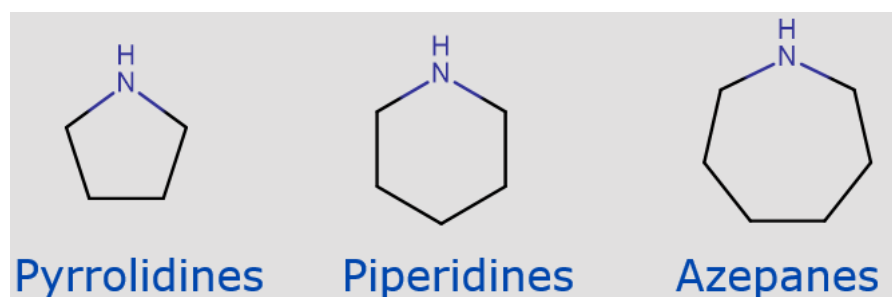


## Assessment of regulatory needs

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

**Group Name: Pyrrolidines, piperidines and azepanes**

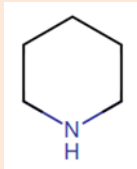
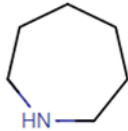
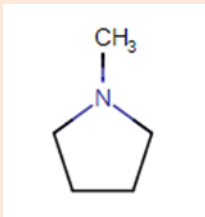
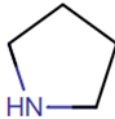
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### Revision history

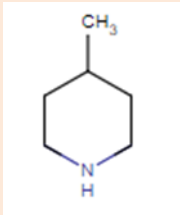
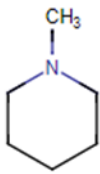
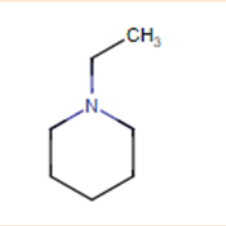
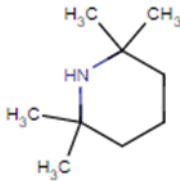
<i>Version</i>	<i>Date</i>	<i>Description</i>
<b>1.0</b>	2 February 2024	

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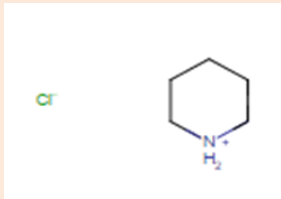
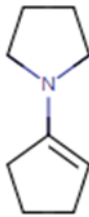
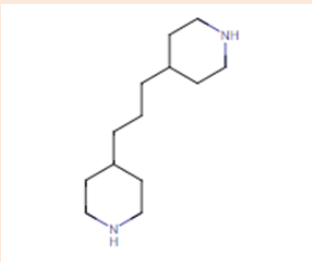
EC/List number	CAS number	Substance name  [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
203-813-0	110-89-4	Piperidine		Full, 100-1000
203-875-9	111-49-9	Perhydroazepine		OSII or TII
204-438-5	120-94-5	1-methylpyrrolidine		OSII or TII
204-648-7	123-75-1	Pyrrolidine		Full, not (publicly) available

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

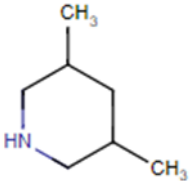
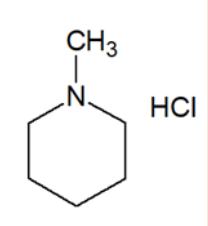
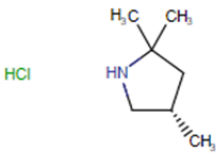
## ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name  [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
210-954-1	626-58-4	4-methylpiperidine		OSII or TII
210-959-9	626-67-5	1-methylpiperidine		Full, not (publicly) available
212-161-6	766-09-6	1-ethylpiperidine		Full, not (publicly) available
212-199-3	768-66-1	2,2,6,6-tetramethylpiperidine		OSII or TII

## ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name  [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
228-033-8	6091-44-7	Piperidinium chloride		OSII or TII
230-463-6	7148-07-4	N-(cyclopent-1-ene-1-yl)pyrrolidine		OSII or TII
240-941-6	16898-52-5	4,4'-trimethylenedipiperidine		Full, 1-10

## ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name  [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
<b>252-730-6</b>	35794-11-7	3,5-dimethylpiperidine		OSII or TII
<b>605-832-3</b>	17874-59-8	Piperidine, 1-methyl-, hydrochloride (1:1)		Not registered
<b>943-629-4</b>	1897428-40-8	(S)-2,2,4-trimethylpyrrolidine hydrochloride		OSII or TII

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

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## **DISCLAIMER**

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

## Foreword

The 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)<sup>2</sup>. 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<sup>3</sup>. 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.

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<sup>2</sup> [Working with Groups - ECHA \(europa.eu\)](https://eucha.europa.eu)

<sup>3</sup> 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).



For more information on assessments of regulatory needs please consult ECHA's website<sup>4</sup>.

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<sup>4</sup> <https://echa.europa.eu/understanding-assessment-regulatory-needs>

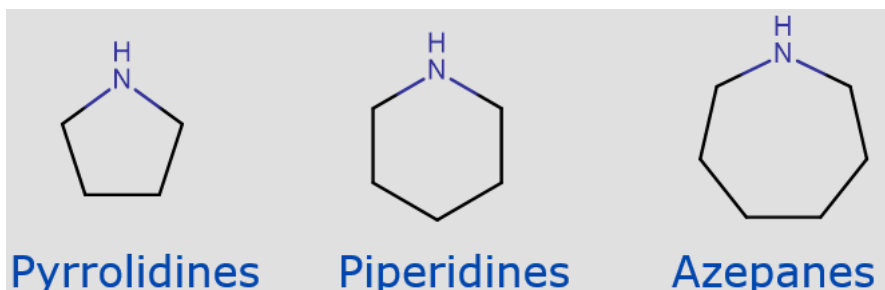
## Glossary

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 pyrrolidine, piperidine and azepane moieties shown in the figure below.



Substances with hydrocarbonyl substituents are included in the group. Substances in the group are therefore 5, 6 and 7 ring cyclic secondary or tertiary amines including some hydrochloric acid salts.

There are 14 substances in the group of which 6 with full registrations, 7 intermediates and one is not registered.

Based on information reported in the REACH registration dossiers the registered substances of the group are mainly used as intermediates in industrial setting. Few other industrial uses (e.g., laboratory chemicals, pharmaceuticals, adhesives, and sealants) are mentioned in the registration dossiers for a limited number of substances. Few dossiers also report professional uses in laboratory settings. Only one substance (EC 240-941-6) has a potential to end up in articles where article service life was reported for uses in adhesives and sealants. The registrants of EC 203-813-0 report industrial and professional uses across several product categories. Potential for exposure is relevant for industrial and professional uses of two substances (EC 203-813-0 and 204-648-7) linked to uses in, e.g., fertilisers, water treatment products, plant protection products, pharmaceuticals, and paper treatment products.

## 2 Conclusions and proposed 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 1: Conclusions and proposed actions**

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
<b>203-813-0</b> <b>204-648-7</b> <b>212-161-6</b>	Inconclusive hazard for Reproductive toxicity and ED  No hazard or unlikely hazard for mutagenicity, carcinogenicity, STOT RE and skin sensitisation.	Inconclusive hazard for ED  No hazard or unlikely hazard for PBT/vPvB, PMT/vPvM and aquatic toxicity	Widespread uses for EC 203-813-0 in industrial and professional settings (e.g., in fertilisers, water treatment, plant protection products, pharmaceuticals) with exposure via the environment being likely significant.  Industrial and professional uses as intermediate (laboratory chemicals), industrial uses as intermediate	CCH  <b>Currently not possible to assess the regulatory needs</b>  <u>Justification:</u> It is not possible to assess the needs for regulatory risk management as information on hazard is not sufficient to conclude on the hazards. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
			<p>(hydraulic fluids, paper treatment products) for EC 204-648-7.</p> <p>Article service life in adhesives and sealants for EC 240-941-6 with potential for exposure.</p> <p>Substances EC 210-959-9 and 212-161-6 used as intermediate.</p>	
<p><b>204-438-5</b>  <b>203-875-9</b>  <b>210-954-1</b>  <b>212-199-3</b>  <b>228-033-8</b>  <b>230-463-6</b>  <b>252-730-6</b>  <b>943-629-4</b>  <b>605-832-3</b>  <b>240-941-6</b>  <b>210-959-9</b></p>	<p>No hazard or unlikely hazard (except for reproductive toxicity for EC 203-875-9 due to presence of a classified impurity)</p>	<p>No hazard or unlikely hazard (except for PMT/vPvM for EC 210-959-9 and EC 240-941-6, which remains inconclusive)</p>	<p>Substances are used only as intermediates in industrial settings with low potential for exposure.</p> <p>EC 212-199-3, 230-463-6 do not report any uses.</p> <p>List 605-832-3 is not registered.</p>	<p><b>Currently no need for EU RRM</b></p> <p><u>Justification:</u>            According to the reported uses, low potential for exposure to both human health and environment is expected. Based on its registration status, no data generation is possible to clarify the hazards for EC 240-941-6 and 210-959-9. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change.</p>

### 3 Justification for the (no) need for regulatory risk management action at EU level

**Based on currently available information, it is not possible to assess the need for regulatory risk management for EC 203-813-0, 204-648-7, 212-161-6** as information on hazard is not sufficient to conclude on reproductive toxicity and ED.

It is currently not possible to conclude on reproductive toxicity and ED as a result of poor data availability and/or reliability. For piperidine and pyrrolidine (EC 203-813-0 and 204-648-7, respectively), adverse effects on seminal vesicles and sperm parameters were described but the effects seen are from a publication (no-GLP, 1978) conducted on only few test animals (5-6 males) and with very limited reporting. While raising a concern, this study is not comparable to a 90d study and it is currently not possible to evaluate whether the effects result from general toxicity or from specific effects on male reproductive organs. Considering the effects seen in the existing studies, these substances are also considered inconclusive for ED human health. For EC 212-161-6, there is no data for reproductive toxicity.

All three substances are considered unlikely mutagenic based on studies with negative results, and unlikely carcinogenic based on unlikely mutagenicity.

EC 212-161-6 is considered unlikely STOT RE based on the absence of effects seen in an OECD TG 407. Considering the low data density and the structural variations between the substances of this subgroup, the conclusion is extrapolated to the other substances from the subgroup with a low level of confidence.

All the substances are corrosive and are considered unlikely sensitising based on negative results for EC 203-813-0 and EC 212-161-6. The corrosivity may also explain the low NOAELs seen in one available OECD 407 study with EC 212-161-6 (NOAEL local 20 mg/kg (male) and 80 mg/kg bw/d (female) and NOAEL syst. >80 mg/kg bw/day (no effects)).

With regard to persistency, EC 203-813-0, EC 204-648-7 and EC 212-161-6 appear unlikely persistent based on available ready biodegradability studies. With regard to bioaccumulation, experimental data indicate a low log Kow for all the substances (estimated either for neutral form or generated under pHs where the substances are not ionised). However, these substances are ionisable under relevant pH and, in the absence of experimental bioaccumulation data in aquatic species, some uncertainty remains. For Mobility the substances would screen as potential M or vM depending on their ionised form when in the environment. It should also be noted that currently no conclusion on the T criteria can be reached as these substances remain inconclusive for reproductive toxicity and ED. However, based on the unlikely persistency of these substances, they are unlikely PBT/vPvB and unlikely PMT/vPvM.

Finally, no aquatic toxicity hazard warranting classification is anticipated based on the available acute and chronic data for the group members. Some uncertainties remain as a result of data reliability and the use of read across.

In the absence of information to assess any ED potential for the environment and considering that the human health ED hazard remains inconclusive, the same conclusion applies for ED ENV.

Compliance check is proposed for substances EC 203-813-0, EC 204-648-7 and EC 212-161-6 in order to clarify reproductive toxicity and ED.

Only one substance, EC 203-813-0, has widespread uses (e.g., in fertilisers, water treatment, plant protection products, pharmaceuticals) with significant exposure. Professional uses are reported in laboratory settings for all the three substances in the group (i.e., EC 203-813-0, EC 204-648-7 and EC 212-161-6). Here, high levels of operational controls and risk management measures are expected to be in place.

Furthermore, for industrial uses, it is expected that following data generation registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use at the workplace.

In addition, for both EC 203-813-0 and EC 204-648-7, an EU-wide exposure limit for workers under Occupational Health and Safety (OSH) legislation or REACH exists. The OEL limits are considered as sufficient to control the (inhalation) risk for industrial workers. Due to differences in chemistry and unknown mode of action posing the hazard, EU wide OELs to other members of the group are not proposed.

Based on the above, it is not possible to assess the needs for regulatory risk management for EC 203-813-0, 204-648-7, 212-161-6 as information on hazard is not sufficient to conclude on reproductive toxicity and ED. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).

**Based on currently available information, there is no need for (further) EU regulatory risk management** for all remaining substances from the group as a result of their registration status (i.e. TII/OSII or not registered).

All the substances in this group are considered unlikely mutagenic (by extrapolation with a high level of confidence) and unlikely carcinogenic based on a consistent pattern of negative results in mutagenicity studies. EC 204-438-5 has a hazard potential which stems from the presence of impurity tetrahydrofuran which has harmonised classification for Carc. 2. However, this impurity is present below classification threshold and therefore the classification as Carc. 2 is not warranted.

EC 203-875-9 is considered unlikely STOT RE based on the absence of effects seen in an OECD TG 422. Considering the low data density and the structural variations between the substances of this subgroup, the conclusion is extrapolated to the other substances from the subgroup with a low level of confidence.

With regard to reproductive toxicity, only one OECD 422 study on EC 203-875-9 is available. This study shows no adverse effects. The conclusion is extrapolated to the other substances from the subgroup with a low level of confidence. It is noted that Cyclohexanamine is present in EC 203-875-9 and has harmonised classification as Repr. 2 with no specific concentration limit. However, this impurity is present below classification threshold and therefore the classification as Repr. 2 is not warranted.

As currently there are no indications for an ED effect from an OECD 422 study on EC 203-875-9, ED is considered for all the substances unlikely with low level of confidence.

All the registered substances (except EC 228-033-8 and EC 252-730-6 which are irritant) are corrosive and all substances are considered unlikely sensitising with

medium certainty based on negative results for EC 240-941-6. The corrosivity may also explain the low NOAELs seen in one available OECD 422 study with a NOAEL systemic effect of 50 mg/kg bw (highest dose chosen due to severe clinical symptoms, body weight loss, decreased organ weights, macroscopic and microscopic findings in the stomach and small intestine at 200 mg/kg bw/d).

With regard to persistency, no consistent pattern emerges within this group. Most substances are unlikely persistent with high uncertainty based on currently available data. However, data density remains low. Concerning EC 210-959-9 and EC 240-941-6, these substances screen as potentially persistent based on screening level information. No simulation study in relevant environmental compartment is available for any of the substances from the group. With regard to bioaccumulation, experimental data indicate a low log Kow for all the substances (estimated either for neutral form or generated under pHs where the substances are not ionised). However, these substances are ionisable under relevant pH and other mechanisms than partitioning to lipid may lead to bioaccumulation. It is noted that an OECD TG 305C study on EC 210-959-9 is available that do not indicate any significant bioaccumulation potential. However, considering structural variation within this group, the conclusion of low potential for bioaccumulation is extrapolated with low confidence. Furthermore, for Mobility, most of the substances do screen for M or vM based on their logKow values and accounting for the potential bias related to their ionised form when measuring Kow. Finally, based on the available toxicological and aquatic toxicity data available, T is considered unlikely with high uncertainty (due to low data density). The same applies for aquatic toxicity where low or no hazard is expected based on the available data. Similarly, to human health, an ED hazard is considered unlikely with a low level of confidence as a result of low data availability.

To summarize, while environmental hazard appears unlikely for most substances in this group, no conclusion on PMT/vPvM can currently be reached for EC 210-959-9 and EC 240-941-6 as no data is available to confirm their P/vP and T properties. Nevertheless, for EC 210-959-9 and EC 240-941-6, compliance check would not allow clarifying the inconclusive hazards as a result of their registration status. Therefore, no compliance check is proposed for these substances.

The overall use profile of the substances is of low concern as the substances are used only as intermediates in industrial settings with low potential for exposure under strictly controlled conditions or only at very low tonnage band. Substance EC 210-959-9 is used as intermediate in industrial settings with low potential for exposure. There is only intermediate use and manufacture in closed process recorded for EC 210-959-9, that do not justify exposure of workers or the environment.

Therefore, no EU regulatory risk management action is currently proposed for any of the aforementioned substances due to low exposure potential. It is worth noting however that the strategy may need to be revisited and need for further regulatory action reconsidered if there is a change in the registration status or reported uses for any of these substances.



## Annex 1: Overview of classifications

Data extracted on 15 May 2023

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations <sup>5</sup>
<b>203- 813-0</b>	110-89- 4	piperidine	<p>Concentration limits for acute toxicity cannot be translated into GHS from the DSD especially when minimum classifications are given; The classification for acute toxicity for this entry may be of special concern</p> <p>Index number: 613-027-00-3 Acute Tox. 3 Hazard Statement: H311 (Minimum classification) Hazard Category: Skin Corr. 1B Hazard Statement: H314 Flam. Liq. 2 Hazard Statement: H225 Acute Tox. 3 Hazard Statement: H331 (Minimum classification)</p>	<p>Flam. Liquid 2 H225 Acute Tox. 4 H302 Acute Tox. 3 H311 Acute Tox. 3 H331 Skin Corr. 1B H314 Eye Damage 1 H318</p>
<b>204- 648-7</b>	123-75- 1	pyrrolidine	-	<p>Flam. Liquid 2 H225 Acute Tox. 4 H302 Acute Tox. 4 H332 Skin Corr. 1A H314 Eye Damage 1 H318</p>

<sup>5</sup> The column gives the classifications in registrations received under REACH. Additional classifications in intermediate and in inactive registrations (if any) are annotated and displayed last. For each classification the table includes information on the hazard category, the hazard statement and any available information on specific effects (relevant for reproductive toxicity), specific concentration limits, M-Factors and affected organs. Two classifications differing in any of these aspects are considered different and are repeated in the table. The columns "Classifications in registrations" and "Classifications in C&L notifications" are empty if there are no Registrations/C&L notifications (hazard is unknown). The value '-' is displayed on the same columns when there are (relevant) submissions but they do not contain self-classifications (substance is not hazardous).

## ASSESSMENT OF REGULATORY NEEDS

<b>203-875-9</b>	111-49-9	perhydroazepine	-	Skin Corr. 1C H314 [intermediate (active)] Flam. Liquid 2 H225 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] Aquatic Chronic 3 H412 [intermediate (active)] Acute Tox. 3 H331 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] STOT Single Exp. 3 H335 [intermediate (active)]
<b>204-438-5</b>	120-94-5	1-methylpyrrolidine	-	Flam. Liquid 2 H225 Acute Tox. 3 H301 Acute Tox. 4 H332 Skin Corr. 1A H314 Eye Damage 1 H318 Aquatic Chronic 2 H411
<b>210-954-1</b>	626-58-4	4-methylpiperidine	-	Eye Irrit. 2 H319 [intermediate (active)] Flam. Liquid 2 H225 [intermediate (active)] Acute Tox. 3 H331 [intermediate (active)] Acute Tox. 3 H311 [intermediate (active)] Aquatic Chronic 3 H412 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Skin Corr. 1A H314 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: Respiratory tracts [intermediate (active)]
<b>210-959-9</b>	626-67-5	1-methylpiperidine	-	Flam. Liquid 2 H225 Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 3 H331 Skin Corr. 1B H314 Eye Damage 1 H319 Aquatic Chronic 3 H412

## ASSESSMENT OF REGULATORY NEEDS

<b>212-161-6</b>	766-09-6	1-ethylpiperidine	-	Flam. Liquid 2 H225 Acute Tox. 3 H301 Acute Tox. 4 H312 Acute Tox. 3 H331 Skin Corr. 1B H314 Eye Damage 1 H318
<b>212-199-3</b>	768-66-1	2,2,6,6-tetramethylpiperidine	-	Acute Tox. 4 H302 [intermediate (active)] Acute Tox. 4 H332 [intermediate (active)] Flam. Liquid 3 H226 [intermediate (active)] Skin Irrit. 2 H314 [intermediate (active)]
<b>228-033-8</b>	6091-44-7	piperidinium chloride	-	Acute Tox. 3 H301 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)]
<b>230-463-6</b>	7148-07-4	N-(cyclopent-1-ene-1-yl)pyrrolidine	-	Skin Corr. 1B H314 [intermediate (active)] Flam. Liquid 3 H226 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)]
<b>240-941-6</b>	16898-52-5	4,4'-trimethylene dipiperidine	-	Acute Tox. 4 H302 Skin Corr. 1C H314 Eye Damage 1 H318 Aquatic Chronic 3 H412
<b>252-730-6</b>	35794-11-7	3,5-dimethylpiperidine	-	STOT Single Exp. 3 H335, affected organs: Respiratory tract [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Flam. Liquid 3 H226 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)]
<b>943-629-4</b>	1897428-40-8	(4S)-2,2,4-trimethylpyrrolidinium chloride	-	-

(\*) 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 27/02/2023

Main types of applications structured by product or article types	EC/List 203-813-0	EC/List 203-875-9	EC/List 204-438-5	EC/List 204-648-7	EC/List 210-954-1	EC/List 210-959-9	EC/List 212-161-6	EC/List 212-199-3	EC/List 228-033-8	EC/List 230-463-6	EC/List 240-941-6	EC/List 252-730-6	EC/List 943-629-4
<b>PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents</b>	F, I, <b>P</b>												
<b>PC 37: Water treatment chemicals</b>	I												
<b>PC 12: Fertilisers</b>	F, I, <b>P</b>												
<b>PC 27: Plant protection products</b>	I												
<b>PC 4: Anti-freeze and de-icing products</b>	F												
<b>PC 29: Pharmaceuticals</b>	I											I	

ASSESSMENT OF REGULATORY NEEDS

<b>PC 17: Hydraulic fluids</b>				I									
<b>PC 32: Polymer preparations and compounds</b>	I												
<b>PC 1: Adhesives, sealants</b>	I										F, I, A		
<b>PC 9b: Fillers, putties, plasters, modelling clay</b>	F, I												
<b>PC 9a: Coatings and paints, thinners, paint removes</b>	F, I												
<b>PC 18: Ink and toners</b>	I												
<b>PC 26: Paper and board treatment products</b>				I									
<b>PC 21: Laboratory chemicals</b>	F, I, P	I		I, P			F, P						
<b>PC 19: Intermediate</b>	I	I	I	I	I	I	I		I			I	I
<b>PC 30: Photo-chemicals</b>	I												

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

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

Data extracted on 15 May 2023

EC entries	RMOA	Authorisation		Restriction Annex XVII	CLH		Actions not under REACH/ CLP*
		Candidate List	Annex XIV		Annex VI (CLP)		
203-813-0	-	-	-	YES	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.