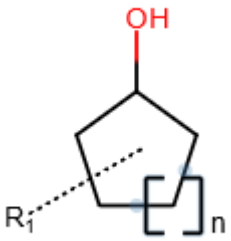
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Aliphatic monocyclic alcohols (OH connected to the cycle)

General structure:

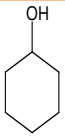
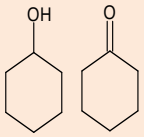
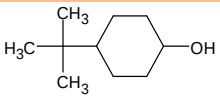
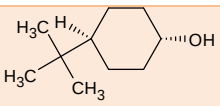
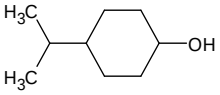
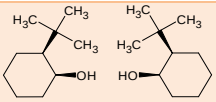
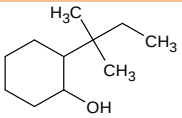
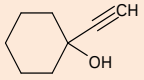
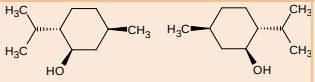


where: n = 1, 2, 3, 4, 8 and R various substituents (alkyl, alkenyl or alkynyl)

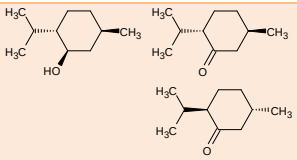
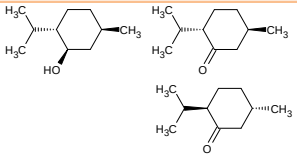
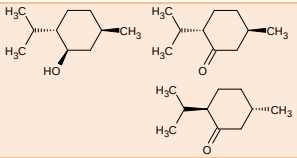
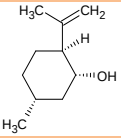
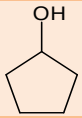
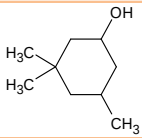
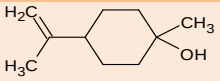
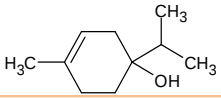
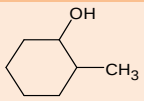
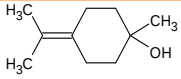
Revision history

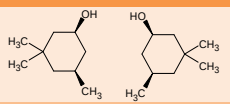
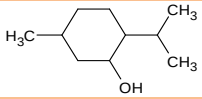
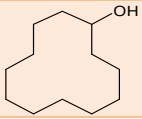
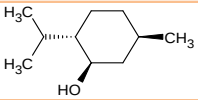
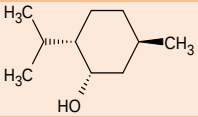
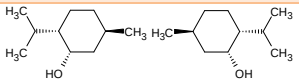
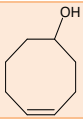
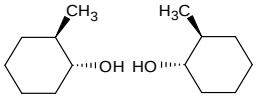
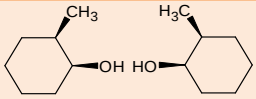
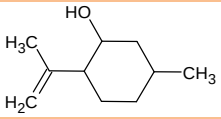
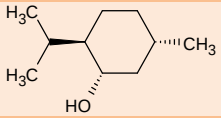
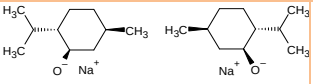
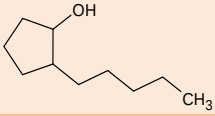
Version	*Date*	*Description*
1.0	18 October 2023	

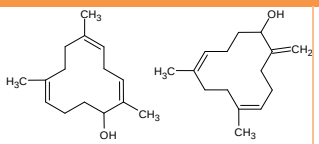
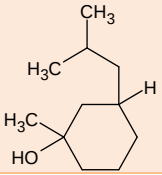
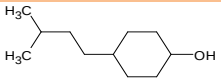
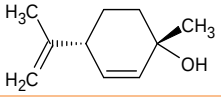
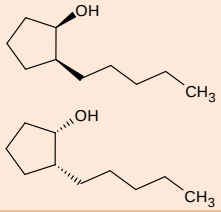
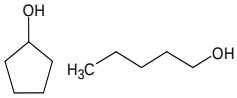
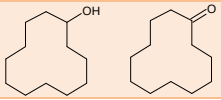
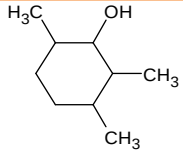
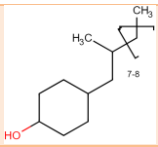
Substances within this group:

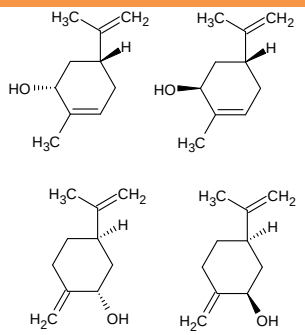
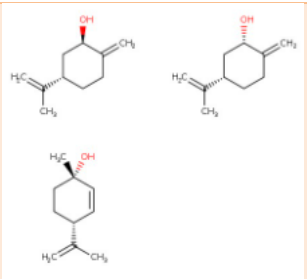
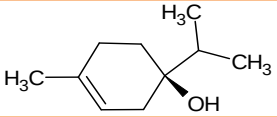
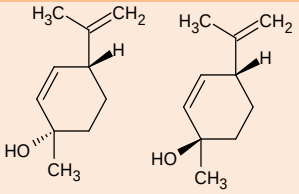
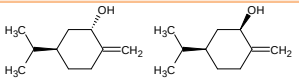
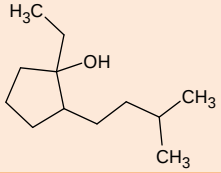
EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
Subgroup A				
203-630-6	108-93-0	cyclohexanol		Full, 100-1000
906-627-4		Reaction mass of cyclohexanol and cyclohexanone		OSII or TII
202-676-4	98-52-2	4-*tert*-butylcyclohexanol		Full, 10-100
700-127-8	21862-63-5	*trans*-4-*tert*-butylcyclohexanol		Full, not (publicly) available
225-035-0	4621-04-9	4-isopropylcyclohexanol		Full, not (publicly) available
230-601-5	7214-18-8	*cis*-2-*tert*-butylcyclohexan-1-ol		OSII or TII
618-712-0	91242-72-7	2-(2-methylbutan-2-yl)cyclohexanol		OSII or TII
201-100-9	78-27-3	1-ethynylcyclohexanol		Full, not (publicly) available
Subgroup B				
201-939-0 (239-388-3)	89-78-1	menthol		Full, >1000

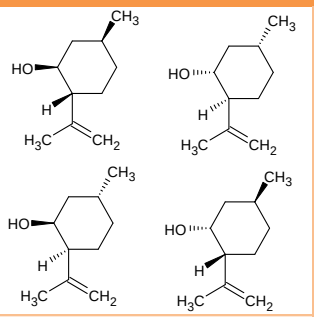
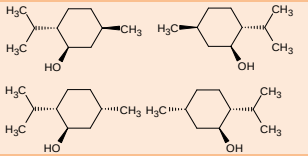
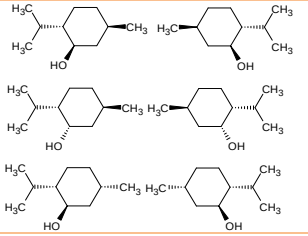
[1]The total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
Subgroup C				
282-015-4	84082-70-2	EC name: Peppermint, ext. IUPAC name: Essential oil of Peppermint obtained from the herb of Mentha piperita, Labiatae by distillation		Full, 100-1000
290-058-5	90063-97-1	EC name: Mentha arvensis, ext. IUPAC name: Essential oil of Cornmint obtained from the herb of Mentha Arvensis Linn (Lamiaceae) by distillation		Full, 100-1000
939-722-4	-	Mentha arvensis, Labiatae, extract		Cease manufacture
201-940-6	89-79-2	L-isopulegol or (-)-isopulegol or (1R,2S,5R)-5-methyl-2-(prop-1-en-2-yl)cyclohexanol		Full, not (publicly) available
202-504-8	96-41-3	cyclopentanol		OSII or TII
204-122-7	116-02-9	3,3,5-trimethylcyclohexanol		C&L notification
205-342-6	138-87-4	1-methyl-4-(1-methylvinyl)cyclohexan-1-ol		C&L notification
209-235-5	562-74-3	p-menth-1-en-4-ol		OSII or TII
209-512-0	583-59-5	2-methylcyclohexanol, mixed isomers		OSII or TII
209-584-3	586-81-2	1-methyl-4-(1-methylethylidene)cyclohexan-1-ol		C&L notification

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
213-268-0	933-48-2	*cis*-3,5,5-trimethylcyclohexan-1-ol		Full, 1-10
216-074-4	1490-04-6	DL-menthol		OSII or TII
217-031-2	1724-39-6	cyclododecanol		OSII or TII
218-690-9	2216-51-5	L-menthol		Full, >1000
218-691-4	2216-52-6	(+)-neomenthol		Full, not (publicly) available
222-824-1	3623-51-6	(±)-neomenthol		Full, not (publicly) available
224-280-0	4277-34-3	cyclooct-4-en-1-ol		OSII or TII
231-186-3	7443-52-9	*trans*-2-methylcyclohexanol		C&L notification
231-187-9	7443-70-1	*cis*-2-methylcyclohexanol		C&L notification
232-102-8	7786-67-6	5-methyl-2-(1-methylvinyl)cyclohexan-1-ol		Full, not (publicly) available
239-387-8	15356-60-2	(+)-menthol		Full, not (publicly) available
242-958-4	19321-38-1	sodium mentholate		Full, not (publicly) available
283-187-3	84560-00-9	2-pentylcyclopentan-1-ol		C&L notification

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
413-530-6	-	ELINCS: reaction mass of: 2,6,9-trimethyl-2,5,9-cyclododecatrien-1-ol; 6,9-dimethyl-2-methylen-5,9-cyclododecadien-1-ol		Full, not (publicly) available
434-380-8	215231-33-7	3-isobutyl-1-methylcyclohexanol		Full, not (publicly) available
454-810-8	830322-14-0	4-(3-methylbutyl)cyclohexanol		Full, not (publicly) available
467-270-3	-	Not (publicly) available		NONS
805-440-4	22972-51-6	(1S,4R)-1-methyl-4-(prop-1-en-2-yl)cyclohex-2-en-1-ol		OSII or TII
812-739-3	157357-30-7	Cyclopentanol, 2-pentyl-, (1R,2S)-*rel*-		Full, not (publicly) available
905-315-5	-	Reaction mass of cyclopentanol and pentanol		OSII or TII
909-034-9	-	Reaction mass of cyclododecanol and cyclododecanone		OSII or TII
918-414-3	58210-03-0	2,3,6-trimethylcyclohexanol		OSII or TII
938-702-2	-	cyclohexanol, 4-C11-12-alkyl, branched		Full, not (publicly) available

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
943-238-9	-	Reaction mass of Cyclohexanol, 2-methylene-5-(1-methylethenyl)-, (1S,5R)- and (1S-trans)-2-methyl-5-(1-methylvinyl)cyclohex-2-en-1-ol and Cyclohexanol, 2-methylene-5-(1-methylethenyl)-, (1R,5R)- and (1R-cis)-2-methyl-5-(1-methylvinyl)cyclohex-2-en-1-ol		OSII or TII
943-903-3	-	Not (publicly) available		OSII or TII
943-985-0	20126-76-5	(1R)-1-isopropyl-4-methyl-cyclohex-3-en-1-ol		Full, 1-10
944-020-6	-	Reaction mass of 2-Cyclohexen-1-ol, 1-methyl-4-(1-methylethenyl)-, (1R,4R)- and 2-Cyclohexen-1-ol, 1-methyl-4-(1-methylethenyl)-, (1S,4R)-		OSII or TII
944-198-5	-	Reaction mass of (1R,5R)-5-isopropyl-2-methylenecyclohexanol and (1S,5R)-5-isopropyl-2-methylenecyclohexanol		OSII or TII
944-561-8	1465004-85-6	1-ethyl-2-(3-methylbutyl)cyclopentanol		Full, not (publicly) available

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
946-911-5	-	Reaction mass of (1S*, 2R*, 5S*)-2-Isopropenyl-5-methylcyclohexanol and (1S*, 2S*, 5R*)-2-Isopropenyl-5-methylcyclohexanol		Full, not (publicly) available
947-851-2	-	Reaction mass of menthol and (±)-isomenthol		Full, not (publicly) available
947-882-1	-	Reaction mass of menthol and (±)-neomenthol and (±)-isomenthol		OSII or TII

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

Contents

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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)[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.

[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).

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 chemical's portfolio.

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

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

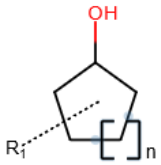
Glossary

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 **51**[5] structurally similar substances based on the presence of a hydroxyl functional group attached to an aliphatic ring, as shown in the figure below:



where: n = 1, 2, 3, 4, 8 and R various substituents (alkyl, alkenyl or alkynyl)

The registration status of the substances is the following: 25 with full (Article 10) registrations, 18 intermediate registrations and 1 updated NONS. Additionally, one substance has the status "ceased manufacture" and 6 substances only have C&L notifications.

Three sub-groups were identified based on the hazard profile of the substances and related regulatory actions planned:

- subgroup A, comprising 8 substances, which have potential hazards for STOT RE (neurotoxicity) and aquatic toxicity.
- subgroup B, comprising menthol (EC 201-939-0), which has inconclusive hazards for human health (reproductive toxicity and ED).
- subgroup C, comprising 43 substances, which has "unlikely" hazards for human health except for 5 substances which are sensitising, while for environment there are 17 substances with (potentially) aquatic toxicity, and a couple with potential PBT and/or PMT hazards.

No harmonised classification is in place for the above listed hazards. Some substances in the group are sensitising and self-classifications are done in the dossiers. Cyclohexanol, EC 203-630-6, is restricted under REACH (REACH Annex XVII, entry 75).

Based on information reported in the REACH registration dossiers, all except three of the fully registered substances in this group are used in cosmetics. Additional common uses include use in washing and cleaning products, biocidal products, perfumes, air care products and polishes and waxes. All except three of the fully registered substances in this group have widespread uses, leading to a high potential for exposure for workers and/or consumers, as well as a high potential for release to the environment. For three substances, article service life (e.g. in scented articles) is also reported. The substances are used in the mentioned applications mostly as a fragrance. In some applications, the substances are used as an intermediate, precursor, processing aid, laboratory chemical, flavouring agent or solvent.

[5]This group of substances comprises 52 EC/List numbers, however the EC 239-388-3 number is invalid, as the associated CAS number 15356-70-4 is deleted from the CAS Registry.

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 12: Conclusions and proposed actions

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
Subgroup A: **201-100-9** **202-676-4** **203-630-6** **225-035-0** **230-601-5** **618-712-0** **700-127-8** **906-627-4**	Known or potential hazard for STOT RE Inconclusive hazard for reproductive toxicity (only EC 202-676-4)	Known or potential hazard for aquatic toxicity (only EC 203-630-6, and List 906-627-4) Inconclusive hazard for PBT/vPvB and/or PMT/vPvM: EC 201-100-9, list 618-712-0 Inconclusive hazard for aquatic toxicity EC 202-676-4	Widespread uses, PROF and CONS uses in cosmetics, cleaning and disinfecting products, air care products, plant protection products. IND uses in cleaning products, inks, paper/board treatment, as intermediate. 201-100-9: PROF uses in laboratory chemicals 230-601-5: intermediate (potential for substitution) 618-712-0: on-site isolated intermediate	**First step:** CCH (201-100-9, 202-676-4, 203-630-6, 700-127-8) Pending action: 225-035-0, 230-601-5 **Potential next steps (if hazard confirmed after data generation):** CLH **Potential last action:** Restriction 618-712-0, 906-627-4: No action Justification: The harmonised classification as STOT RE 1 will support implementation of necessary RRMs at the workplace and regulatory action under Biocidal Products Regulation.

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
			906-627-4: intermediate	Restriction to address all other professional and consumer uses, except in cosmetics and in foodstuff flavouring.
Subgroup B: **201-939-0 (239-388-3)**	Known or potential hazard for skin sensitisation Inconclusive hazard for reproductive toxicity and for ED	No hazard or unlikely hazard for aquatic toxicity for PBT/vPvB	Widespread uses, IND and/or PROF and/or CONS uses in cosmetics, perfumes, cleaning and disinfecting products, air care products, pharmaceuticals.	**First step:** CCH **Potential last action:** Currently not possible to assess the regulatory needs

Subgroup C: **201-940-6** **202-504-8** [1)] **204-122-7** [2)] **205-342-6** [2)] **209-235-5** [1)] **209-512-0** [1)] **209-584-3** [2)] **213-268-0** **216-074-4** [1)] **217-031-2** [1)] **218-690-9, 218-691-4, 222-824-1** **224-280-0** [1)] **231-187-9** [2)] **231-186-3** [2)] **232-102-8, 239-387-8, 242-958-4,** **282-015-4,** **283-187-3** [2)] **290-058-5, 413-530-6, 434-380-8,** **454-810-8, 467-270-3,**	Known or potential hazard for skin sensitisation (222-824-1, 282-015-4, 290-058-5, 938-702-2, 939-722-4) Inconclusive hazard for STOT RE (213-268-0, 909-034-9, 812-739-3) for skin sensitisation (413-530-6)	Known or potential hazard for aquatic toxicity (213-268-0, 217-031-2, 231-187-9, 231-186-3, 282-015-4, 290-058-5, 413-530-6, 909-034-9, 918-414-3, 939-722-4, 944-561-8, 947-851-2) for PBT/vPvB (454-810-8, 938-702-2) Inconclusive hazard for PBT/vPvB and/or PMT/vPvM (209-235-5, 224-280-0, 282-015-4, 290-058-5, 467-270-3, 618-712-0, 805-440-4, 939-722-4) for aquatic toxicity (209-235-5, 434-380-8, 454-810-8, 467-270-3, 805-440-4)	Widespread uses: PROF and CONS uses in cosmetics, cleaning and disinfecting products, air care products. IND uses in the some of the applications. 242-958-4: IND uses in plant protection products, pharmaceuticals, laboratory chemicals. 938-702-2: IND uses in coatings and paints and as intermediate. 218-690-9, 239-387-8, 282-015-4: ASL in e.g. scented articles 939-722-4: inactive registration	**First step:** CCH (213-268-0, 218-690-9, 222-824-1, 232-102-8, 242-958-4, 282-015-4, 290-058-5, 812-739-3, 938-702-2) **Potential last action:** Currently no need for EU RRM <u>Justification:</u> Harmonised/self-classification (will) require company level risk management measures (RMM) for workers to be in place. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation. Aquatic tox: Harmonised/self-classification (will) require company level risk management measures (RMM) for environment to be in place. Due to low tonnage and NONs, no data generation is possible to clarify the PBT hazards currently. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change. Intermediates: According to the reported uses, low potential for exposure to both human health and environment is expected. Actions may be re-considered if there is a change in the

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
805-440-4 [1)] **812-739-3** **905-315-5** [1)] **909-034-9** [1)] **918-414-3** [1)] **938-702-2** **939-722-4** **943-238-9** [1)] **943-903-3** [1)] **943-985-0** **944-020-6** [1)] **944-198-5** [1)] **944-561-8, 946-911-5, 947-851-2,** **947-882-1** [1)]				registration status and/or reported uses. when the assessment will be revisited.

1) Intermediate use; 2) C&L notification

3 Justification for the (no) need for regulatory risk management action at EU level (if hazards confirmed)

Suggested regulatory risk management action for all subgroup A members, except List no. 618-712-0 and 906-627-4, if STOT RE (neurotoxicity) hazard is confirmed.

Based on ECHA's assessment of currently available hazard information and considerations of structural similarity and presence of common functional moiety, all the substances in subgroup A have a potential hazard for STOT RE (neurotoxicity). This hazard is identified based on observed effects from a limited number of substances in the subgroup (3 out of 6 substances with registration dossiers).

Potential neurotoxicity (STOT RE 1) was identified in repeated dose studies for: EC 201-100-9 (1-ethynylcyclohexanol) and EC 202-676-4 (4-tert-butylcyclohexanol), and EC 203-630-6 (cyclohexanol).

An OECD 422 with EC 201-100-9 derived a NOAEL of 30 mg/kg bw based on uncoordinated movements, flat posture, and hunched posture in both sexes at 150 mg/kg bw/d. Reduced grip strength noted for one male and three females were also noted at this dose level. Also, in an OECD 408 there were semi closed eyelids, slight ataxia and abdominal position in some individuals on study day 53 at 150 mg/kg bw.

An OECD 407 with EC 202-676-4 found a NOAEL of 150 mg/kg bw/d based on effects on neurobehaviour, motor activity, body weight at 300 mg/kg bw/d (highest dose). These effects were seen at doses below the guidance values when adjusted for study duration. Overall, the effects seen may warrant classification as STOT RE 1.

The data screened in the cyclohexanol (EC 203-630-6) dossier also revealed potential for classification as STOT RE 1 for neurotoxicity. A 90-d study via inhalation in rat found a NOAEL 0.057 mg/m^3 based on decreased cholinesterase activity (indicated by an increased time needed for hydrolysis of acetylcholin) and an increase in the ascorbic acid content of the liver (by 30% after 2 months) in the high dose of 0.061 mg/m3.

Also, at this dose, changes in the interrelationship of the chronaxia of the extensor and flexor muscles (decrease) was observed after 7 weeks. The effects described in this study and the overall neurotoxic profile from the other studies seem to fit the cholinesterase inhibitors mode of action (MoA). Cholinesterase inhibitors (anticholinesterases), (a typical neurotoxic MoA for e.g., for carbamates & organophosphates) causes increased levels of acetylcholine neurotransmitter that influences e.g., skeletal muscle contraction. There are also some findings supporting such MoA for cyclohexanol presented in scientific literature.

Based on structural similarity the findings from the repeated dose toxicity studies are extrapolated with medium uncertainty to List 906-627-41, EC 700-127-8, EC 225-035-0, EC 230-601-5, EC 618-712-0, where there is limited information for these endpoints.

Based on the available data (repeated dose toxicity studies and reproductive toxicity studies), there are no indications for an ED hazard potential.

Subgroup A has unlikely reproductive toxicity. For the substance EC 201-100-9 (1-ethynylcyclohexanol) an OECD 422 showed no reproductive toxicity up to 150 mg/kg bw/d (highest dose). On the basis of structural similarity this outcome was extrapolated with low confidence (due to low data density) to the other members of sub-group A. It cannot yet be concluded if the *tert*-butyl moiety in EC 202-676-4 may cause reproductive toxicity hazard or if its hazard profile is similar to the others in the same subgroup. A CCH is proposed to clarify the hazard.

No carcinogenicity data are available for this subgroup, but the substances are unlikely mutagenic. Due to availability of negative genotoxicity studies and lack of indication for neoplastic changes in the available repeated dose studies in all the sub-groups, the negative findings in a carcinogenicity study with menthol (EC 201-939-0) were extrapolated for the other sub-groups. Therefore, the related substances in sub-group A are also considered having unlikely hazard for this endpoint.

For the environmental assessment, there is no PMT/vPvM or PBT/vPvB hazard potential in this subgroup except for one substance for which it is not possible to conclude on the PBT and PMT hazards in absence of sufficient information. Most of the substances are not persistent and fulfil the criteria for ready biodegradation, hence cannot be considered as potential PBT. They also have low log Kow and insufficient data on aquatic toxicity or human health toxicity, proving they would fulfil T criteria.

For PMT, the considerations are similar as for PBT – when assessing persistence and toxicity most of the substances are readily biodegradable, so would not fulfil PMT. Concerning mobility, some substances may be mobile, but the PMT hazard remains inconclusive in the absence of reliable data on persistence or on toxicity. For instance, EC 201-100-9 is considered inconclusive for PMT while it fulfils persistence criteria; based on screening data only, it has potential for mobility but is not conclusive for toxicity. Consequently, the potential hazards will need to be further confirmed or not via CCH.

Based on ECHA's assessment of currently available hazard information, the substances are otherwise mainly unlikely aquatic toxic, except for List number 906-627-4 which is self-classified as Aquatic chronic 2. In addition, two substances could also be potentially aquatic toxic, but this needs to be clarified via CCH.

For toxicity, the data provided for ECs 222-824-1 and 218-690-9 are relying on read-across (except for skin sensitisation), and for key hazards also for EC 812-739-3, 222-824, 218-690-9, 290-058-5, EC 282-015-4, EC 242-958-4, and EC 232-102-8, and toxicity is considered as inconclusive whether for human health or aquatic toxicity. Therefore, most of the substances do not have data of their own to confirm if they have or not this hazard, despite their similarities.
Based on the above, the potential and inconclusive hazards for STOT RE, PBT, PMT and aquatic toxicity need to be further clarified via CCH.

In terms of uses, most substances in the group are used in cosmetics by consumers. Additional uses include consumer and/or professional uses in cleaning and disinfecting products, perfumes, air care products and plant protection products. Some of the applications seem to be of particular relevance due to the potential hazards (neurotoxicity) and route of exposure (inhalation) and lead to a high potential for exposure for workers and/or consumers, as well as a high potential for release to the environment. One substance (EC 201-100-9) has only one declared widespread use by professionals in laboratory chemicals, and three substances (EC 230-601-5 and Lists 618-712-0 and 906-627-4) are used as

intermediates, but potential for substitution cannot be excluded for EC 230-601-5 and List 618-712-0.

Based on the above considerations on hazards and uses and other needs to clarify hazards, the first proposed action is **compliance check** (for ECs 201-100-9, 202-676-4, 203-630-6 and List 700-127-8) to confirm the hazards (including STOT RE, skin sensitisation, PMT and aquatic toxicity) and low concern for other endpoints.

The first step of the regulatory risk management, should the hazard(s) exist, is the confirmation of hazard via **harmonised classification (CLH)** as STOT RE cat 1 for all substances in the sub-subgroup.

When preparing the proposals, it may be considered what would be the best way to develop them, for instance whether to make a proposal for the group of substances, to submit them individually or jointly. For EC 203-630-6, it may also be considered to take into account the aquatic toxicity.

CLH:

i) will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place,
ii) is needed or highly recommended for further regulatory processes under REACH.

CLH will also support regulatory action under other regulations. For instance, in this specific case, for ECs 202-676-4 and 225-035-0 harmonised classification as STOT RE 1 will trigger regulatory action under the biocidal product regulation (EU) 528/2012, for products containing the substances.

The professional uses in cleaning products, plant protection products and polishes and waxes 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.

Consumers may be co-exposed to the substances used by professionals, *e.g.*, cleaning and disinfection activities, particularly those applications involving spraying due to the route of exposure that leads to the hazards – inhalation, and also cosmetics used by professionals in e.g. beauty salons. Moreover, some of the substances are used as flavouring agents.

Therefore, a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by consumers and professionals** is suggested after CLH, for all substances in subgroup A except List 618-712-0, which is registered as an on-site isolated intermediate, and List 906-627-4.

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[6] which aims to extend to professional users under REACH the level of protection granted to consumers.

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

It is suggested to cover possibly also industrial uses as part of the restriction.

Currently not possible to suggest regulatory risk management actions for of EC 201-939-0 in subgroup B

Based on currently available information, it is not possible to assess the needs for regulatory risk management for menthol (EC 201-939-0) as information on hazard is not sufficient to conclude on developmental toxicity and ED (human health) hazards. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).

From the human health side, based on ECHA's assessment of currently available hazard information, the available EOGRTS study with EC 201-939-0 indicates an unlikely hazard for fertility but is inconclusive for ED, since the ED effects observed appeared to be transitory. Findings in the EOGRTS are also suggestive for potential developmental toxicity (reduced pre-weaning growth in both generations) but remain inconclusive as there is no PNDT study available to confirm this observation. CCH may clarify the developmental hazard potential. Based on the outcome, the need to further address the potential ED HH properties should be reconsidered. Additionally, for EC 201-939-0 the potential for skin sensitisation (suggested by some human data in the dossier) needs to be clarified via CCH.

From the environmental side based on ECHA's assessment of currently available hazard information, the substance is unlikely ED, PBT, PMT or aquatic toxic as the substance is readily biodegradable and has very low aquatic toxicity.

Currently no need to suggest (further) regulatory risk management actions for all substances in subgroup C

From the human health side, based on ECHA's assessment of currently available hazard information, all substances in the subgroup C are unlikely to have the following human health hazards: C/M/R, ED, skin sensitisation with the following exceptions:

- sensitising potential for EC 282-015-4, EC 290-058-5, List 939-722-4, EC 222-824-1 (due to impurity EC 905-013-3) and List 938-702-2.

Several genotoxicity studies are available with negative results. Due to availability of negative genotoxicity studies and lack of indication for neoplastic changes in the available repeated dose studies in all the sub-groups, the negative findings in a carcinogenicity study with menthol (EC 201-939-0) were extrapolated for the other sub-groups. Therefore, the related substances in sub-group C are also considered "unlikely" for this endpoint.

Based on the available data (repeated dose toxicity studies and reproductive toxicity studies), there are no indication for an ED hazard potential.

From the environmental assessment, for the PBT/vPvB hazard, only EC 454-810-8 and List 938-702-2 of the subgroup C screen for persistence and bioaccumulation based only though on screening criteria. Nevertheless, due to the registration status for both substances no further data generation is possible to conclude on this hazard. Consequently, no need for further RRM is foreseen either for these substances.

In absence of reliable data, the following substances in the subgroup C are considered as potential or inconclusive PBT – ECs 209-235-5 and 224-280-0, ECs

282-015-4, 290-058-5 and List 939-722-4, but also 467-270-3 and List 805-440-4, where the information on PBT properties is not sufficient to conclude. These substances are screening either P/vP based only on screening level information or inconclusive for persistency because of their complex compositions as multi-constituents and UVCBs substances. Concerning ECs 282-015-4, 290-058-5 and List 939-722-4, these substances would screen potentially for bioaccumulation due to their complex and different constituents. But in absence of data other than QSAR and read-across from other substances for log Kow, it is not possible to conclude on the property and determine whether there is indeed a bioaccumulation potential.

Furthermore, for the following substances in subgroup C: EC numbers 213-268-0, 218-691-4, 222-824-1, 209-235-5 and 224-280-0, 413-530-6, 434-380-8, 454-810-8, 467-270-3, List numbers 805-440-4 and 944-561-8, it is not possible to conclude on the PMT/vPvM hazard in absence of sufficient information. The substances are potentially P and are expected to be mobile in the environment due to low log Kow and/or Log Koc and are also potentially toxic. However, in absence of reliable data or because of the registration status of most of these substances, the potential hazard as PMT or vPvM cannot be further assessed or clarified.

For all the other substances of sub-group C, based on ECHA's assessment of currently available hazard information, the following hazard is considered unlikely: PBT and PMT, as the substances are readily biodegradable or not persistent.

In the subgroup C, 17 substances have the potential aquatic toxicity hazard; in particular, the following substances are either self-classified as Aquatic chronic 2 or 3: EC numbers 213-268-0,217-031-2, 231-187-9, 231-186-3, 282-015-4, 290-058-5, 413-530-6, 434-380-8, List numbers 909-034-9, 918-414-3, 939-722-4, 944-561-8, 947-851-2 and this confirms their aquatic toxicity hazard.

In addition, aquatic toxicity is considered as inconclusive for EC numbers 209-235-5, 224-280-0, 454-810-8 despite the self-classification as aquatic chronic 2, 467-270-3 and List numbers 805-440-4 and 947-851-2 in absence of relevant data in the dossiers. All the others are considered as unlikely aquatic toxic based on acute aquatic toxicity data showing very low or no aquatic toxicity effects. Nevertheless, due to the diversity in chemical structures between the substances, it is not possible to extrapolate the absence of hazards in this subgroup and the absence of hazard is based on data provided for the substances with medium uncertainty.

In terms of uses, most of the registered substances have declared widespread uses in cosmetics. Additional common widespread uses are reported for cleaning products, polishes and waxes, biocides, perfumes, air care products and pharmaceuticals, leading to a high potential for exposure for workers and/or consumers, as well as a high potential for release to the environment. Three substances (ES numbers 218-690-9, 239-387-8 and 282-015-4) have declared articles service life in e.g. scented articles. Two of the registered substances (EC 242-958-4 and List 938-702-2) have only industrial uses and one of the registered substances (List 909-034-9) has only intermediate uses. The other substances are registered as intermediates or not registered. No potential for substitution is envisaged. The registration as an intermediate of List 939-722-4 is inactive.

Based on the above considerations on hazards and uses, the proposed action is **compliance check**, for some substances (EC numbers 213-268-0, 218-690-9, 222-824-1, 232-102-8, 242-958-4, 282-015-4, 290-058-5 and List numbers 812-739-3 and 938-702-2) to confirm low concern for human health hazard or clarify the hazards for aquatic toxicity and PBT or PMT.

In relation to the skin sensitising substances, EC numbers 282-015-4 and 290-058-5 are self-classified as Skin Sens. 1. These two substances are used in many widespread applications, such as cleaning and disinfecting products, perfumes, air care products and cosmetics. EC 222-824-1 is self-classified as Skin Sens 1 and is reported as being used only in cosmetics by consumers.

For industrial and professional uses, sufficient and consistent self-classification by registrants should require company level risk management measures (RMM) to be in place for workers.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing these skin sensitising substances.

For the use of the substances in cosmetics, sufficient and consistent self-classification by registrants would inform on the need or not for classification of the final product and safety assessment to be done according to Cosmetic product regulation (EC) No 1223/2009.

However, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern.

Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

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

Due to their registration or NONS status it is not possible to clarify the potential PBT and/or PMT and aquatic toxicity hazards of substances EC numbers 209-235-5, 213-268-0, 224-280-0, 413-530-6, 434-380-8, 454-810-8 and 467-270-3 and List numbers 805-440-4, 938-702-2 and 944-561-8. 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.

It is expected that, following data generation for aquatic toxicity, registrants would adequately self-classify the substances and, as well as based on existing self-classifications (*e.g.*, List 947-851-2), implement necessary RMMs to ensure safe use. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management to address aquatic toxicity.

Overall, for the other substances in this subgroup, there is no or unlikely hazard that would lead to concern for the reported uses. Additionally, several substances are registered as intermediates only and other substances are not registered.

If the registration status changes for the non-registered substances and the substances subject to NONS registration, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

Annex 1: Overview of classifications

Data extracted on 17 January 2023.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
201-100-9	78-27-3	1-ethynylcyclohexanol	-	*Acute Tox. 4 H302* *Acute Tox. 3 H311* *Skin Irrit. 2 H315*
201-939-0 (239-388-3)	89-78-1	menthol	-	*Skin Irrit. 2 H315, specific concentration: >25* *Eye Irrit. 2 H319, specific concentration: >25*
201-940-6	89-79-2	EINECS: isopulegol Correct name: L-isopulegol or (-)-isopulegol or (1R,2S,5R)-5-methyl-2-(prop-1-en-2-yl)cyclohexanol	-	*Acute Tox. 4 H302* *Skin Irrit. 2 H315* *Eye Irrit. 2 H319*
202-504-8	96-41-3	cyclopentanol	-	*Acute Tox. 4 H302* *STOT Single Exp. 3 H335, affected organs: Respiratory system* *Eye Irrit. 2 H319* *Flam. Liquid 3 H226* *Acute Tox. 4 H332* *Skin Irrit. 2 H315*
202-676-4	98-52-2	4-*tert*-butylcyclohexanol	-	*Eye Irrit. 2 H319* *Eye Irrit. 2A H319*
203-630-6	108-93-0	cyclohexanol	*Acute Tox. 4 H302* *Skin Irrit. 2 H315* *STOT SE 3 H335* *Acute Tox. 4 H332*	*Flam. Liquid 3 H226* *Acute Tox. 4 H302* *Acute Tox. 4 H312* *Acute Tox. 4 H332* *Skin Irrit. 2 H315* *Eye Damage 1 H318* *Eye Irrit. 2 H319* *STOT Single Exp. 3 H335, affected organs: Respiratory tract* *STOT Single Exp. 3 H335, affected organs: respiratory tract* *Aquatic Chronic 3 H412*
204-122-7	116-02-9	3,3,5-trimethylcyclohexanol	-	-
205-342-6	138-87-4	1-methyl-4-(1-methylvinyl)cyclohexan-1-ol	-	-
209-235-5	562-74-3	p-menth-1-en-4-ol	-	*Acute Tox. 4 H332* *Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Skin Sens. 1 H317* *Acute Tox. 4 H302* *STOT Single Exp. 3 H336, affected organs: CNS*
209-512-0	583-59-5	2-methylcyclohexanol, mixed isomers	*Acute Tox. 4 H332* *Notes: C*	*Acute Tox. 4 H302* *Eye Irrit. 2 H319* *Acute Tox. 4 H332*

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
209-584-3	586-81-2	1-methyl-4-(1-methylethylidene)cyclohexan-1-ol	-	-
213-268-0	933-48-2	*cis*-3,5,5-trimethylcyclohexan-1-ol	-	*Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Aquatic Chronic 3 H412*
216-074-4	1490-04-6	DL-menthol	-	*Skin Irrit. 2 H315, specific concentration: >25* *Eye Irrit. 2 H319, specific concentration: >25*
217-031-2	1724-39-6	cyclododecanol	-	*Aquatic Chronic 2 H411*
218-690-9	2216-51-5	L-menthol	-	*Skin Irrit. 2 H315, specific concentration: >25* *Eye Irrit. 2 H319, specific concentration: >25*
218-691-4	2216-52-6	(+)-neomenthol	-	*Skin Irrit. 2 H315*
222-824-1	3623-51-6	(±)-neomenthol	-	*Skin Irrit. 2 H315, specific concentration: >25-<=100* *Eye Irrit. 2 H319, specific concentration: >25-<=100* *Skin Sens. 1 H317*
224-280-0	4277-34-3	cyclooct-4-en-1-ol	-	-
225-035-0	4621-04-9	4-isopropylcyclohexanol	-	*Eye Irrit. 2 H319*
230-601-5	7214-18-8	*cis*-2-*tert*-butylcyclohexan-1-ol	-	-
231-186-3	7443-52-9	*trans*-2-methylcyclohexanol	*Acute Tox. 4 H332* *Notes: C*	-
231-187-9	7443-70-1	*cis*-2-methylcyclohexanol	*Acute Tox. 4 H332* *Notes: C*	-
232-102-8	7786-67-6	5-methyl-2-(1-methylvinyl)cyclohexan-1-ol	-	*Acute Tox. 4 H302* *Skin Irrit. 2 H315* *Eye Irrit. 2 H319*
239-387-8	15356-60-2	(+)-menthol	-	*Skin Irrit. 2 H315*
242-958-4	19321-38-1	sodium mentholate	-	*Flam. Solid 1 H228* *Self Heat. 1 H251* *Skin Corr. 1 H314* *Eye Damage 1 H318*
282-015-4	84082-70-2	EC name: Peppermint, ext. IUPAC name: Essential oil of Peppermint obtained from the herb of Mentha piperita, Labiatae by distillation	-	*Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Skin Sens. 1 H317* *Aquatic Chronic 3 H412*
283-187-3	84560-00-9	2-pentylcyclopentan-1-ol	-	-
290-058-5	90063-97-1	EC name: Mentha arvensis, ext. IUPAC name: Essential oil of Cornmint obtained from the	-	*Acute Tox. 4 H302* *Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Skin Sens. 1 H317* *Aquatic Chronic 2 H411*

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
		herb of Mentha Arvensis Linn (Lamiaceae) by distillation		*Aquatic Chronic 3 H412* *Aquatic Chronic 3 H413*
413-530-6	-	ELINCS: reaction mass of: 2,6,9-trimethyl-2,5,9-cyclododecatrien-1-ol; 6,9-dimethyl-2-methylen-5,9-cyclododecadien-1-ol	-	*Eye Irrit. 2 H319* *Aquatic Chronic 2 H411*
434-380-8	21523 1-33-7	3-isobutyl-1-methylcyclohexanol	-	*Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Aquatic Chronic 3 H412*
454-810-8	83032 2-14-0	4-(3-methylbutyl)cyclohexanol	-	*Skin Irrit. 2 H315* *Eye Damage 1 H318* *Aquatic Chronic 2 H411*
467-270-3	-	-	-	
618-712-0	91242 -72-7	2-(2-methylbutan-2-yl)cyclohexanol	-	-
700-127-8	21862 -63-5	*trans*-4-*tert*-butylcyclohexanol	-	-
805-440-4	22972 -51-6	(1S,4R)-1-methyl-4-(prop-1-en-2-yl)cyclohex-2-en-1-ol	-	*STOT Single Exp. 3 H335, affected organs: Respiratory system*
812-739-3	15735 7-30-7	Cyclopentanol, 2-pentyl-, (1R,2S)-rel-	-	*Skin Irrit. 2 H315* *Eye Irrit. 2 H319*
905-315-5	-	Reaction mass of cyclopentanol and pentanol	-	*STOT Single Exp. 3 H335, affected organs: respiratory tract* *Flam. Liquid 3 H226* *Skin Irrit. 2 H315* *Acute Tox. 4 H332*
906-627-4		Reaction mass of cyclohexanol and cyclohexanone	-	*Flam. Liquid 3 H226* *Eye Irrit. 2 H319* *Aquatic Chronic 3 H412* *Acute Tox. 4 H312* *STOT Single Exp. 3 H335, affected organs: respiratory tract* *Acute Tox. 4 H332* *Skin Irrit. 2 H315* *Acute Tox. 4 H302*
909-034-9	-	Reaction mass of cyclododecanol and cyclododecanone	-	*Aquatic Chronic 2 H411*
918-414-3	58210 -03-0	2,3,6-trimethylcyclohexanol	-	*Aquatic Chronic 3 H412* *Eye Irrit. 2 H319* *Skin Irrit. 2 H315*
938-702-2	-	cyclohexanol, 4-C11-12-alkyl, branched	-	*Skin Irrit. 2 H315* *Skin Sens. 1B H317* *Aquatic Chronic 4 H413*
939-722-4	-	Mentha arvensis, Labiatae, extract	-	*Eye Irrit. 2 H319* *Skin Irrit. 2 H315* *Skin Sens. 1 H317* *Acute Tox. 4 H302* *Aquatic Chronic 2 H411*
943-238-9	-	Reaction mass of Cyclohexanol, 2-methylene-5-(1-methylethenyl)-, (1S,5R)- and (1S-trans)-2-methyl-5-(1-	-	-

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
		methylvinyl)cyclohex-2-en-1-ol and Cyclohexanol, 2-methylene-5-(1-methylethenyl)-, (1R,5R)- and (1R-cis)-2-methyl-5-(1-methylvinyl)cyclohex-2-en-1-ol		
943-903-3	-	-	-	*Acute Tox. 4 H302*
943-985-0	20126-76-5	(1R)-1-isopropyl-4-methyl-cyclohex-3-en-1-ol	-	*Acute Tox. 4 H302* *Skin Irrit. 2 H315* *Eye Irrit. 2 H319*
944-020-6	-	Reaction mass of 2-Cyclohexen-1-ol, 1-methyl-4-(1-methylethenyl)-, (1R,4R)- and 2-Cyclohexen-1-ol, 1-methyl-4-(1-methylethenyl)-, (1S,4R)-	-	*Acute Tox. 4 H302*
944-198-5	-	Reaction mass of (1R,5R)-5-isopropyl-2-methylenecyclohexanol and (1S,5R)-5-isopropyl-2-methylenecyclohexanol	-	-
944-561-8	14650 04-85-6	1-ethyl-2-(3-methylbutyl)cyclopentanol	-	*Acute Tox. 4 H332* *Eye Irrit. 2 H319* *Aquatic Chronic 2 H411*
946-911-5	-	Reaction mass of (1S*, 2R*, 5S*)-2-Isopropenyl-5-methylcyclohexanol and (1S*, 2S*, 5R*)-2-Isopropenyl-5-methylcyclohexanol	-	*Acute Tox. 4 H302* *Skin Irrit. 2 H315*
947-851-2	-	Reaction mass of menthol and (±)-isomenthol	-	*Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Aquatic Acute 1 H400* *Aquatic Chronic 3 H412*
947-882-1	-	Reaction mass of menthol and (±)-neomenthol and (±)-isomenthol	-	*Skin Irrit. 2 H315* *Eye Irrit. 2 H319*

(*) 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 20/12/2022

Main types of applications structured by product or article types	201-100-9	201-939-0	201-940-6	202-676-4	203-630-6	213-268-0	218-690-9	218-691-4	222-824-1	225-035-0	232-102-8	239-387-8	242-958-4	282-015-4	290-058-5	413-530-6	434-380-8	454-810-8	700-127-8	812-739-3	938-702-2	943-985-0	944-561-8	946-911-5	947-851-2
PC 20: Products such as ph-regulators, (...)					I, **P**		**C**																		
PC 12: Fertilisers							**C**						I												
PC 27: Plant protection products					F, **P**, **C**		**C**																		
PC 4: Anti-freeze and de-icing products							**C**							**C**	**C**										
PC 35: Washing and cleaning products		I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	F, I	I, **P**, **C**	F, I, **P**, **C**	I, **P, A**		F, I, **P**, **C**	I, **P**, **C**	**P**, **C, A**		F, I, **P**, **C**	F, I, **P**, **C**		F, I, **P**, **C**			I, **P**, **C**		F, I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	I, **P**, **C**
PC 8: Biocidal products (e.g. disinfectants, pest control)		**C**	**C**	**C**		**C**	F, **C**	**C**		F, I, **P**, **C**	**C**	**C**		**C**	**C**		F, I, **P**, **C**			**C**		**P**, **C**	**C**	**C**	**C**

Main types of applications structured by product or article types	201-100-9	201-939-0	201-940-6	202-676-4	203-630-6	213-268-0	218-690-9	218-691-4	222-824-1	225-035-0	232-102-8	239-387-8	242-958-4	282-015-4	290-058-5	413-530-6	434-380-8	454-810-8	700-127-8	812-739-3	938-702-2	943-985-0	944-561-8	946-911-5	947-851-2
PC 28: Perfumes, fragrances		F, I, **C**	F, **C**	F, **C**		F, **C**	F, I, **P, C**	F, **C, A**		F, **C**	F, **C**	F, **A**		F, I, **P, C**	F, I, **P, C**		F, **C**	I, **P**		F, **C**		F, **C**	F, **C**	**C**	**C**
PC 3: Air care products		**C**	**C**	**C**		**C**	F, I, **C**	**C**		F, **C**	**C**	**C**		F, I, **C**	**C**		F, **C**			**C**		**C**	**C**	**C**	**C**
PC 39: Cosmetics, personal care products		F, I, **C**	**C**	**C**	F, **P, C**	F, **P, C**	F, I, **P, C**	**C**	F, **C**	**P, C**	**C**	**C**		F, I, **P, C**	F, I, **P, C**	**P, C**	**P, C**	**P**	**C**	**C**		F, **P, C**	**P, C**	**C**	**C**
PC 29: Pharmaceuticals		F, I, **C**					F, I, **P, C**				F, **C**		I	F, I	I, **C**										
PC 31: Polishes and wax blends		**P, C**	**P, C**	**P, C**		**P, C**	F, **P, C**	**P, C**		F, **P, C**	**P, C**	**P, C**		**P, C**	**P, C**		F, **P, C**			**P, C**		**P, C**	**P, C**	**P, C**	**P, C**
PC 24: Lubricants, greases, release products							**C**							**C**	**C**										
PC 13: Fuels							**C**					**C**													
PC 32: Polymer preparations							F, **C**														F				

Main types of applications structured by product or article types	201-100-9	201-939-0	201-940-6	202-676-4	203-630-6	213-268-0	218-690-9	218-691-4	222-824-1	225-035-0	232-102-8	239-387-8	242-958-4	282-015-4	290-058-5	413-530-6	434-380-8	454-810-8	700-127-8	812-739-3	938-702-2	943-985-0	944-561-8	946-911-5	947-851-2
and compounds																									
PC 1: Adhesives, sealants							**C**							**P**											
PC 9c: Finger paint							**C**					**C**													
PC 9b: Fillers, putties, plasters, modelling clay							**C**					**C**		**P**											
PC 9a: Coatings and paints, thinners, paint removes					F		**C**					**C**		**P**							F, I				
PC 18: Ink and toners					I		**C**					**C**		**P**											
PC 26: Paper and board treatment products					F, I																				
PC 14: Metal surface treatment products										I															

Main types of applications structured by product or article types	201-100-9	201-939-0	201-940-6	202-676-4	203-630-6	213-268-0	218-690-9	218-691-4	222-824-1	225-035-0	232-102-8	239-387-8	242-958-4	282-015-4	290-058-5	413-530-6	434-380-8	454-810-8	700-127-8	812-739-3	938-702-2	943-985-0	944-561-8	946-911-5	947-851-2
PC 21: Laboratory chemicals	I, **P**			**P**	F, I, **P**		F, I, **P**, **C**						I												
PC 19: Intermediate	I	I	I	I	F, I	I	F, I		I		I	I		F, I	I						F, I	I			
PC 30: Photo-chemicals							**C**																		
PC x1: Food and feed additives							**C**							F, **A**	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.

Note:

For EC 218-690-9 (L-menthol) – according to the registration dossiers, widespread (consumer) uses are declared for almost all product categories. Additional PCs, not included in the table, for which consumer uses are declared: PC 2 (adsorbents), PC 23 (leather treatment products), PC 34 (textile dyes and impregnation products), PC 36 (water softeners) and PC 37 (water treatment chemicals). It is believed that industry may have over-reported uses for this substance.

For EC 282-015-4 – service life is indicated for food and feed additives and substance indicated as "intended to be released". No explicit article category is mentioned.

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

Data extracted on 10/01/2022

EC/List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
203-630-6				YES	YES	
209-235-5						PPP
209-512-0					YES	
231-186-3 [1)]					YES	
231-187-9 [1)]					YES	
282-015-4						PPP, BPR

*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).

[1)] Not registered/no active registrations

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