

Assessment of regulatory needs

Authority: ECHA

Group name: Piperazine-functionalised polyamines

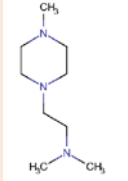
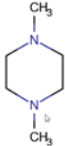
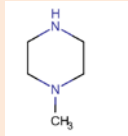
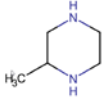
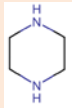
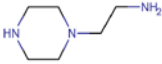
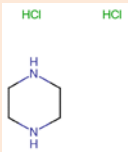
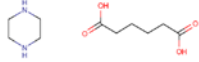
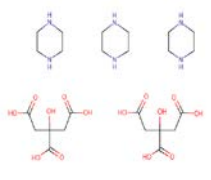
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Revision history

<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	26 October 2020	

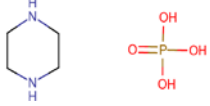
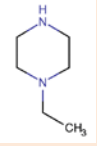
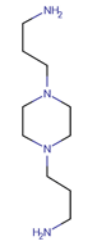
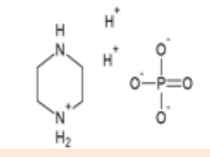
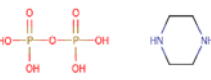
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Substances within this group:

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full/OSI or TII/NONS), highest tonnage band among all the registrations (t/y) ¹
203-183-7	104-19-8	N,N,4-trimethylpiperazine-1-ethylamine		Full, not (publicly) available
203-412-0	106-58-1	1,4-dimethylpiperazine		Full, not (publicly) available
203-639-5	109-01-3	1-methylpiperazine		Full, 100-1000T
203-644-2	109-07-9	2-methylpiperazine		OSII or TII, not (publicly) available
203-808-3	110-85-0	Piperazine		Full, 1000+T
205-411-0	140-31-8	2-piperazin-1-ylethylamine		Full, 1000+T
205-551-2	142-64-3	Piperazine dihydrochloride		C&L notification
205-569-0	142-88-1	Piperazine adipate		Full, not (publicly) available
205-622-8	144-29-6	Tripiperazine dicitrate		Full, not (publicly) available

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

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EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full/OSI or TII/NONS), highest tonnage band among all the registrations (t/y) ¹
217-775-8	1951-97-9	Piperazine, compound with phosphoric acid		Full, not (publicly) available
226-166-6	5308-25-8	1-ethylpiperazine		Full, not (publicly) available
230-589-1	7209-38-3	N,N'-bis(3-aminopropyl)piperazine		Full, not (publicly) available
238-572-0	14538-56-8	Piperazinium dihydrogen phosphate		C&L notification
296-543-8	92731-41-4	Ethanol, 2-amino-, reaction products with ammonia, 1-piperazineethanamine fraction	UVCB	OSII or TII, not (publicly) available
457-330-7	66034-17-1	Diphosphoric acid, compd. with piperazine (1:1);		Full, 10-100T

This table contains also 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.

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Foreword

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

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

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

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on 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 website².

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
EOGRTS	Extended one generation reproductive toxicity study
NOAEL	No observed adverse effect level
NOEL	No observed effect level
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 simple piperazine salts as well as other piperazine structures where additional N-alkyl or N-alkyl-amine functional groups are present. The group is composed of 15 members, 13 of which are registered under REACH (2 as intermediates only) and 2 notified to the C&L inventory.

Based on information reported in the REACH registration dossiers, the uses among the fully registered substances (11) are quite diverse, including e.g. use in adhesives/sealing, coatings, polymer, functional fluids and curing agent. There is not a (one) common use across all substances in the group, however, some substances have similar or very similar use patterns.

Of the 13 registered substances, seven have only formulation and industrial uses reported. Professional uses are reported for four substances; for two further substances there is industrial use and article service life reported. None of the substances in the group has consumer uses reported.

Of the four substances having professional uses reported, EC 203-183-7 and EC 203-412-0 have an almost identical use pattern indicating potential for exposure and releases to the environment e.g. use in coatings, metal fluids, and use in adhesive and sealing. The substance EC 205-411-0 has professional use as epoxy resin hardener even though claimed to be an intermediate use. The fourth substance with a reported professional use (EC 203-808-3) has been assessed not to be a use of the substance but of the polymer.

For the two substances for which article service life is reported, potential exposure to consumers and releases to the environment are expected only for EC 457-330-7 from the use as flame retardant in various articles.

Several substances have a harmonised classification for different endpoints: EC 217-775-8 (Repr2. Skin Sens.1, Resp. Sens.1, Skin/Eye Irrit. 2, Aq. Chronic 3), EC 205-411-0 (Skin Sens.1, Skin Corr.1B, Acute Tox4, Aq. Chronic 3), EC 203-808-3 (Repr2. Skin Sens.1, Corr.1B, Resp. Sens.1). Detailed information on ongoing regulatory actions for substances in the group is available in Annex 3.

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

Piperazine (EC 203-808-3, chemical structure is common in all the substances in this group) is a mild hepatotoxin and neurotoxin. In dogs, which appear to be among the more sensitive laboratory animals, no observed effect level (NOEL) values of 25 mg/kg body weight/ day and 50 mg/kg body weight /day have been identified (*RAR Report 2005*³).

Neurotoxic effects have also been observed in humans generally at relatively high levels. However, some individuals do appear to be rather more sensitive than the general population to the neurotoxic effects. A NOEL for humans has not been

³ RAR Report 2005 <https://echa.europa.eu/documents/10162/35f9602c-cb84-448f-9383-250e1a5ad350>

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established satisfactorily but it is assumed to be of the order of 30 mg/kg body weight/ day (*RAR Report 2005*⁴).

Piperazine has harmonized classification as Repro2 (H361 FD) on the basis of the findings (reduced pregnancy index, decreased number of implantation sites and decreased litter size as the main effect) from a 2-gen study (OECD 416) with piperazine-dihydrochloride (EC 205-551-2, not registered but part of this group).

The available hazard information in registration dossiers from other substances in this group also indicate a potential hazard for repeated dose toxicity (including neurotoxicity) and reproductive toxicity. Five out of 13 substances in this group are (self) classified for reproductive toxicity: 4 substances (EC 205-411-0, EC 203-808-3, EC 217-775-8 and EC 203-639-5 – only C&L notification but not in the dossier). as Repr.2 H361 FD and one substance (EC 296-543-8, intermediate and substance of unknown or variable composition, complex reaction products or biological materials (UVCB) with 40-70% EC 205-411-0, 2-piperazin-1-ylethylamine) as Repr.1 H360FD. There are the following additional indications of reproductive toxicity for five group members (EC 203-183-7, EC 203-639-5, EC 203-808-3, EC 205-551-2 and EC 205-411-0) based on available OECD 422 and 416 studies and prenatal developmental toxicity studies: histopathology changes in testes, lower offspring survival and growth, reduced pregnancy index, decreased number of implantation sites and decreased litter size, resorptions, retardation of ossification and reduced fetal weights; and decreased embryofetal survival, with lowest no observed adverse effect levels (NOAELs) reported at the level of 50 - 125 mg/kg bw/day. One substance was positive to at least one of the in-vitro assays from ToxCast related to estrogenic mode of action.

From the human health hazard point of view data generation mainly under compliance check (CCH) is proposed to clarify in particular the potential hazards for reproductive toxicity of EC 203-412-0, EC 203-639-5, EC 203-808-5 and EC 457-330-7. For substance EC 203-183-7 it is suggested to clarify the potential hazards for mutagenicity, reproduction toxicity and repeated dose toxicity partly under substance evaluation (SEv) due to the low registration tonnage of 10-100 tpa dossier. The substance has STOT RE 2 classification but a 90-day repeated dose toxicity study or extended one generation study could maybe lead to stronger classification. SEv is justified due to the presence of wide-dispersive professional uses in various applications. EC 230-589-1 is awaiting for a EOGRTS study on the related substance EC 205-411-0 (which has similar uses). Depending on the outcome SEv might also be needed.

Furthermore, based on the available information in the registration dossiers and/or (self) classification (see Annex 1) ten substances are known or potential Skin sens.1/B and out of these three are also Resp. sens.1B.

For environment, the hazards are inconclusive due to presence of unreliable data and/or many data gaps. In addition, many substances in the group are of low tonnage and therefore the level of hazard information is limited. Compliance check is therefore suggested as a next step and data generation where possible.

⁴ RAR Report 2005 <https://echa.europa.eu/documents/10162/35f9602c-cb84-448f-9383-250e1a5ad350>

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for reproductive toxicity and STOT RE hazards due to the potential for release/ exposure of the substances EC 203-183-7, EC 203-412-0, EC 205-411-0, EC 230-589-1 and EC 457-330-7 in the group.

EC 203-183-7 and EC 203-412-0 have professional use reported in coatings, metal fluids, and use in adhesive and sealings. EC 205-411-0 has professional use as epoxy resin hardener even though claimed to be an intermediate use. EC 230-589-1 has industrial use as catalyst/curing agent and article service life is also reported. EC 457-330-7 has industrial use and article service life reported as fire preventing agent.

The substances are suspected to be toxic for reproduction, however, generation of data is needed first.

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. 1A/B.

CLH i) will require company level risk management measures (RMM) for workers, to be in place and 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 (no consumer uses however reported), by means of the restriction entry 28, 29, 30.

For EC 457-330-7, CLH is also a prerequisite to restrict the presence of the substance in clothing, other textiles, and footwear articles, by means of the restriction entry 72 of REACH Annex XVII (this would require addition of the substance to Appendix 12 by the Commission through Article 68(2)).

The professional uses in adhesives/sealing, coatings, functional fluids, epoxy resin hardeners and in curing agents are expected to be widespread (at many sites and by many users). Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation.

Therefore, a **restriction of the 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 Sustainability⁵ which aims to extend to professional users under REACH the level of protection granted to consumers.

Moreover, **restricting substances in articles** used by professionals or consumers is suggested for EC 457-330-7 which is used in articles as flame retardant, as potential for exposure from articles is likely based on the high percentage of substance reported as being present in articles in the registration dossiers. EC

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>

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230-589-1 is reported to be used in adhesives, construction or processing aid products, as catalyst or curing agents. Releases from articles might be low however this would need to be looked at more closely during the restriction process.

It is suggested to cover possibly also industrial uses (to note- only industrial use is reported for EC 457-330-7 and EC 230-589-1) as part of the restriction. However, the need for authorisation might be considered for industrial uses excluded from the scope of the restriction as it may not be proportionate to restrict all uses.

There is no need for additional regulatory risk management to address skin sensitisation as either harmonised or self-classification provide already sufficient company level risk management measures to achieve adequate protection.

Based on currently available information, there is no need for (further) EU regulatory risk management for reproductive toxicity/STOT RE/ skin sensitiser/ aquatic toxicity hazards of the substances EC 203-639-5, EC 203-808-3, EC 217-775-8, EC 205-569-0, EC 205-622-8, EC 226-166-6, , EC 203-644-2, EC 296-543-8, EC 205-551-2 and EC 238-572-0 in the group.

CCH is suggested to confirm hazards for EC 203-639-5 and EC 203-808-3.

EC 203-639-5 is used as intermediate/ laboratory chemical in the textile and pharmaceutical industry. EC 203-808-3 is reported to be used as monomer (intermediate) by industrial and professional workers, however, professional use is assessed to be the use of the polymer. Also, use as functional fluid in semiconductor production and adsorbant in gas washers and scrubbers in industrial settings is reported for the substance. However, overall, the use in industrial settings appears to be mainly use as an intermediate with limited exposure for workers for both substances.

EC 217-775-8, EC 205-569-0, EC 205-622-8, EC 226-166-6 are used mainly as pharmaceuticals and are therefore assumed from a human health perspective to be adequately regulated by other EU legislation. The other uses (if any) are not widespread.

For all substances listed above, sufficient and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation.

Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

For EC 203-639-5 it will be important after CCH to check that registrants apply the correct self-classification in case the hazard is confirmed.

Due to intermediate registration/ not registered exposure is assumed to be low and it is not possible to clarify the potential hazards of substances EC 203-644-2, EC 296-543-8, EC 205-551-2 and EC 238-572-0. Therefore, it is proposed that there is currently no need for EU RRM action on these substances. If the registration status changes, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

3 Conclusions and actions

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

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
203-183-7 203-412-0	Known or potential hazard for reproductive toxicity, STOT RE	Inconclusive hazard	Wide-dispersive professional uses in various applications e.g. adhesives, sealings, coatings, metal fluids & lubricants. Potential for exposure for workers.	Need for EU RRM: Restriction <u>Justification:</u> The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. Industrial uses to be considered as part of the	First step: CCH SEV for 203-183-7, 230-589-1 and 457-330-7 Next steps (if hazard confirmed): CLH Restriction
205-411-0	Known or potential hazard for skin sensitisation for all except 203-412-0		Some industrial uses but also wide-dispersive professional use as epoxy resin hardener. Potential for exposure for workers.		
230-589-1			Industrial use as catalyst/curing agent and article service life reported. Potential for exposure for industrial workers. Low releases from articles expected.		

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EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
457-330-7			Industrial use as fire preventing agent. Substance in high percentages present in articles used by consumers and professionals. Potential for exposure for workers and consumers and release from articles.	restriction Specific restriction for use in articles is proposed as potential exposure from articles is likely at least for 457-330-7 and possibly for 230-589-1.	
203-639-5	Known or potential hazard for reproductive toxicity, STOT RE, skin sensitisation	Inconclusive hazard	Only industrial uses as intermediate and laboratory chemical. Exposure for workers is expected to be low.	Currently no need for EU RRM <u>Justification:</u> According to the reported uses, low potential for exposure to both human health and environment is expected. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change. Harmonised/self-classification followed by implementation of necessary RRM should be sufficient to ensure safe use at the workplace.	First step: CCH
203-808-3			Substance registered as monomer as industrial and professional use (intermediate use). Professional use assessed to be the use of the polymer. Exposure for workers is expected to be low.		

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EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
217-775-8	Known or potential hazard for reproductive toxicity and skin sensitisation	Known or potential hazard for aquatic toxicity	Only industrial uses, mainly pharmaceutical but also laboratory. 217-775-8 registered as plant protection product and elastomer. Potential for exposure for industrial workers. No significant releases expected.	<p>Currently no need for EU RRM</p> <p><u>Justification:</u> Use as pharmaceutical assumed to be adequately regulated by other EU legislation or otherwise no widespread uses No hypothesis can be developed for the time being for environment due to lack of hazard information. Harmonised/self-classification followed by implementation of necessary RRM should be sufficient to ensure safe use at the workplace.</p>	No action
205-569-0	Inconclusive hazard				
205-622-8 226-166-6					
203-644-2	Inconclusive hazard	Inconclusive hazard	Intermediate registration. Exposure for workers is expected to be low	<p>Currently no need for EU RRM</p> <p><u>Justification:</u> According to the reported uses, low potential for exposure to both human health and environment is expected.</p>	No action

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EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
296-543-8				Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change.	
205-551-2	Known or potential hazard for reproductive toxicity and skin sensitisation	Known or potential hazard for aquatic toxicity	Not registered, C&L notification	<p>Currently no need for EU RRM</p> <p><u>Justification:</u> Substances are not registered so no exposure and no data generation is possible to clarify the hazards currently. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change.</p>	No action
238-572-0	Inconclusive hazard	Inconclusive hazard			

Annex 1: Overview of classifications

Data extracted on 17 January 2020.

EC No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
203-183-7	<i>N,N,4-trimethylpiperazine-1-ethylamine</i>		Acute Tox 4 oral, Skin corr.1B, Eye Damage 1, Skin sens.1B, STOT Re 2 (brain, respiratory tract, testes)	<i>Acute Tox. 3, H331 Acute Tox. 4, H303 STOT SE 3, H335</i>
203-412-0	<i>1,4-dimethylpiperazine</i>		Skin corr.1C, Eye Damage 1	<i>Flam. Liq. 3, H226</i>
203-639-5	1-methylpiperazine		Acute Tox 4 inhal, Skin corr.1B, Eye Damage 1, Skin sens.1B,	<i>Repr. 2, H361</i>
203-644-2	<i>2-methylpiperazine</i>		Skin corr.1B	<i>STOT SE 3, H335</i>
203-808-3	<i>Piperazine</i>	Repr 2. Skin sens.1 B, corr.1B, Resp. sens 1B	Skin corr.1B, Eye Damage 1, Skin sens.1B, Resp. Sens. 1B, Repr. 2,	
205-411-0	2-piperazin-1-ylethylamine	Skin sens.1, Skin corr.1B, Acute tox 4 (oral and dermal), Aq Chronic 3	Acute Tox 3 dermal, Skin corr.1B, Eye Damage 1, Skin sens.1B, STOT Rep. Exp. 1 (resp tract), Repr. 2	
205-551-2		Repr 2. Skin sens.1, Skin corr.1B, Resp. Sens1, Skin/Eye Irrit. 2, Aq Chronic 3		
205-569-0	<i>piperazine adipate</i>			
205-622-8	tripiperazine dicitrate		Skin corr.1B, Eye Irrit 2, Skin sens.1	
217-775-8	<i>Piperazine, compound with phosphoric acid</i>	Repr 2., Skin sens.1, Resp. Sens 1, Skin/Eye Irrit. 2, Aq Chronic 3		
226-166-6	1-ethylpiperazine		Acute Tox 4 oral, Skin corr.1B, Eye Damage 1, Skin sens.1B,	<i>STOT SE 3, H335</i>
230-589-1	N,N'-bis(3-aminopropyl)piperazine		Acute Tox 4 oral, Skin corr.1B, Eye Damage 1, Skin sens.1B,	
238-572-0				

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EC No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
296-543-8	<i>Ethanol, 2-amino-, reaction products with ammonia, 1-piperazineethanamine fraction</i>		Acute Tox 4 oral, Acute Tox 3 dermal, Skin corr.1B, Eye Damage 1, Skin sens.1B, Repro 1B	
457-330-7	<i>Piperazine pyrophosphate</i>			

(*) 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 17 January 2020.

Main types of applications structured by product or article types	203-183-7	203-412-0	203-639-5	203-644-2	203-808-3	205-411-0	205-569-0	205-622-8	217-775-8	226-166-6	230-589-1	296-543-8	457-330-7
Use in adhesives and sealing	F, I, P	F, I, P											
Use in coatings	F, I, P	F, I, P											
Metal fluids and lubricants	F, I, P												
Rigid polyurethane foam	F, I, P	F, I, P											
Elastomers	F, I, P	F, I, P							I				
Intermediate		I	I	I	I							I	
Flexible polyurethane foam		I											
Textile industry (fiber spinning)			F, I										
Use in laboratory			I					I					
Pharmaceutical			I				I	I	I	F, I			
Monomer (sometimes in imported polymers)					F, I, P	F, I							
Adsorbant (in gas washers and scrubbers); Gas sweetening					F, I	F, I							
Functional fluid					I								
Epoxy resin curing agent						F, I, P							
Plant protection active substance									I				

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	203-183-7	203-412-0	203-639-5	203-644-2	203-808-3	205-411-0	205-569-0	205-622-8	217-775-8	226-166-6	230-589-1	296-543-8	457-330-7
Catalyst/Curing agent											F, I, A		
Fire preventing agent													F, I, A

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

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

Data extracted on 22 January 2020.

EC/List number	RMOA	Authorisation		Restriction*		CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)		
203-808-3						YES	
205-411-0						YES	
205-551-2						YES	
217-775-8						YES	

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

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