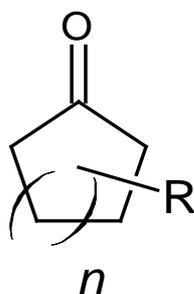


Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Branched aliphatic-substituted cyclic ketones and polycyclic ketones

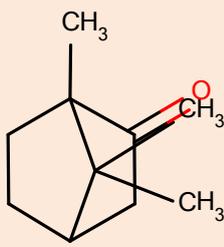
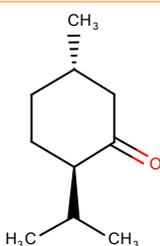
General structure:



Revision history

<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	02 February 2023	

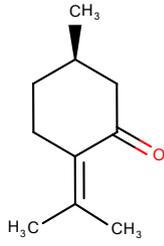
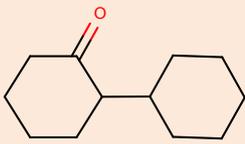
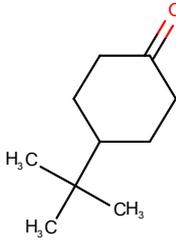
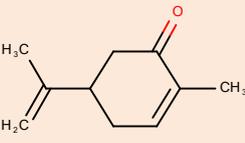
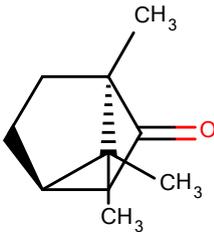
Substances within this group:

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
200-945-0*	76-22-2	bornan-2-one		Full, 100-1000
201-941-1*	89-80-5	trans-menthone		Full, 10-100
201-942-7	89-81-6	6-isopropyl-3-methylcyclohex-2-enone		OSII or TII

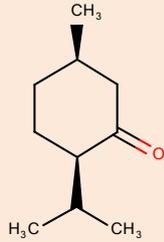
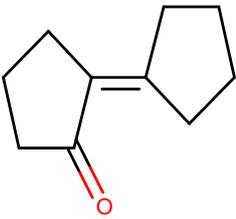
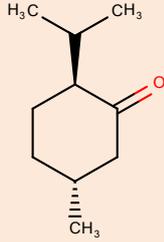
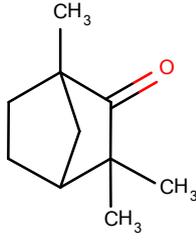
¹ Note that the total aggregated tonnage band may be available on ECHA's webpage at <https://echa.europa.eu/information-on-chemicals/registered-substances>

* Based on substance identifiers and information included in submission dossiers, in this Group the following are considered duplicate entries: EC 200-945-0 and EC 244-350-4; EC 430-460-1 and EC 801-871-7; possibly also: EC 201-941-1 and EC 214-049-2

ASSESSMENT OF REGULATORY NEEDS

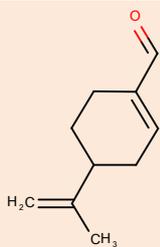
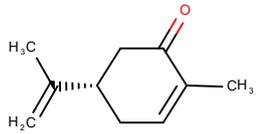
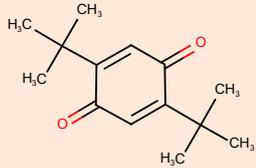
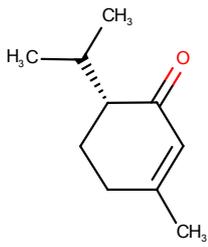
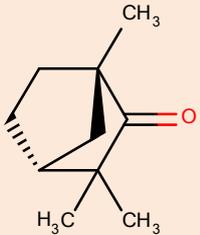
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201-943-2	89-82-7	p-menth-4(8)-en-3-one		C&L notification
201-991-4	90-42-6	2-cyclohexylcyclohexanone		C&L notification
202-678-5	98-53-3	4-tert-butylcyclohexanone		Full, not (publicly) available
202-759-5	99-49-0	d-p-mentha-1(6),8-dien-2-one		C&L notification
207-355-2	464-49-3	(+) -bornan-2-one		Full, 100-1000

ASSESSMENT OF REGULATORY NEEDS

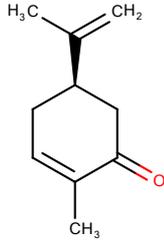
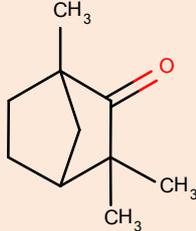
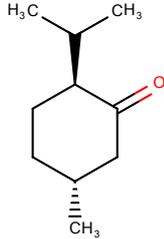
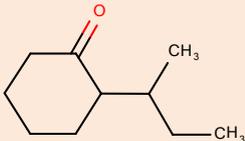
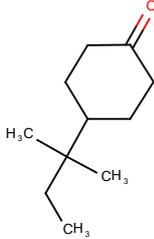
EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
207-727-4	491-07-6	isomenthone		C&L notification
212-542-7	825-25-2	cyclopentyliden ecyclopentan-2-one		OSII or TII
214-049-2*	1074-95-9 (obsolete)	(±)-menthone		Full, 10-100
214-804-6	1195-79-5	3,3-dimethyl- 8,9- dinorbornan-2-one		Full, not (publicly) available

* Based on substance identifiers and information included in submission dossiers, in this Group the following are considered duplicate entries: EC 200-945-0 and EC 244-350-4; EC 430-460-1 and EC 801-871-7; possibly also: EC 201-941-1 and EC 214-049-2

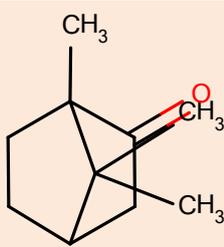
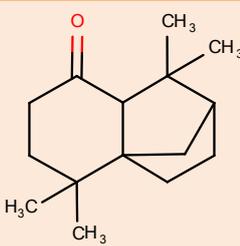
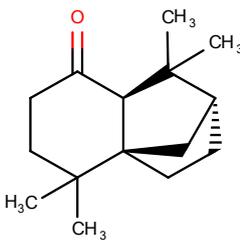
ASSESSMENT OF REGULATORY NEEDS

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) ¹
218-302-8	2111-75-3	4-isopropenylcyclohex-1-enecarbaldehyde		C&L notification
218-827-2	2244-16-8	(S)-2-methyl-5-(1-methylvinyl)cyclohex-2-en-1-one		Full, not (publicly) available
219-552-0	2460-77-7	2,5-di-tert-butyl-p-benzoquinone		Full, not (publicly) available
224-957-0	4573-50-6	(R)-6-(isopropyl)-3-methylcyclohex-2-en-1-one		Full, not (publicly) available
225-160-0	4695-62-9	(1S)-1,3,3-trimethylbicyclo[2.2.1]heptan-2-one		C&L notification

ASSESSMENT OF REGULATORY NEEDS

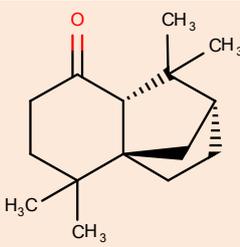
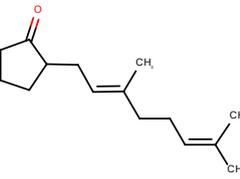
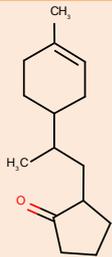
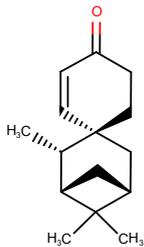
EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
229-352-5	6485-40-1	l-p-mentha-1(6),8-dien-2-one		Full, 100-1000
232-107-5	7787-20-4	1,3,3-trimethylnorbornan-2-one		Full, not (publicly) available
237-926-1	14073-97-3	L-menthan-3-one		Full, 100-1000
238-830-2	14765-30-1	2-sec-butylcyclohexan-1-one		Full, 10-100
240-642-0	16587-71-6	4-tert-pentylcyclohexanone		Full, not (publicly) available

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) ¹
244-350-4*	21368-68-3 (obsolete)	DL-bornan-2-one		OSII or TII
244-662-0	21922-58-7	1,5-dimethylbicyclo[3.2.1]octan-8-one		OSII or TII
245-890-3	23787-90-8	1,3,4,6,7,8a-hexahydro-1,1,5,5-tetramethyl-2H-2,4a-methanonaphthalen-8(5H)-one		Full, 1-10
249-648-8	29461-13-0	(2α,4α,8β)-hexahydro-1,1,5,5-tetramethyl-2H-2,4a-methanonaphthalen-8(5H)-one		Cease manufacture

* Based on substance identifiers and information included in submission dossiers, in this Group the following are considered duplicate entries: EC 200-945-0 and EC 244-350-4; EC 430-460-1 and EC 801-871-7; possibly also: EC 201-941-1 and EC 214-049-2

ASSESSMENT OF REGULATORY NEEDS

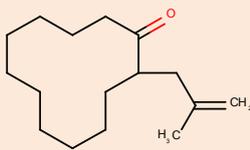
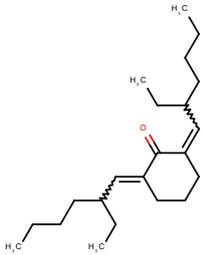
EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
249-649-3	29461-14-1	(2a,4a,8a)-hexahydro-1,1,5,5-tetramethyl-2H-2,4a-methanonaphthalen-8(5H)-one		Full, not (publicly) available
268-706-3	68133-79-9	2-(3,7-dimethylocta-2,6-dienyl)cyclopentan-1-one		Full, not (publicly) available
404-240-0	95962-14-4	2-(2-(4-methyl-3-cyclohexen-1-yl)propyl)cyclopentanone		Full, 10-100
430-460-1*	133636-82-5	(+)-(1S,2S,3S,5R)-2,6,6-trimethylbicyclo[3.1.1]heptane-3-spiro-1'-(cyclohex-2'-en-4'-one)		Full, not (publicly) available

* Based on substance identifiers and information included in submission dossiers, in this Group the following are considered duplicate entries: EC 200-945-0 and EC 244-350-4; EC 430-460-1 and EC 801-871-7; possibly also: EC 201-941-1 and EC 214-049-2

ASSESSMENT OF REGULATORY NEEDS

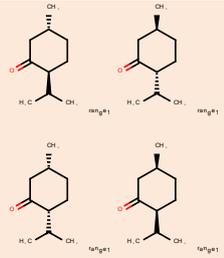
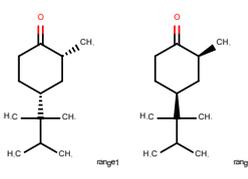
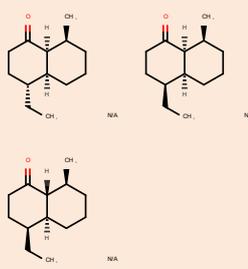
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610-371-6	476332-63-5	1,1,2,3,3-pentamethyl-5-(2-methylprop-2-en-1-yl)octahydro-4H-inden-4-one		OSII or TII
617-391-4	82832-73-3	[1,1'-Bicyclohexyl]-4-one, 4'-propyl-, trans-		OSII or TII
617-638-6	84868-02-0	4'-trans-pentyl-[1,1'-bicyclohexyl]-4-one		OSII or TII
618-848-0	92413-47-3	4'-trans-Butyl-[1,1'-bicyclohexyl]-4-on		OSII or TII
682-803-1	13019-04-0	No public or meaningful name is available		C&L notification

ASSESSMENT OF REGULATORY NEEDS

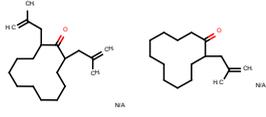
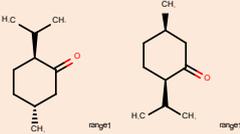
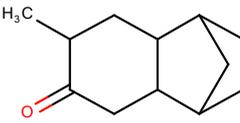
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691-657-8	62599-49-9	Cyclododecanone, 2-(2-methyl-2-propen-1-yl)-		OSII or TII
700-817-9	-	Reaction product of 2-ethylhexanal and cyclohexanone		OSII or TII
801-871-7*	133636-82-5	No public or meaningful name is available		C&L notification
818-398-7	34748-64-6	rel-(3aR,4R,7R,7aR)-octahydro-5H-4,7-methanoinden-5-one		OSII or TII

* Based on substance identifiers and information included in submission dossiers, in this Group the following are considered duplicate entries: EC 200-945-0 and EC 244-350-4; EC 430-460-1 and EC 801-871-7; possibly also: EC 201-941-1 and EC 214-049-2

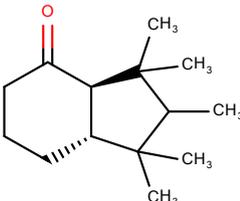
ASSESSMENT OF REGULATORY NEEDS

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) ¹
905-013-3	-	2-isopropyl-5-methyl-cyclohexanone		Full, 100-1000
938-347-3	28068-91-9	Cyclohexanone, 2-methyl-4-(1,1,2-trimethylpropyl)-, cis-		Full, not (publicly) available
939-400-3	-	Reaction mass of (4RS,4aRS,8RS,8aRS)-4-ethyl-8-methyloctahydronaphthalen-1(2H)-one and (4RS,4aSR,8SR,8aRS)-4-ethyl-8-methyloctahydronaphthalen-1(2H)-one and (4RS,4aSR,8SR,8aSR)-4-ethyl-8-methyloctahydronaphthalen-1(2H)-one		Full, not (publicly) available

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) ¹
941-245-1	1689576-43-9	Cyclododecanone, reaction products with 3-chloro-2-methyl-1-propene		OSII or TII
941-717-7	-	Reaction mass of L-Menthan-3-one and (+)-Isomenthone		OSII or TII
942-400-6	-	Reaction mass of (+-)-(1RS,2SR,5SR,7RS,8SR)-5-METHYLTRICYCLO[6.2.1.0 ^{2,7}]UNDECAN-4-ONE and (+-)-(1RS,2SR,5RS,7RS,8SR)-5-METHYLTRICYCLO[6.2.1.0 ^{2,7}]UNDECAN-4-ONE		Full, not (publicly) available
944-329-6	-	Reaction product of o-cresol and camphene, obtained by addition, hydrogenation and distillation	Not (publicly) available	Full, not (publicly) available

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) ¹
945-048-1	-	rel-(3aR,7aR)-1,1,2,3,3-pentamethyloctahydro-4Hinden-4-one		OSII or TII
946-604-6	-	Essential oil camphor-rich of Artemisia herba-alba (Asteraceae) obtained from herb by steam distillation	Not (publicly) available	Full, not (publicly) available
947-806-7	-	Reaction products of 6,10-dimethylundeca-5,9-dien-2-one, cyclized	Not (publicly) available	OSII or TII

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

Contents

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

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

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

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

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

For more information on Assessment of regulatory needs please consult ECHA website².

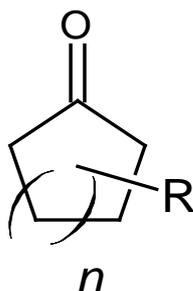
² <https://echa.europa.eu/understanding-assessment-regulatory-needs>

Glossary

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

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of a cyclic ketone moiety shown in the figure below. With one exception, all substances are mono ketones and members of this group may have more than one ring in their structure. The ring(s) may be unsaturated, bridged, spiro, or fused. Likewise, the substituent(s) R (there may be more than one) is/are branched aliphatic chain(s) or bridged to form polycyclic structures. Molecular structures in this group have often more than one stereocentre which provide enantiomers with different chiral activity but majority of substances is identified as racemates.



The group consists of 54 substances, out of which 26 have a full registration within REACH (including 1 registration with ceased manufacturing), 17 are intermediates, 2 are NONS, 9 are not registered. With few exceptions (*e.g.* EC 700-817-9, EC 905-013-3, EC 946-604-6, EC 947-806-7) majority of the substances in this group can be identified as mono-constituent (including racemates). Based on information reported in the REACH registration dossiers, many substances in the group are present in natural oils. The majority of the registered (non-intermediate) substances in the group have industrial, widespread professional and consumer uses as fragrance/odour agent in washing and cleaning products, biocidal products, cosmetics, personal care products, polishes and wax blends, perfumes, fragrances, air care products.

Beyond the use as fragrances in washing and cleaning products, EC 229-352-5 (*l-p*-mentha-1(6),8-dien-2-one) and EC 938-347-3 also are used by consumers in pharmaceuticals, EC 938-347-3 is notified to be used as odour agent in 17 other product categories; fuels, coatings and paints, thinners, paint removes, and ink and toners are among them. Some are used as intermediates in organic synthesis, fungicides, solvents. EC 200-945-0 and 207-355-2 also are used in fuels, coatings and paints, thinners, paint removes, and ink and toners by professional users and consumers. Both substances are used in polymer preparations and compounds in industrial settings.

High exposure potential and release in the environment can be assumed for most of the full registered substances in the group, except for the following substances: EC 201-942-7 (registered intermediate; no further information on the intermediate uses is provided); EC 939-400-3 has no reported uses; EC 219-552-0 has only reported formulation and intermediate uses and EC 485-460-4 has only intermediate use.

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

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

Based on currently available information, there is a need for EU regulatory risk management- restriction for ED hazard, due the presence of 4-*tert*-butylphenol (4-TBP) in substances EC 201-942-7 and EC 202-678-5 and their potential for release and exposure.

4-TBP is a known environmental endocrine disruptor (included in the candidate list for eventual inclusion in Annex XIV in July 2019) and is present in substances EC 201-942-7 and EC 202-678-5 at concentrations above 0.1%. This is combined with a potential for exposure/releases to the environment from the uses of the two substances and the reasonable assumption that the sum of low-level emissions from many widespread sources contributes significantly to the overall release of 4-TBP to the environment.

It is important to note that these two substances belong also to the group of substances containing 4-*tert*-butylphenol for which ECHA has developed an assessment of regulatory needs.

ECHA concluded that for substances containing 4-TBP, restriction is the most appropriate EU-wide regulatory risk management to mitigate the risks associated with 4-TBP and stated the following: *"Restriction of 4-TBP as a substance, constituent or impurity in other substances, mixtures and articles up to a certain threshold is proposed to ensure that environmental emissions of 4-TBP are minimised. Ideally the entry should address both emissions from the production stage and emissions/exposure as a result of use. The entry would cover a wide scope - potentially all substances containing 4-TBP, including those that may be*

placed on the market in the future. This would help address the additivity effect of many low-level emissions".

Furthermore, the report clarified that *"the existing SVHC identification of 4-TBP as environmental ED is already sufficient for confirming the hazard as ED ENV of all substances containing 4-TBP (when present in the substance above 0.1 %)"*.

The conclusions presented in the Assessment of regulatory needs on the group "Substances containing 4-tert-butylphenol"¹ equally apply to EC 201-942-7 and EC 202-678-5.

Based on currently available information, there is a need for EU regulatory risk management -restriction for potential PBT/vPvB hazard due to the potential release and exposure of the substance EC 201-941-1.

Confirmation of the hazard properties via SVHC identification is not considered sufficient to minimise potential release of the substance EC 201-941-1 in the environment. A restriction is seen as the most appropriate option as potential for exposure is expected from its professional uses as fragrance/odour agent in washing and cleaning products, cosmetics, personal care products and polishes and wax blends and from its consumer uses as perfumes, fragrances, air care products and pharmaceuticals. Also, from its industrial uses as washing and cleaning products, perfumes, fragrances, cosmetics, personal care products, hydraulic fluids, laboratory chemical, as well as intermediate (precursor) releases to the environment cannot be excluded. Widespread professional uses are typically non-contained and non-automated leading to releases to the environment.

Releases to the environment from consumer uses cannot be avoided.

Therefore, a restriction of the substance as such or in mixtures (concentration limit in mixtures) used by consumers, professional workers, industrial workers is suggested after SVHC identification, with the aim to minimise exposures and emissions to humans and the environment.

The use of PBT and vPvB substances by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability³.

It is suggested to cover possibly also industrial uses as part of the restriction. However, the need for authorisation might be considered for industrial uses excluded from the scope of the restriction as it may not be proportionate to restrict all uses.

Based on currently available information, it is not possible to assess the need for regulatory risk management as information on hazard is not sufficient to conclude on mutagenicity hazards of the substance EC 232-107-5 in the group.

³ European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

EC 232-107-5 has showed positive results in an in vitro gene mutation assay, which would require an in vivo follow up to conclude on mutagenicity. It is for the moment not possible to conclude on mutagenicity on the basis of the in vitro findings.

A CCH is proposed for EC 232-107-5 (Industrial, widespread professional and consumer uses). CLH (human health) is proposed as an adequate follow-up step in case the information gathered under the CCH process proves to be sufficient to classify the substance as hazardous under the CLP Regulation.

The needs for regulatory risk management actions will be assessed once generation of data is completed.

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

Based on ECHA's assessment of currently available hazard information, no potential hazards were identified for mutagenicity (except for the substance 232-107-5), carcinogenicity, reproductive toxicity, or endocrine disruption for the other substances in the group, except those discussed below. These conclusions are based on the toxicological data available on the registered substances in the group.

Based on ECHA's assessment of currently available hazard information, 16 substances in the group are known skin sensitisers, with either harmonised classification or self-classification as Skin Sens. (see details in Annex I). Studies showing no skin sensitisation are available on 21 of the substances with full REACH registrations. Based on the chemical structures, it is not possible to predict which of the non-registered substances would be likely to cause sensitisation.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing substances EC/List 202-759-5, 218-827-2, 229-352-5, 801-871-7.

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.

Pulegone (EC 201-943-2) has been reported to cause hepatocellular adenoma and carcinoma in male and female mice. Furthermore, there was an increase in urinary bladder papilloma or carcinoma in female rats. The conclusion by IARC for pulegone is "*possibly carcinogenic to humans (Group 2B)*".⁴ Pulegone is not registered and no further action is proposed.

Some of the structural features of pulegone (double bond in 1,3-position to keto group) are also present in other substances within this GMT-group. However, the double bond in pulegone is outside the cyclohexanone whereas in all other similar structures it is within the ring. There are no data indicating carcinogenicity of these substances. One of them is registered at 100-1000 t/y, but there is a

⁴ <https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono108-05.pdf>

carcinogenicity study on its stereoisomer, showing no effects. The other similar substances are all registered at low tonnage / intermediate / not registered. There is no subchronic/chronic toxicity data available on these.

Cyclohexanone monoterpenoids; EC 201-941-1, 214-049-2, 237-926-1, 905-013-3, 240-642-0, 218-827-2 share some structural similarity with 3,5,5-trimethylcyclohex-2-enone (isophorone; EC 201-126-0, not in this group), which has a harmonised classification as Carc. 2. There are no studies or indications of carcinogenic effects of these substances in the group. CCHs are proposed to be opened (to generate data on reproductive toxicity; see below) and may result also in data generation on mutagenicity and target organ toxicity effects, also relevant as indicators of carcinogenic effects.

Isophorone was added to the CoRAP for Substance Evaluation (SEv) as a suspected reproductive toxicant. An Extended one-generation reproductive toxicity study (EOGRTS) on isophorone has recently been conducted and is currently under evaluation. As the final EOGRTS report was not yet available when SEv was concluded, the outcome of the isophorone SEv was that no conclusion can for the moment be reached regarding reproductive toxicity and endocrine disruption (concern unresolved). The data density on reproductive and developmental toxicity of the identified substances being similar to isophorone is low.

EC 229-352-5 showed some malformations in a rat developmental toxicity study, but the observed developmental effects would not be sufficient for classification. As the registration dossiers of the isophorone-related substances rely either on read across or have data gaps, CCH is suggested to clarify the reproductive toxicity potential. The currently available information on hazard is not sufficient to conclude on reproductive toxicity and ED hazard for these substances, and therefore it is proposed to wait until the ongoing processes are concluded.

Cyclododecanone, reaction products with 3-chloro-2-methyl-1-propene (EC 941-245-1) has correct self-classification applied for Repr. 2 based on possible toluene content up to 6 %. Same is true for (2*a*,4*aa*,8*a*)-hexahydro-1,1,5,5-tetramethyl-2*H*-2,4*a*-methano-naphthalen-8(5*H*)-one (EC 249-649-3) which might contain toluene up to 5 %. Correct self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation.

Based on currently available hazard information most substances in the group have potential hazards for the environment Aquatic toxicity. All substances show different levels of aquatic toxicity varying from not toxic to very toxic. In the group, substance EC 430-460-1 has a harmonised classification of Aquatic Acute 1, H400 and Aquatic Chronic 1 H411. 37 substances (including EC 430-460-1) are self-classified ranging from, Aquatic Acute 1 to Aquatic Chronic 3. Most substances where information is available in the dossier are soluble thus the acute information is considered valid. Overall, it is not possible to indicate a clear trend. There are only 4 ketones in the group with rings \geq C12, 2 which are classified for aquatic toxicity and 2 which are not. However, the substances with long alkyl chain substituents and/or multiple short-chain substituents tend to show higher aquatic toxicity. CCHs are proposed for EC 207-355-2 (not yet classified), and for three substances for which there is an extensive use of read-across, weight-of-evidence and QSARs (EC 214-049-2, 218-827-2, 240-642-0) to confirm potential chronic aquatic toxicity.

It is expected that following data generation for aquatic toxicity registrants would adequately self-classify the substances and implement necessary RMMs to ensure

safe use. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management for the substances above.

In addition, 13 substances meet the screening criteria for PBT/vPvB. As stated above, a CCH is proposed for one substance registered at the higher tonnage (Annex VIII), EC 201-941-1 (Industrial, widespread professional and consumer uses). The remaining 12 substances have low tonnages or are registered as intermediates or are unclaimed NONS with limited dataset available or not registered. Therefore, data generation to clarify PBT under CCH is not possible and unlikely/disproportionate under SEV due to the low potential for exposure.

3 Conclusions and actions

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

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
201-942-7 202-678-5	Known or potential hazard for reproductive toxicity	Known or potential hazard for ED	For EC 202-678-5: Industrial, widespread professional and consumer uses as fragrance/odour agent in washing and cleaning products, biocidal products, cosmetics, personal care products, polishes and wax blends, perfumes, fragrances, air care products. For EC 201-942-7: no known uses.	Need for EU RRM: Restriction <u>Justification:</u> See conclusions of the Assessment of regulatory needs on GMT "Substances containing 4-tert-butylphenol" ⁵ .	First step: Restriction
	-			Need for EU RRM: Restriction	

⁵ Assessment of regulatory needs: Substances containing 4-tert-butylphenol, ECHA, 19/11/2021, <https://euon.echa.europa.eu/documents/10162/8e39cccd-b03c-cc78-e8de-73dba4785e1e>, last accessed online 02/09/2022

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
201-941-1	No hazard or unlikely hazard	<p>Known or potential hazard for PBT/vPvB</p> <p>Known or potential hazard for aquatic toxicity</p>		<p>Justification:</p> <p>Releases to the environment from consumer and widespread professional uses cannot be avoided. Widespread professional uses are typically non-contained and non-automated leading to releases to the environment.</p> <p>Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. Industrial uses to be considered as part of the restriction</p>	<p>First step: CCH</p> <p>Next step (if hazard confirmed): SVHC identification followed by Restriction</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
232-107-5	Inconclusive hazard Mutagenicity	Known or potential hazard for aquatic toxicity	Industrial, widespread professional and consumer uses as fragrance/odour agent in washing and cleaning products, biocidal products, cosmetics, personal care products, polishes and wax blends, perfumes, fragrances, air care products. Use in industrial settings as intermediates.	Currently not possible to assess the regulatory needs <u>Justification:</u> CCH is proposed to follow up on the positive results. No mutagenicity was observed with the other substances in the group, and it is for the moment not possible to conclude on mutagenicity of the substance based on the <i>in vitro</i> findings.	First step: CCH Next steps (if hazard confirmed): CLH
202-759-5 219-552-0 224-957-0 229-352-5 237-926-1 245-890-3 430-460-1 801-871-7 905-013-3	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity except of 202-759-5, 941-717-7 Known or potential hazard for PBT/vPvB	Industrial, widespread professional and consumer uses as fragrance/odour agent in washing and cleaning products, biocidal products, cosmetics, personal	Currently no need for EU RRM <u>Justification:</u> Harmonised/self-classification followed by implementation of necessary RRM should be sufficient to	First step: No action

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
<p>938-347-3 939-400-3 941-717-7 942-400-6 944-329-6 946-604-6</p>		<p>(245-890-3, 430-460-1, 939-400-3, 942-400-6, 944-329-6)</p> <p>No hazard or unlikely hazard for aquatic toxicity (224-957-0, 237-926-1)</p> <p>Inconclusive hazard for PBT/vPvB, ED (202-759-5, 801-871-7, 941-717-7)</p>	<p>care products, polishes and wax blends, perfumes, fragrances, air care products.</p> <p>EC 229-352-5 and EC 938-347-3 also are used by consumers in pharmaceuticals.</p> <p>In addition, EC 938-347-3 is notified to be used as odour agent in 17 other product categories; fuels, coatings and paints, thinners, paint removes, and ink and toners are among them.</p> <p>EC 219-552-0 has only reported formulation and intermediate uses.</p> <p>EC 430-460-1 is used by professional and consumer users only in cosmetics, personal care products.</p>	<p>ensure safe use at the workplace. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation.</p>	

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			EC 939-400-3 has no notified uses. EC 202-759-5 and EC 801-871-7 are not registered.		
<p>214-049-2 240-642-0 404-240-0</p> <p>The three substances below are also indicated above as Skin Sens. 218-827-2 237-926-1 905-013-3</p>	<p>Inconclusive hazard for reproductive toxicity for ED (except EC 404-240-0)</p>	<p>Known or potential hazard for aquatic toxicity (214-049-2, 240-642-0, 404-240-0, 905-013-3)</p> <p>Inconclusive hazard for PBT/vPvB, ED (214-049-2, 218-827-2, 240-642-0)</p>	<p>Industrial, widespread professional and consumer uses as fragrance/odour agent in washing and cleaning products, biocidal products, cosmetics, personal care products, polishes and wax blends, perfumes, fragrances, air care products. EC 214-049-2 is used in industrial settings and by consumers in pharmaceuticals. Use in industrial settings as intermediates (EC 214-049-2, 237-926-1, 905-013-3), metal surface treatment products (EC 237-926-1, 905-013-3),</p>	<p>Currently no need for EU RRM</p> <p><u>Justification:</u> CCHs will be opened and may result in data generation on reproductive toxicity, mutagenicity and target organ toxicity effects, also relevant as indicators of carcinogenic effects. Harmonised/self-classification followed by implementation of necessary RRM should be sufficient to ensure safe use at the workplace.</p>	<p>First step: CCH (214-049-2, 237-926-1, 905-013-3, 240-642-0, 218-827-2)</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			laboratory chemicals (EC 232-107-5).		
<p>All the other substances in the group</p> <p>Registered:</p> <p>200-945-0 207-355-2 238-830-2 214-804-6 249-649-3 249-648-8 268-706-3 485-460-4</p> <p>Other non-registered substances:</p> <p>201-943-2 201-991-4 207-727-4 212-542-7 218-302-8 225-160-0 244-350-4 244-662-0 450-020-2 458-980-4</p>	<p>Known or potential hazard for carcinogenicity (EC 201-943-2 (Pulegone))</p> <p>Known or potential hazard for reproductive toxicity (EC 249-649-3, 941-245-1 - repro impurities (toluene or 4-TBP))</p>	<p>Known or potential hazard for aquatic toxicity except of 244-662-0, 249-648-8, 458-980-4, 606-984-3, 945-048-1</p> <p>Known or potential hazard for PBT/vPvB (249-648-8, 249-649-3, 458-980-4, 485-460-4, 617-638-6, 618-848-0, 691-657-8)</p> <p>Inconclusive hazard for PBT/vPvB, ED for other, non-registered substances.</p>	<p>Registered substances: Industrial, widespread professional and consumer uses as fragrance/odour agent in washing and cleaning products, biocidal products, cosmetics, personal care products, polishes and wax blends, perfumes, fragrances, air care products. Except EC 268-706-3 is notified for consumer uses in washing and cleaning products, cosmetics, personal care products, perfumes, fragrances. Substance EC 485-460-4 has only intermediate use.</p>	<p>Currently no need for EU RRM</p> <p><u>Justification:</u> Harmonised/self-classification followed by implementation of necessary RRM should be sufficient to ensure safe use at the workplace.</p>	<p>First step: CCH (EC 207-355-2)</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
604-824-7 606-984-3 610-371-6 617-391-4 617-638-6 618-848-0 682-803-1 691-657-8 700-817-9 818-398-7 941-245-1 945-048-1 947-806-7			No information is available for the non-registered substances		

Annex 1: Overview of classifications

Data extracted on 30 May 2022.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
200-945-0	76-22-2	bornan-2-one	-	Flam. Solid 2 H228 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Damage 1 H318 STOT Single Exp. 2 H371, affected organs: lungs
201-941-1	89-80-5	trans-menthone	-	Acute Tox. 4 H302 Aquatic Chronic 3 H412
201-942-7	89-81-6	6-isopropyl-3-methylcyclohex-2-enone	-	-
201-943-2	89-82-7	p-menth-4(8)-en-3-one	-	-
201-991-4	90-42-6	2-cyclohexylcyclohexanone	-	-
202-678-5	98-53-3	4-tert-butylcyclohexanone	-	Acute Tox. 4 H302 Aquatic Chronic 2 H411
202-759-5	99-49-0	d-p-mentha-1(6),8-dien-2-one	Skin Sens. 1, H317	-
207-355-2	464-49-3	(+)-bornan-2-one	-	Flam. Solid 2 H228 Acute Tox. 4 H332 Skin Irrit. 2

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classificatio n	Classification in registrations
				H315 Eye Damage 1 H318 STOT Single Exp. 2 H371, affected organs: lungs
207- 727-4	491- 07-6	isomenthone	-	-
212- 542-7	825- 25-2	cyclopentylidenecyclopentan-2- one	-	-
214- 049-2	1074- 95-9	(±)-menthone	-	Aquatic Chronic 3 H412
214- 804-6	1195- 79-5	3,3-dimethyl-8,9-dinorbornan-2- one	-	-
218- 302-8	2111- 75-3	4-isopropenylcyclohex-1- enecarbaldehyde	-	-
218- 827-2	2244- 16-8	(S)-2-methyl-5-(1- methylvinyl)cyclohex-2-en-1-one	Skin Sens. 1, H317	Skin Sens. 1 H317
219- 552-0	2460- 77-7	2,5-di-tert-butyl-p-benzoquinone	-	Acute Tox. 4 H302 Skin Sens. 1 H317 Aquatic Acute 1 H400
224- 957-0	4573- 50-6	(R)-6-(isopropyl)-3- methylcyclohex-2-en-1-one	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1B H317
225- 160-0	4695- 62-9	(1S)-1,3,3- trimethylbicyclo[2.2.1]heptan-2- one	-	

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
229-352-5	6485-40-1	l-p-mentha-1(6),8-dien-2-one	Skin Sens. 1, H317	Acute Tox. 4 H302 Skin Sens. 1B H317 Skin Sens. 1 H317
232-107-5	7787-20-4	1,3,3-trimethylnorbornan-2-one	-	Aquatic Chronic 2 H411
237-926-1	14073-97-3	L-menthan-3-one	-	Skin Irrit. 2 H315 Skin Sens. 1B H317
238-830-2	14765-30-1	2-sec-butylcyclohexan-1-one	-	Skin Irrit. 2 H315
240-642-0	16587-71-6	4-tert-pentylcyclohexanone	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Chronic 2 H411
244-350-4	21368-68-3	DL-bornan-2-one	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT Single Exp. 3 H335, affected organs: Damage to organs Flam. Solid 2 H228 Acute Tox. 4 H302
244-662-0	21922-58-7	1,5-dimethylbicyclo[3.2.1]octan-8-one	-	-
245-890-3	23787-90-8	1,3,4,6,7,8a-hexahydro-1,1,5,5-tetramethyl-2H-2,4a-methanonaphthalen-8(5H)-one	-	Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Acute 2

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classificatio n	Classification in registrations
				H401 Aquatic Chronic 2 H411
249- 648-8	29461- 13-0	(2 α ,4 α ,8 β)-hexahydro-1,1,5,5-tetramethyl-2H-2,4a-methanonaphthalen-8(5H)-one	-	-
249- 649-3	29461- 14-1	(2 α ,4 α ,8 α)-hexahydro-1,1,5,5-tetramethyl-2H-2,4a-methanonaphthalen-8(5H)-one	-	Repr. 2 H361 Skin Irrit. 2 H315 Aquatic Chronic 2 H411
268- 706-3	68133- 79-9	2-(3,7-dimethylocta-2,6-dienyl)cyclopentan-1-one	-	Skin Irrit. 2 H315 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
404- 240-0	95962- 14-4	2-(2-(4-methyl-3-cyclohexen-1-yl)propyl)cyclopentanone	-	Aquatic Chronic 1 H410 [Article 10 (inactive)] Eye Irrit. 2 H319 Aquatic Acute 1 H400 Aquatic Chronic 3 H412
430- 460-1	-	(+)-(1S,2S,3S,5R)-2,6,6-trimethylbicyclo[3.1.1]heptane-3-spiro-1'-(cyclohex-2'-en-4'-one)	-	Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H411-
450- 020-2	-	No public or meaningful name is available	-	-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classificatio n	Classification in registrations
458-980-4	-	No public or meaningful name is available	-	-
485-460-4	-	4'-trans-ethyl-[1,1'-bicyclohexyl]-4-one	-	Skin Irrit. 2 H315 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
604-824-7	15210-25-0	1H-Cyclopentacyclododecen-1-one, 2,3,4,5,6,7,8,9,10,11,12,13-dodecahydro-	-	-
606-984-3	22327-32-8	Bicyclo[4.1.0]hept-3-en-2-one, 4,7,7-trimethyl-, (1R,6S)-	-	-
610-371-6	47633-2-63-5	1,1,2,3,3-pentamethyl-5-(2-methylprop-2-en-1-yl)octahydro-4H-inden-4-one	-	-
617-391-4	-	[1,1'-Bicyclohexyl]-4-one, 4'-propyl-, trans-	-	Aquatic Chronic 1 H410
617-638-6	84868-02-0	4'-trans-pentyl-[1,1'-bicyclohexyl]-4-one	-	Aquatic Chronic 1 H410 Skin Corr. 1 H314 Aquatic Acute 1 H400
618-848-0	92413-47-3	4'-trans-Butyl-[1,1'-bicyclohexyl]-4-on	-	Aquatic Acute 1 H400, M- factor: 10.00 Aquatic Chronic 1 H410
682-803-1	13019-04-0	No public or meaningful name is available	-	-
691-657-8	62599-49-9	Cyclododecanone, 2-(2-methyl-2-propen-1-yl)-	-	Aquatic Acute 1 H400 Aquatic Chronic 1 H410

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classificatio n	Classification in registrations
700-817-9	-	Reaction product of 2-ethylhexanal and cyclohexanone	-	-
801-871-7	13363 6-82-5	No public or meaningful name is available	-	-
818-398-7	34748- 64-6	rel-(3aR,4R,7R,7aR)-octahydro-5H-4,7-methanoinden-5-one	-	Acute Tox. 4 H312 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Acute Tox. 4 H302
905-013-3	-	2-isopropyl-5-methyl-cyclohexanone	-	Skin Irrit. 2 H315 Skin Sens. 1B H317
938-347-3	-	Cyclohexanone, 2-methyl-4-(1,1,2-trimethylpropyl)-, cis-	-	Skin Irrit. 2 H315 Skin Sens. 1 H317 Aquatic Chronic 2 H411
939-400-3	-	Reaction mass of (4RS,4aRS,8RS,8aRS)-4-Ethyl-8-methyloctahydronaphthalen-1(2H)-one and (4RS,4aSR,8SR,8aRS)-4-Ethyl-8-methyloctahydronaphthalen-1(2H)-one and (4RS,4aSR,8SR,8aSR)-4-Ethyl-8-methyloctahydronaphthalen-1(2H)-one	-	Acute Tox. 4 H332 Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Chronic 2 H411
941-245-1	-	Cyclododecanone, reaction products with 3-chloro-2-methyl-1-propene	-	Aquatic Chronic 1 H410 [intermediate (active)] Aquatic Acute 1 H400

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classificatio n	Classification in registrations
				[intermediate (active)] Repr. 2 H361, specific effect: Suspecte d of damaging the unborn child [intermediate (active)]
941- 717-7	-	Reaction mass of L-Menthan-3-one and (+)-Isomenthone	-	Skin Irrit. 2 H315 Eye Irrit. 2A H319 Skin Sens. 1B H317 Aquatic Chronic 3 H412
942- 400-6	-	Reaction mass of (+)- (1RS,2SR,5SR,7RS,8SR)-5- METHYLTRICYCLO[6.2.1.02,7]UND ECAN-4-ONE and (+)- (1RS,2SR,5RS,7RS,8SR)-5- METHYLTRICYCLO[6.2.1.02,7]UND ECAN-4-ONE	-	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Sens. 1B H317 Aquatic Chronic 3 H412
944- 329-6	-	Reaction product of o-cresol and camphene, obtained by addition, hydrogenation and distillation	-	Skin Sens. 1B H317 Aquatic Chronic 3 H412
945- 048-1	-	rel-(3aR,7aR)-1,1,2,3,3- pentamethyloctahydro-4Hinden- 4-one	-	-
946- 604-6	-	Essential oil camphor-rich of Artemisia herba-alba (Asteraceae) obtained from herb by steam distillation	-	Flam. Liquid 3 H226 Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classificatio n	Classification in registrations
				H319 Skin Sens. 1B H317 STOT Single Exp. 2 H371 Aquatic Chronic 3 H412
947- 806-7	-	Reaction products of 6,10- dimethylundeca-5,9-dien-2-one, cyclized	-	-

(*) 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 19/05/2022

EC number	PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation	PC 36: Water softeners	PC 2: Adsorbents	PC 12: Fertilisers	PC 27: Plant protection products	PC 4: Anti-freeze and de-icing products	PC 35: Washing and cleaning products	PC 8: Biocidal products (e.g. disinfectants, pest control)	PC 28: Perfumes, fragrances	PC 3: Air care products	PC 39: Cosmetics, personal care products	PC 29: Pharmaceuticals	PC 31: Polishes and wax blends	PC 24: Lubricants, greases, release products	PC 17: Hydraulic fluids	PC 13: Fuels	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removes	PC 18: Ink and toners	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 14: Metal surface treatment products	PC 21: Laboratory chemicals	PC 19: Intermediate	PC 30: Photo-chemicals
200-945-0							I, P, C	C	F, C	P, C	C		P, C			F, I, P, C	I			F, P	F, C					F	F, I	
224-957-0							I, P, C	C	C	C	C		P, C														I	
238-830-2							F, I, P, C	F, I, P, C	F, I, C	F, C	P, C		F, P, C												I			
219-552-0																		F		F	F, I							

ASSESSMENT OF REGULATORY NEEDS

938-347-3	C	C	C	C	C	C	F, C	F, C	F, I, P, C, A	F, C	F, C	C	C	C		F, C		C	F, C	F, C	F, C	F, C	C	F, C		C		C
202-678-5							I, P, C	C	F, C	C	P, C		P, C														I	
905-013-3							F, I, P, C	F, I, P, C	F, C	F, C	P, C		F, P, C													I		I
240-642-0							I, P, C	C	F, C	C	C		P, C															
207-355-2							I, P, C	C	F, C	C	C		P, C			F, I, P, C	I				F, P	F, C					F	F, I
214-804-6							I, P	C	F, C	C	C		P, C															
237-926-1							F, I, P, C	F, I, P, C	F, I, C	F, C	P, C		F, P, C													I		I
232-107-5							I, P, C	C	F, C	C	F, C		P, C															I
214-049-2							C		F, I, C	C	F, I, P, C	F, I, C	C													I		F, I
944-329-6							I, P, C	C	C	C	C		P, C															
245-890-3							F, I, P, C	F, I, P, C	F, C	F, C	P, C		F, P, C													I		
218-827-2							I, P, C	C	F, C	C	C		P, C															
229-352-5							F, I, P, C, A	F, C	F, C	F, C	F, P, C	C	F, P, C														F	I

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

Data extracted on 02/06/2022.

EC/List number	RMOA	Authorisation		Restriction*		CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)		
200-945-0							Food contact materials
201-942-7	Group entry						
202-678-5	Group entry						
202-759-5 (C&L notification)				YES		Group entry	PPP
218-302-8 (C&L notification)							Cosmetics
218-827-2				YES		Group entry	PPP
229-352-5				YES		Group entry	
404-240-0							Claimed & unclaimed NONs, JS under REACH

*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.