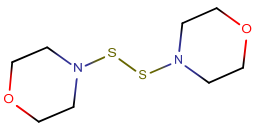
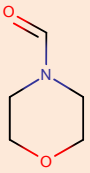
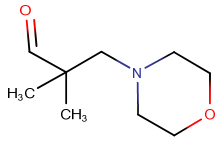
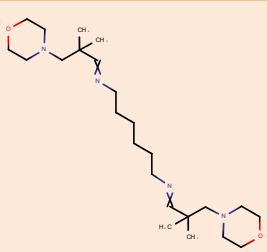
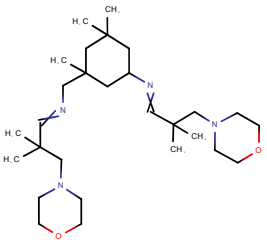
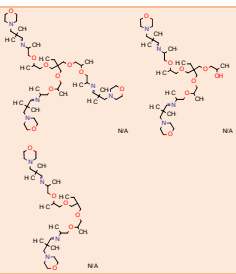
Version	*Date*	*Description*
1.0	5 August 2024	

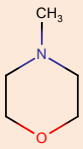
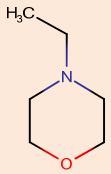
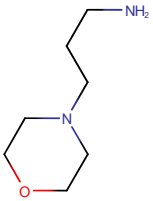
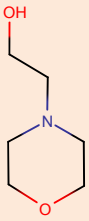
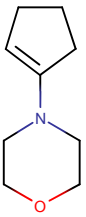
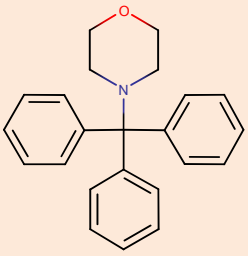
Substances within this group:

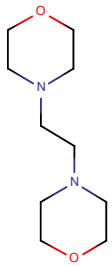
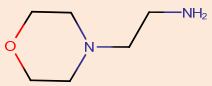
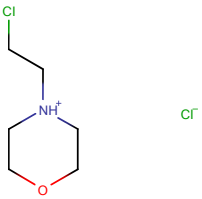
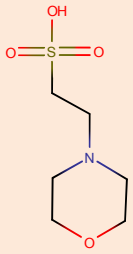
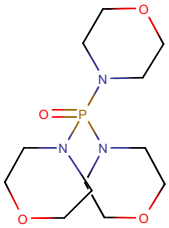
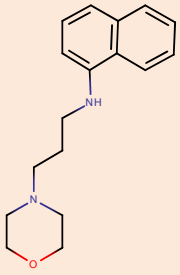
EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
Subgroup A				
203-815-1	110-91-8	Morpholine		Full, >1000
214-139-1	1095-66-5	Oleic acid, compound with morpholine (1:1)		C&L notification
214-478-5	1132-61-2	4-morpholinopropane sulphonic acid		Full, 10-100
216-913-4	1696-20-4	4-acetylmorpholine		Full, not (publicly) available
229-194-7	6425-39-4	2,2'-dimorpholinyldiethyl ether		Full, >1000
233-029-4	10024-89-2	Morpholine hydrochloride		C&L notification
237-301-3	13732-62-2	Morpholinium toluene-4-sulphonate		Full, 100-1000

[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 no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
258-061-6	52636-67-6	Morpholinium sulphamate		Full, not (publicly) available
276-986-3	72906-09-3	Morpholine, 4-coco alkyl derivs.		C&L notification
800-906-3	1402434-48-3	Morpholine, 4-C12-14-alkyl derivs.		Full, not (publicly) available
915-372-8	-	Reaction mass of lauric acid, compound with morpholine (1:1) and 2-ethylhexyl dihydrogen phosphate, compound with morpholine (1:2) and bis(2-ethylhexyl) hydrogen phosphate, compound with morpholine (1:1)		Full, not (publicly) available
Subgroup B				
237-335-9	13752-51-7	4-[(morpholinothio)thioxomethyl]morpholine		Full, not (publicly) available
Subgroup C				

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
203-103-0	103-34-4	Di(morpholin-4-yl) disulphide		Full, not (publicly) available
224-518-3	4394-85-8	4-morpholinecarbaldehyde		Full, not (publicly) available
700-569-1	23588-51-4	4-Morpholinepropanal, .alpha.,.alpha.-dimethyl-		Full, not (publicly) available
700-570-7	1217271-49-2	1,6-Hexanediamine, N1,N6-bis[2,2-dimethyl-3-(4-morpholinyl)propylidene]-		Full, not (publicly) available
700-584-3	1217271-02-7	N-[3-({[2,2-dimethyl-3-(morpholin-4-yl)propylidene]amino}methyl)-3,5,5-trimethylcyclohexyl]-2,2-dimethyl-3-(morpholin-4-yl)propan-1-imine		Full, not (publicly) available
700-879-7	1379822-00-0	Reaction product of propylidynetrimethanol, propoxylated, reaction products with ammonia and 2,2-Dimethyl-3-(4-morpholinyl)propanal		Full, not (publicly) available
Subgroup D				

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
203-640-0	109-02-4	4-methylmorpholine		Full, 10-100
Subgroup E				
202-885-0	100-74-3	4-ethylmorpholine		Full, not (publicly) available
204-590-2	123-00-2	3-morpholinopropylamine		Full, 1-10
210-734-5	622-40-2	2-morpholinoethanol		Full, not (publicly) available
213-316-0	936-52-7	N-(cyclopent-1-en-1-yl)morpholine		OSII or TII
215-812-2	1420-06-0	Trifenmorph		C&L notification

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
217-026-5	1723-94-0	4,4'-(ethane-1,2-diyl)bismorpholine		C&L notification
218-011-6	2038-03-1	2-morpholinoethylamine		OSII or TII
222-881-2	3647-69-6	4-(2-chloroethyl)morpholinium chloride		OSII or TII
224-632-3	4432-31-9	2-morpholinoethanesulphonic acid		Full, 10-100
224-662-7	4441-12-7	Trimorpholinophosphine oxide		Full, not (publicly) available
226-033-2	5235-82-5	4-[3-(1-naphthylamino)propyl]morpholine		Full, 10-100

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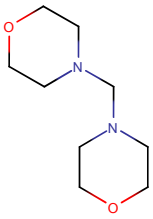
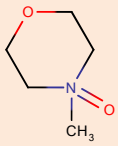
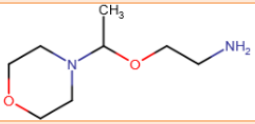
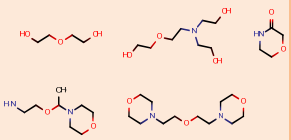
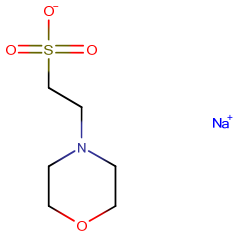
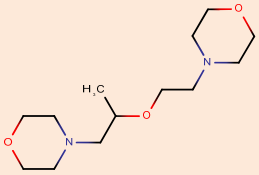
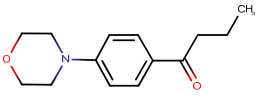
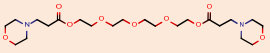
227-062-3	5625-90-1	N,N'-methylenebismorpholine		C&L notification
231-391-8	7529-22-8	4-methylmorpholine 4-oxide, monohydrate		Full, not (publicly) available
243-595-4	20207-13-0	4-[(2-aminoethoxy)ethyl]morpholine		C&L notification
272-712-1	68909-77-3	Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine derivs. residues		Full, not (publicly) available
275-203-2	71119-23-8	Sodium 4-morpholin-1-ylethylsulphonate		Full, not (publicly) available
407-940-4	111681-72-2	4-[2-(1-methyl-2-(4-morpholinyl)ethoxy)ethyl]morpholine		NONS
413-790-0	-	1-(4-morpholinophenyl)butan-1-one		NONS
414-560-2	-	MORPHOLINE ADDUCT		NONS

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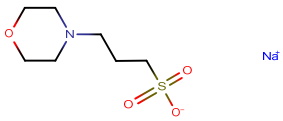
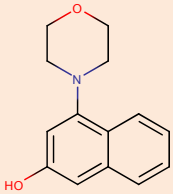
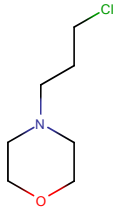
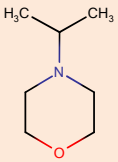
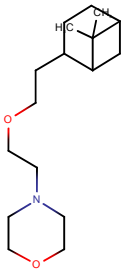
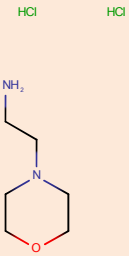
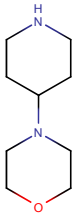
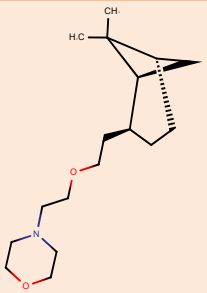
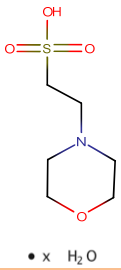
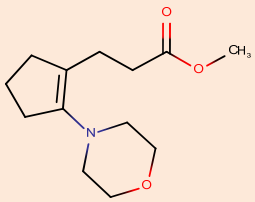
428-420-3	71119-22-7	Sodium 3-morpholin-4-ylpropane-1-sulfonate		Full, 1-10
435-700-9	-	4-MORPHOLINO-2-NAPHTHOL		NONS
461-510-0	7357-67-7	4-(3-chloropropyl)morpholine		NONS
469-290-8	-	[No public or meaningful name is available]		NONS
609-541-2	38284-47-8	2-((6,6-diméthylbicyclo[3.1.1]hept-2-yl)éthoxy)éthyl morpholine		OSII or TII
611-095-9	5409-41-6	4-Morpholineethanamine, hydrochloride (1:2)		OSII or TII

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
627-580-3	53617-35-9	4-(piperidin-4-yl)morpholine		Full, not (publicly) available
700-519-9	-	(cis)-4-[2-[2-((1S,2S,5S)-6,6-dimethylnorpinan-2-yl)ethoxy]ethyl]morpholine		OSII or TII
838-777-0	1266615-59-1	2-(N-Morpholino)ethane sulfonic acid hydrate		C&L notification
949-350-4	-	methyl 3-(2-morpholinocyclopenten-1-yl)propanoate		OSII or TII

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

Contents

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Foreword

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

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

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

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

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

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

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

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

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

[3] Regarding hazard properties the focus is for instance on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).

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

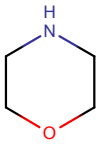
Glossary

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

1 Overview of the group

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

ECHA has grouped together structurally similar substances based on the presence of the morpholine moiety shown in the figure below:



The group contains 48 substances (43 mono-constituents, 4 UVCB, 1 multi-constituent). Within these, 29 substances are fully registered, 7 substances are registered as intermediates, 4 substances are NONS and 8 substances have C&L notifications. The different morpholine derivatives are all substituted at the nitrogen atom, and include e.g. morpholine salts, ethers, alkanes, alkylamines, aldehydes and its imines, amides, alkanesulfonates, thioethers.

Initial considerations for subgrouping substances in this group were based on structural similarity. Although this type of subgrouping seems relevant to environmental hazards, it was not possible to systematically relate specific structural features to different toxicological properties for human health. Reasons for the heterogeneity of toxicity profiles remain unclear but could be due to differences in metabolism and variable hydrolysis into morpholine or other metabolites with toxicological properties, or to the presence of specific impurities. Therefore, the below subgroups are rather based on proposals for further actions and regulatory risk management.

Based on information reported in the REACH registration dossiers, the substances in this group have a diverse pattern of use, which can be explained by the heterogeneity of this group. Around half of the registered substances has widespread uses where high exposure to workers and consumers, and releases to the environment can be expected, e.g. in polymer preparations and compounds, adhesives/sealants, filler/putties, paints/coatings. The other half of the substances in the group is mostly used as intermediate, and substitution potential cannot be excluded with other substances that are structurally similar to morpholine derivatives.

The substances are used in the above applications as process regulator, intermediate, monomer, processing aid, and hardener.

There are relevant completed or ongoing regulatory risk management activities for some of the substances in the group. For EC 203-815-1 there is a RMOA intention from Germany for CMR concern, and EC 227-062-3 is currently not registered, but has a CLP Annex VI entry as skin sensitiser 1, STOT RE 2, mutagenic 2 and carcinogenic 1B, and it is approved as active substance under BPR.

2 Conclusions and actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g., strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g., on hazards through evaluation processes, or on uses) will become available, the document may be updated, and conclusions and actions revisited.

Table: Conclusions and proposed actions

Subgroup name, EC no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
Subgroup A 203-815-1 (morpholine) [1)] 214-139-1 *** 214-478-5 216-913-4 * 229-194-7 233-029-4 *** 237-301-3 * 258-061-6 * 276-986-3 *** 800-906-3 915-372-8 *	Known or potential hazard for reproductive toxicity for skin sensitisation (only 216-913-4)	Known or potential hazard for aquatic toxicity for 800-906-3, 915-372-8	Industrial uses; professional and/or consumer uses in e.g. cleaning products, biocides, cosmetics, lubricants, paints, adhesives, paper and surface treatment, laboratory chemicals with (high) exposure potential to workers, consumers and to the environment. Potential article service life (237-301-3 and 258-061-6)	**First step:** CCH (except for 203-815-1, 214-139-1, 233-029-4, 237-301-3, 258-061-6, 276-986-3, and 915-372-8) **Potential next steps (if hazard confirmed after data generation):** CLH <u>Justification:</u> The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce

Subgroup name, EC no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
			EC 800-906-3: no info	controls at the level of placing on the market rather than at the level of uses. Industrial uses to be potentially addressed with a restriction (e.g. with limit value) – except for EC 203-815-1 (existing OEL). The harmonised classification as CMR 1 B would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the relevant concentration limits. Potential exposure from articles due to function of the substance needs further investigation (ECs 237-301-3 and 258-061-6 only).
Subgroup B 237-335-9	Known or potential hazard for carcinogenicity for mutagenicity	Known or potential hazard for aquatic toxicity	Industrial uses with exposure potential to workers; possible article service life in general rubber articles and tyres with exposure potential to consumers and to the environment	**First step:** CCH **Potential next steps (if hazard confirmed):** CLH <u>Justification:</u> Industrial uses cannot ensure containment.
Subgroup C 203-103-0 224-518-3	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity	Industrial uses and/or professional and/or consumer uses in eg.	**First step:** CLH

Subgroup name, EC no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
700-569-1 700-570-7 * 700-584-3 * 700-879-7 *		(except for 224-518-3, 700-569-1)	adhesives, paints, paper/board and leather treatment products and polymer preparations with high exposure potential to workers, consumers and to the environment. Potential article service life (List 700-570-7 and 700-879-7).	**Potential next steps (if hazard confirmed):** No action Justification: Harmonised classification followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace and for leather articles' manufacturers to consider. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation.
Subgroup D 203-640-0	Known or potential hazard for carcinogenicity	No hazard or unlikely hazard	Industrial uses; professional uses in adhesives, coatings & paints and polymer preparations, with high exposure potential to workers. Possible article service life with exposure potential to consumers and to the environment	**First step:** No action **Potential next steps (if hazard confirmed):** No action Justification: Correct self-classification to be discussed during CCH. Hazard is due to presence of impurity, volumes are low and there are alternative suppliers.
Subgroup E 202-885-0 204-590-2 210-734-5	Known or potential hazard for reproductive toxicity (213-316-0,	Known or potential hazard for aquatic toxicity ,	Mostly used as intermediates or intermediate registrations, few professional uses in	**First step:** No action **Potential next steps (if hazard confirmed):**

Subgroup name, EC no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
213-316-0 #, ** 215-812-2 *** 217-026-5 *** 218-011-6 ** 222-881-2 ** 224-632-3 224-662-7 226-033-2 1) 227-062-3 *** 231-391-8 1) 243-595-4 *** 272-712-1 1) 275-203-2 407-940-4 413-790-0 414-560-2 428-420-3 435-700-9 461-510-0 469-290-8 609-541-2 ** 611-095-9 627-580-3 700-519-9 ** 838-777-0 *** 949-350-4 #	231-391-8, 949-350-4) for mutagenicity (226-033-2, 461-510-0) for STOT RE (213-316-0, 461-510-0) for skin sensitisation (210-734-5, 222-881-2, 226-033-2, 461-510-0, 469-290-8, 627-580-3, 949-350-4) No hazard or unlikely hazard (202-885-0, 204-590-2, 218-011-6, 224-632-3, 224-662-7, 272-712-1, 275-203-2, 428-420-3, 609-541-2, 611-095-9, 700-519-9)	for 226-033-2, 272-712-1, 469-290-8, 627-580-3	laboratory chemicals or products such as pH regulators with no or low exposure potential to workers. ECs 202-885-0, 224-632-3, 226-033-2: Industrial uses; professional and/or consumer uses in product categories with high exposure potential to workers and consumers and to the environment (eg. adhesives, lubricants, polishes, fuels, polymer preparations)	No action <u>Justification:</u> No or unlikely hazard that would lead to concern for the reported uses, or, harmonised/self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use by workers at industrial settings or, low exposure potential or, the concern related to the presence of skin sensitisers in professional mixtures is under investigation. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change

* potential for substitution; ** Intermediate registrations; *** CnL notified substances; # Hazard classification due to an impurity

1) CCH / FUP ongoing

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

Based on currently available information, the suggested regulatory management action is Restriction for reproductive toxicity, due to the potential for release / exposure of morpholine, its salts and EC 216-913-4 (subgroup A). Aquatic toxicity hazard was also identified as potential additional hazard for some of the substances.

Morpholine, EC 203-815-1, is a suspected reproductive toxicant currently self-classified as Repr. 2 for fertility and developmental effects, but a follow-up of a CCH is ongoing, with the potential for classification as Repr. 1B. The substance is used in several applications, such as cleaning and disinfecting products, cosmetics, lubricants, adhesives and paints, with either professional and/or consumer uses, with high exposure potential for workers, consumers and the environment. Should hazards be confirmed, then also the morpholine salts may warrant classification as Repr. 1B, assuming that they will dissociate into morpholine.

EC 216-913-4 is also part of this group because it is self-classified as Repr. 2 but, from the data available, a Repr. 1B classification could be warranted. Despite not having widespread uses registered, it could potentially substitute EC 224-518-3 (from subgroup C and with widespread uses) as both substances are morpholinamides and have very similar chemical structures and technical functions.

Additionally, three substances (ECs 214-478-5, 229-194-7 and List 800-906-3) are included in this subgroup to check read across validity and decide if regulatory measures are justified for them as well. EC 276-986-3 is a C&L notified substance which, from the chemical structure can be the same substance as List 800-906-3 and was therefore also added to this group.

List 800-906-3, 915-372-8 have been identified as having aquatic toxicity hazard based on available short-term toxicity studies on these substances.

For all substances in this subgroup (except morpholine and its salts, i.e. ECs 203-815-1, 214-139-1, 233-029-4, 237-301-3, 258-061-6 and List 915-372-8), CCH is proposed as a first step to generate further data and clarify concerns for reproductive toxicity.

To address the reproductive toxicity concern, the first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Repr. 1B. In the specific case of morpholine and its salts, a CLH group entry could be considered. CLH:

i) will require company level risk management measures (RMM) under the occupational safety and health (OSH) legislation for workers, to be in place,
ii) is needed or highly recommended for further regulatory processes under REACH and
iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 30
iv) is also a prerequisite to restrict the presence of the substances in clothing, other textiles, and footwear articles, by means of the restriction entry 72 of REACH Annex XVII (this would require addition of the relevant substances to Appendix 12 by the Commission through Article 68(2)). For EC 216-913-4 the

potential for substitution with EC 224-518-3, which is used in leather, cannot be excluded.

CLH will also support regulatory action under other regulations. For instance, in the specific case of morpholine, harmonised classification as Repr. 1B will trigger further restrictions under:

- the Cosmetic products regulation (EC) No 1223/2009;
- the Biocidal product regulation (EU) 528/2012.

The professional uses in lubricants, cleaning products, paints, coatings, adhesives and paper and surface treatment products are expected to be widespread (at many sites and by many users). Professional use is often widespread with relatively low levels of operational controls and risk management measures, but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by OSH legislation.

Consumers may be co-exposed to the substances used by professionals, e.g. house painters, construction workers.

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

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

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[5] which aims to extend to professional users under REACH the level of protection granted to consumers.

For the industrial uses, there is an OEL for EC 203-815-1 (morpholine), but, for the other substances, even if it can be expected that any restriction in the use of the substances by consumers and professionals will have an impact upstream, it could be considered to create a restriction with a limit value (either an OEL or a DNEL) as some of the process conditions reported in the Chemical Safety Reports (e.g. transfer of substance/mixture, spraying, treatment of articles by dipping and pouring) give opportunity for exposure of the workers.

To note that article service life cannot be excluded for EC 237-301-3 and 258-061-6, both used in polymer preparations. In any case, further investigation would be needed before proposing additional regulatory actions and the actions recommended to address the concerns from other life cycle stages could also impact the use in articles.

Based on currently available information, the suggested regulatory risk management action is CLH for carcinogenicity, due to the potential for release / exposure of EC 237-335-9 (subgroup B). Aquatic toxicity hazard has also been identified for this substance.

EC 237-335-9 is a thiomorpholine which is self-classified as Carc. 1B. For this substance, CCH is proposed to generate further data on mutagenicity, aquatic

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

toxicity and persistency potential. This substance has a very specific use, in polymer preparations and compounds. In the registration dossier no uses other than the industrial ones are reported, but article service life cannot be excluded because, despite the statement of the registrant that the substance will react and will no longer be present as such, there is no detailed information in the Chemical Safety Report about e.g. chemistry, reaction rates and concentrations. Even if the substance is already self-classified and this is enough to trigger OSH measures in case of carcinogenicity, the Operational Conditions and RMMs described by the registrant (e.g. no containment ensured) aren't sufficient to prevent exposure of workers. For that reason, CLH is proposed because this hazard is a priority for harmonised classification and this would allow for it to be enforced.

Following data generation, industry should update their registration dossiers and this may also include new RMMs to be put in place. If the RMMs will not be seen as sufficient to prevent exposure of workers, those uses will be considered for further regulatory risk management.

This substance has also been identified as having aquatic toxicity hazard based on available short-term toxicity studies.

Based on currently available information, the suggested regulatory risk management is CLH for skin sensitisation due to the potential for release / exposure of all the substances in subgroup C.

Subgroup C was built around some substances with a known hazard for skin sensitisation. For this subgroup, CLH can be proposed as first action because the available data support the already existing self-classifications as skin sensitisers 1(B).

Two substances in the group, EC/List 224-518-3 and 700-569-1, are used in leather treatment products and it cannot be excluded that some residues of the substance will be present in the leather articles. CLH for skin sensitisation seems adequate for the article manufacturer to take this aspect into consideration and for the substances to be considered under the restriction for skin sensitisers in textiles in leather, under discussion. For the other substances of the group, self-classification could be enough to address the risks from the reported industrial, professional and consumer uses, but as the potential for substitution in leather treatment products cannot be excluded, it is proposed to consider them for CLH too.

To note that article service life cannot be excluded for EC 203-103-0 (in rubber articles) and Lists 700-570-7 and 700-879-7, both used in polymer preparations. In any case, skin sensitisation in articles other than textiles and leather is not considered for further regulatory action and skin contact with rubber articles is often too infrequent to lead to a concern.

For EC/List 203-103-0, 700-570-7, 700-584-3, 700-879-7, aquatic toxicity has also been identified as an additional hazard, based on available short-term aquatic toxicity studies available on these substances.

Based on currently available information, currently no need to suggest (further) EU regulatory risk management for carcinogenicity, mutagenicity, reproductive toxicity, skin sensitiser, STOT RE, PBT/vPvB, aquatic toxicity hazards of all the substances in subgroup D and E.

Subgroup D

EC 203-640-0 is a particular case because, for two of the member registrations, formaldehyde (harmonised classification carc 1B) is declared as an impurity, but no self-classification is applied. It is believed that the hazard is only due to the presence of the impurity.

According to data from the registration dossiers of those two members, the substance is imported and only used in the formulation of mixtures. These mixtures, e.g. coatings and polymer preparations, can be included in articles and it cannot be excluded that unreacted residues may still be present. Nevertheless, in addition to only formulation being declared, the volumes are low (below 10 t/y) and the concentration of the impurity in the mixture is expected to be low (not more than 1%). Also, there are alternative suppliers without the formaldehyde as an impurity – the other registrants.

Based on the above, it is proposed that, via CCH, it is ensured that the correct self-classification is applied by the two co-registrants, as this would allow for the adequate OSH provisions to apply.

To be noted that, should the substance be present in articles and be a formaldehyde releaser, it could be considered under the upcoming restriction for articles with formaldehyde releasers.

EC 203-640-0 is unlikely to have aquatic toxicity based on existing short and long-term aquatic toxicity data.

Subgroup E

Some substances in this subgroup have either no or unlikely hazards. For other substances, potential hazards (skin sensitisation, reproductive toxicity, mutagenicity, STO RE, aquatic chronic) have been identified, but no further EU RRM is needed due to one or a combination of several factors, e.g: other measures already in place (e.g. self-classification leading to necessary RRMs, ongoing actions), tonnage, intermediate use, no substitution potential envisaged based on the chemical structure.

EC 227-062-3 is an approved active substance in biocides (approval end date: 31/03/2022) which releases formaldehyde and morpholine. There is a CLP Annex VI entry for this substance as skin sensitiser 1, STOT RE 2, mutagenic 2 and carcinogenic 1B – these classifications being linked to formaldehyde. As this substance is not registered and, from the chemical structure, no substitution potential with other substances in the group could be envisaged, no further action is proposed as it is believed that CLH and actions required under BPR sufficiently address concerns that may be caused by this substance in uses in biocidal products. In particular, the harmonised classification as Carc. 1B:

- requires that the necessary safety measures are in place for specific sensitive workers, i.e. pregnant women in accordance with Directive 92/85/EEC and young people in accordance with Directive 94/33/EC;
- triggers regulatory action under the biocidal product regulation (EU) 528/2012, which does not allow the use by the general public of a product containing substances above the concentration limit leading to classification of the mixture as CMR cat 1.

In case registrations under REACH will be submitted for this substance, reporting further uses not covered by BPR, the assessment will be revisited considering among others potential endocrine disrupting properties.

The strategy may need to be revisited and further regulatory action reconsidered if there is a change in the registration status or reported uses for any of these substances, or when the discussions on the possible regulatory actions for skin sensitisers in consumer and professional mixtures are concluded.

Remaining uncertainties

As described above, several substances in the group are hazardous. However, no clear toxicity pattern could be identified for human health hazards. Therefore, further investigation is needed to determine the different mechanisms of toxicity and confirm to which extent structural similarity can be assumed across the group or whether the different read-across approaches used by registrants are valid.

Besides, it should be noted that there is some uncertainty regarding the exact carcinogenicity potential of the substances in the group. Only one substance in the group (EC 237-335-9) was found to be carcinogenic. Although the majority of substances as such seem not to have any carcinogenic potential, the formation of carcinogenic nitrosamines cannot be excluded. Of note, the German CA prepared in 2010 a RMOA analysis of the most appropriate risk management option for preventing nitrosamine formation especially in cooling lubricants or anticorrosion agents by restricting the use of certain precursor substances, including morpholine and other secondary amines. Therefore, a concern for carcinogenicity is provisionally identified in relation to the use of each substance in the group and potential presence of nitrosating agents that can result in the formation of carcinogenic nitrosamines. The potential of all the substances in the group to react with nitrosating agents and to form potential carcinogenic nitrosamines has not been explored further in terms of actions. A common approach needs to be developed regarding substances with a potential to form nitrosamines as part of co-exposure with nitrosating agents, and the subsequent regulatory measures where relevant. This is a more generic topic that is of relevance also for other groups of substances.

In addition to uncertainty related to human health hazards, there is also uncertainty remaining related to the environmental hazards for many of the substances. This is because most of the substances of the group are unstable (i.e., hydrolytically unstable or dissociating at environmentally relevant pH) and hazard property information on the resulting transformation products is currently not available.

It is also relevant to note that ECs 214-478-5 – one of the substances included in subgroup A for read across validity confirmation – is part of a group of N-morpholinoalkanesulfonates which are all very similar from a structural point of view. Also, all substances have a similar use profile. Nevertheless, the other substances (ECs 224-632-3, 275-203-2 and List 428-420-3, as well as the C&L notified List 838-777-0) were not considered under subgroup A because, even if the available data is limited, there are no indications (e.g. toxicokinetic data) about the release of morpholine. The available OECD TG 422 with substance EC 224-632-3 did not show any reproductive or developmental effects. The other substances are registered at lower tonnages and not much data could be requested under CCH that would clarify about a potential reproductive or developmental hazard.

Annex 1: Overview of classifications

Data extracted on 20.01.2022

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations
202-885-0	100-74-3	4-ethylmorpholine	-	Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314 Eye Damage 1 H318
203-103-0	103-34-4	di(morpholin-4-yl) disulphide = 4,4'-Dithiodimorpholine	-	Skin Sens. 1A H317 STOT Single Exp. 3 H335, affected organs: Respiratory tract Aquatic Acute 2 H401 Aquatic Chronic 2 H411
203-640-0	109-02-4	4-methylmorpholine	-	Flam. Liquid 2 H225 Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318
203-815-1	110-91-8	morpholine	Flam. Liq. 3 H226 Acute Tox. 4 H302 Skin Corr. 1B H314 Acute Tox. 4 H332 Acute Tox. 4 H312	Repr. 2 H361 [intermediate (active)] Repr. 2 H361, specific effect:fertility and development Acute Tox. 3 H311 Acute Tox. 3 H331 Eye Damage 1 H318
204-590-2	123-00-2	3-morpholinopropylamine	-	Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318
210-734-5	622-40-2	2-morpholinoethanol	-	Eye Damage 1 H318 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] Acute Tox. 4 H332 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: Respiratory System [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Acute Tox. 4 H312 [intermediate (active)] Eye Irrit. 2 H319
213-316-0	936-52-7	N-(cyclopent-1-en-1-yl)morpholine	-	STOT Single Exp. 3 H335, affected organs: respiratory system [intermediate (active)] Asp. Tox. 1 H304 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] Repr. 2 H361, specific effect:H361d: Suspected of damaging the unborn child [intermediate (active)] Flam. Liquid 3 H226 [intermediate (active)] Skin Corr. 1A H314 [intermediate (active)] STOT Rep. Exp. 2 H373, affected

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations
				organs: Neurologic: other (neuropsychological effects, auditory dysfunction and effects on colour vision) [intermediate (active)]
214-139-1	1095-66-5	oleic acid, compound with morpholine (1:1)		
214-478-5	1132-61-2	4-morpholinopropanesulphonic acid	-	-
215-812-2	1420-06-0	trifenmorph / 4-tritylmorpholine	Acute Tox. 4 H302 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	
216-913-4	1696-20-4	4-acetylmorpholine	-	Repr. 2 H361, specific effect:Suspected of damaging fertility Skin Sens. 1B H317
217-026-5	1723-94-0	4,4'-(ethane-1,2-diyl)bismorpholine		
218-011-6	2038-03-1	2-morpholinoethylamine	-	Acute Tox. 3 H311 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)]
222-881-2	3647-69-6	4-(2-chloroethyl) morpholinium chloride	-	Acute Tox. 3 H301 [intermediate (active)] Acute Tox. 4 H312 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Skin Corr. 1C H314 [intermediate (active)] Aquatic Chronic 3 H412 [intermediate (active)]
224-518-3	4394-85-8	4-morpholinecarbaldehyde	-	Skin Sens. 1B H317
224-632-3	4432-31-9	2-morpholinoethanesulphonic acid	-	-

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations
224-662-7	4441-12-7	trimorpholinophosphine oxide	-	-
226-033-2	5235-82-5	4-[3-(1-naphthylamino)propyl]morpholine	-	Eye Irrit. 2 H319 Skin Sens. 1B H317 Aquatic Chronic 2 H411
227-062-3	5625-90-1	N,N'-methylenebismorpholine	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314 Eye Dam. 1 H318 Skin Sens. 1 H317 Acute Tox. 4 H332 Muta. 2 H341 Carc. 1B H350 STOT RE 2 H373 (gastrointestinal tract, respiratory tract)	
229-194-7	6425-39-4	2,2'-dimorpholinyldiethyl ether	-	Eye Irrit. 2 H319
231-391-8	7529-22-8	4-methylmorpholine 4-oxidemonohydrate	-	Repr. 2 H361 Flam. Solid 1 H228 Oxid. Solid 2 H272
233-029-4	10024-89-2	morpholine hydrochloride		
237-301-3	13732-62-2	morpholinium toluene-4-sulphonate	-	-
237-335-9	13752-51-7	4-[(morpholinothio)thioxomethyl]morpholine	-	Carc. 1B H350 Aquatic Chronic 2 H411
243-595-4	20207-13-0	4-[(2-aminoethoxy)ethyl]morpholine		
258-061-6	52636-67-6	morpholinium sulphamate	-	-
272-712-1	68909-77-3	Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine		Aquatic Chronic 3 H412 Eye Damage 1 H318

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations
		derivs. residues		
275-203-2	71119-23-8	sodium 4-morpholin-1-ylethylsulphonate	-	-
276-986-3	72906-09-3	Morpholine, 4-coco alkyl derivs.		
407-940-4	111681-72-2	4-[2-(1-methyl-2-(4-morpholinyl) ethoxy)ethyl]morpholine	Eye Dam. 1 H318	-
413-790-0		1-(4-morpholinophenyl)butan-1-one	Aquatic Chronic 2 H411	-
414-560-2		414-560-2	-	-
428-420-3		sodium 3-morpholin-4-ylpropane-1-sulfonate	-	-
435-700-9		435-700-9		?
461-510-0		461-510-0		Muta. 2 H341 Acute Tox. 4 H302 Eye Damage 1 H318 STOT Rep. Exp. 2 H373, affected organs:
469-290-8		469-290-8		Flam. Liquid 3 H226 Acute Tox. 4 H302 Skin Corr. 1B H314 Skin Sens. 1 H317 Aquatic Chronic 3 H412
609-541-2	38284-47-8	609-541-2		-
611-095-9	5409-41-6	611-095-9		Acute Tox. 3 H311 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)]
627-580-3	53617-35-9	4-(piperidin-4-		Skin Corr. 1 H314 Eye Damage 1 H318

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations
		yl)morpholine		Skin Sens. 1B H317 Aquatic Chronic 3 H412
700-519-9		(cis)-4-(2-[2-{(1S,2S,5S)-6,6-Dimethylbicyclo[3.1.1]hept-2-yl}ethoxy]ethyl)morpholine		Acute Tox. 4 H332 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Acute Tox. 4 H312 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)]
700-569-1	23588-51-4	2,2-Dimethyl-3-(morpholin-4-yl)propanal		Skin Corr. 1C H314 Eye Damage 1 H318 Skin Sens. 1B H317
700-570-7	1217271-49-2	N,N'-hexane-1,6-diylbis[2,2-dimethyl-3-(morpholin-4-yl)propan-1-imine]		Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Chronic 3 H412
700-584-3	1217271-02-7	N-[3-({[2,2-dimethyl-3-(morpholin-4-yl)propylidene]amino}methyl)-3,5,5-trimethylcyclohexyl]-2,2-dimethyl-3-(morpholin-4-yl)propan-1-imine		Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Chronic 3 H412
700-879-7		700-879-7		Eye Irrit. 2 H319 Skin Sens. 1B H317 Aquatic Chronic 2 H411
800-906-3	1402434-48-3	800-906-3		Acute Tox. 4 H302 Skin Irrit. 2 H315 Aquatic Acute 1 H400, M-factor: 10.00 Aquatic Chronic 1 H410
838-777-0	1266615-59-1	838-777-0		
915-372-8		Reaction mass of 2-ethylhexyl dihydrogen phosphate, compound with morpholine		Flam. Liquid 3 H226 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1B H317 Aquatic Chronic 2 H411

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations
		(1:2) and bis(2-ethylhexyl) hydrogen phosphate, compound with morpholine (1:1) and lauric acid, compound with morpholine (1:1)		
949-350-4		methyl 3-[2-(morpholin-4-yl)cyclopent-1-en-1-yl]propanoate		Skin Sens. 1 H317 [intermediate (active)] Repr. 2 H361, specific effect:H361d: Suspected of damaging the unborn child [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratory system [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)]

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

Data extracted on 6/09/2021

Note: for Lists 609-541-2, 611-095-9 and 800-906-3 there is no information on uses.

Main types of applications structured by product or article types	Subgroup A							Subgroup B	Subgroup C						Subgroup D
	203-815-1	214-478-5	216-913-4	229-194-7	237-301-3	258-061-6	915-372-8	237-335-9	203-103-0	224-518-3	700-569-1	700-570-7	700-584-3	700-879-7	203-640-0
PC 20: Products such as ph-regulators,	I,	F, I, P,													
PC 4: Anti-freeze and de-icing products	C,														

Main types of applications structured by product or article types	Subgroup A							Subgroup B	Subgroup C						Subgroup D
	203-815-1	214-478-5	216-913-4	229-194-7	237-301-3	258-061-6	915-372-8	237-335-9	203-103-0	224-518-3	700-569-1	700-570-7	700-584-3	700-879-7	203-640-0
PC 35: Washing and cleaning products	I, P, C,										I,	I,		I,	
PC 8: Biocidal products (e.g. disinfectants, pest	C,														
PC 39: Cosmetics, personal care products	P,														
PC 29: Pharmaceuticals		F,													
PC 31: Polishes and wax blends	C,														

Main types of applications structured by product or article types	Subgroup A							Subgroup B	Subgroup C						Subgroup D
	203-815-1	214-478-5	216-913-4	229-194-7	237-301-3	258-061-6	915-372-8	237-335-9	203-103-0	224-518-3	700-569-1	700-570-7	700-584-3	700-879-7	203-640-0
PC 15: Non-metal-surface treatment products	F, I, P, C,									C,					
PC 24: Lubricants, greases, release products	I, P,			I,											
PC 25: Metal working fluids	I, P,			I,											
PC 17: Hydraulic fluids	I, P,			I,											
PC 13: Fuels	C,														

Main types of applications structured by product or article types	Subgroup A							Subgroup B	Subgroup C						Subgroup D
	203-815-1	214-478-5	216-913-4	229-194-7	237-301-3	258-061-6	915-372-8	237-335-9	203-103-0	224-518-3	700-569-1	700-570-7	700-584-3	700-879-7	203-640-0
PC 32: Polymer preparations and compounds	I,	F,		I, P, C,	I, A	I, A		F, I, C, A,	F, I, A		F, I, P, C,	F, I, P, C, A		F, I, P, C, A	I, P, C, A
PC 1: Adhesives, sealants	F, I, P, C,			I, P, C,	I, P,					P, C,	F, I, P, C,	F, I, P, C,	F, I, P, C,	F, I, P, C,	I, P,
PC 9c: Finger paint	F, I, P, C,														
PC 9b: Fillers, putties, plasters, modelling clay	F, I, P, C,										F, P, C,	F, P, C,	F, I, P, C,	F, P, C,	
PC 9a: Coatings and paints, thinners, paint	F, I, P, C,		I,	I, P, C,	I, P,		I,			I, P, C,	F, I, P, C,	F, I, P, C,	F, I, P, C,	F, I, P, C,	I, P,

Main types of applications structured by product or article types	Subgroup A							Subgroup B	Subgroup C						Subgroup D
	203-815-1	214-478-5	216-913-4	229-194-7	237-301-3	258-061-6	915-372-8	237-335-9	203-103-0	224-518-3	700-569-1	700-570-7	700-584-3	700-879-7	203-640-0
PC 18: Ink and toners	F, I, P, C,									I, P, C,					
PC 26: Paper and board treatment products	I, P, C,				I,						P, C,	P,		P,	
PC 23: Leather treatment products										C, A	C, A				
PC 14: Metal surface treatment products	F, I, P, C,														
PC 21: Laboratory chemicals		F, I, P,													

Main types of applications structured by product or article types	Subgroup A							Subgroup B	Subgroup C						Subgroup D
	203-815-1	214-478-5	216-913-4	229-194-7	237-301-3	258-061-6	915-372-8	237-335-9	203-103-0	224-518-3	700-569-1	700-570-7	700-584-3	700-879-7	203-640-0
PC 19: Intermediate	I,	I,	I,	I,	I,	I,	I,								I, P,
PC 30: Photo-chemicals	C,														

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

Subgroup E

Main types of applications structured by product or article types	202-885-0	204-590-2	210-734-5	213-316-0	218-011-6	222-881-2	224-632-3	224-662-7	226-033-2	231-391-8	272-712-1	275-203-2	428-420-3	461-510-0	469-290-8	609-541-2	627-580-3	700-519-9	838-777-0	949-350-4
PC 20: Products such as ph-regulators, ...		F,					F, I, P,					F, I, P,	F, I, P,							
PC 29: Pharmaceuticals							F, I, P,	F,					F,	I,			F,	I,		
PC 31: Polishes and wax blends									F, I, P, C,											
PC 24: Lubricants, greases, release products		F,					P,		F, I, P, C,											
PC 25: Metal working fluids		F,																		
PC 13: Fuels									F, I, P, C,											

Main types of applications structured by product or article types	202-885-0	204-590-2	210-734-5	213-316-0	218-011-6	222-881-2	224-632-3	224-662-7	226-033-2	231-391-8	272-712-1	275-203-2	428-420-3	461-510-0	469-290-8	609-541-2	627-580-3	700-519-9	838-777-0	949-350-4
PC 32: Polymer preparations and compounds	I, P,	F,					F,						F,							
PC 1: Adhesives, sealants	I, P,	F,																		
PC 9b: Fillers, putties, plasters, modelling clay		F,																		
PC 9a: Coatings and paints, thinners, ...	I, P,	F, I,									I,									
PC 33: Semiconductors		I,																		
PC 21: Laboratory chemicals		I, P,					F, I, P,					F, I, P,	F, I, P,							

Main types of applications structured by product or article types	202-885-0	204-590-2	210-734-5	213-316-0	218-011-6	222-881-2	224-632-3	224-662-7	226-033-2	231-391-8	272-712-1	275-203-2	428-420-3	461-510-0	469-290-8	609-541-2	627-580-3	700-519-9	838-777-0	949-350-4
PC 19: Intermediate	I,	I,	I,	I,	I,	I,				I,	I,			I,	I,		I,	I,		I,
PC 30: Photo-chemicals													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

Data consulted on 15.10.2021

EC / List number	RMOA	Authorisation		Restriction	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
203-815-1	YES					
227-062-3					YES	BPR active substance

In blue: not registered

No relevant completed or ongoing regulatory risk management activities for the other substances in the group.