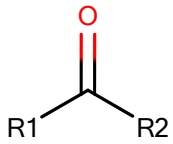
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Alicyclic ketones (other than with fused cycles only)

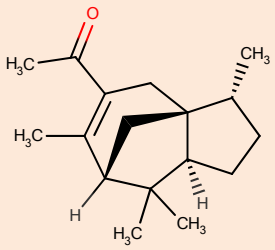
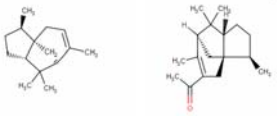
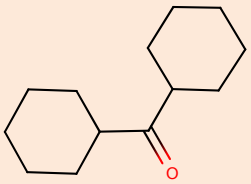
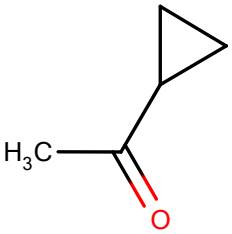
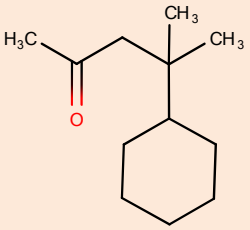
General structure:



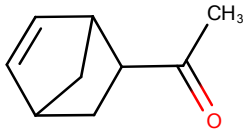
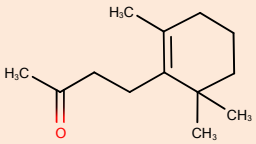
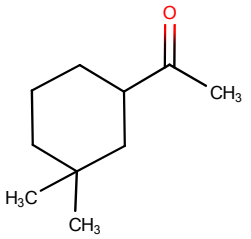
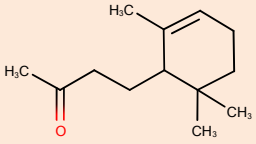
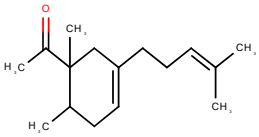
Revision history

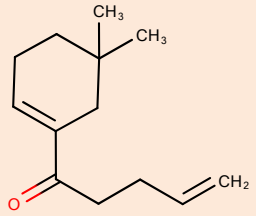
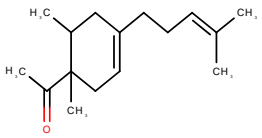
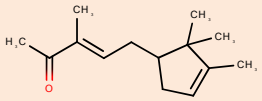
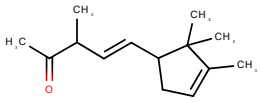
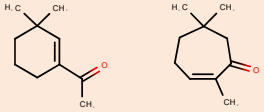
Version	*Date*	*Description*
1.0	9 April 2024	

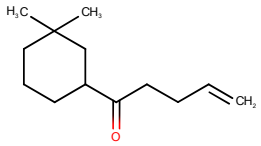
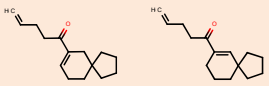
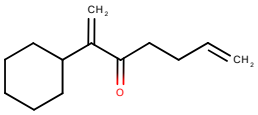
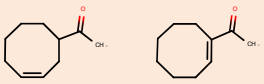
Substances within this group:

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]
251-020-3	32388-55-9	[3R-(3α,3aβ,7β,8aα)]-1-(2,3,4,7,8,8a-hexahydro-3,6,8,8-tetramethyl-1H-3a,7-methanoazulen-5-yl)ethan-1-one		Full, 100-1000
293-297-3	91053-33-7	Juniper, Juniperus mexicana, ext., isomerized, acetylated		Full, not (publicly) available
204-336-0	119-60-8	dicyclohexyl ketone		OSII or TII
212-146-4	765-43-5	cyclopropyl methyl ketone		OSII or TII
225-562-6	4927-39-3	4-cyclohexyl-4-methylpentan-2-one		Full, not (publicly) available

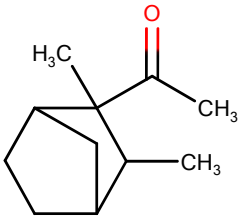
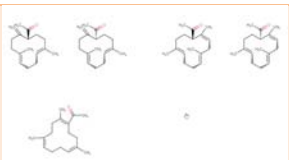
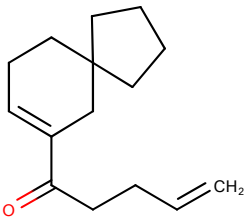
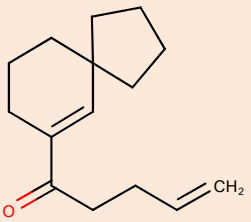
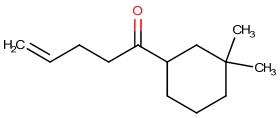
[1] Note that the total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

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]
225-767-0	5063-03-6	Methyl (8,9,10-trinorborn-5-en-2-yl) ketone		OSII or TII
241-318-1	17283-81-7	4-(2,6,6-trimethyl-1-cyclohexen-1-yl)butan-2-one		Full, 1-10
246-799-1	25304-14-7	1-(3,3-dimethylcyclohexyl)ethan-1-one		C&L notification
250-657-4	31499-72-6	4-(2,6,6-trimethyl-2-cyclohexen-1-yl)butan-2-one		OSII or TII
259-173-8	54464-54-9	1-[1,6-dimethyl-3-(4-methylpent-3-enyl)-3-cyclohexen-1-yl]ethan-1-one		OSII or TII

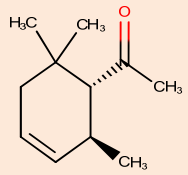
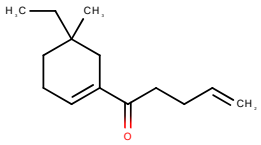
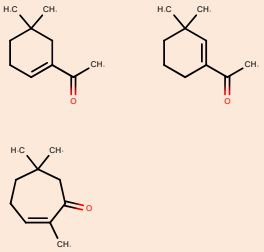
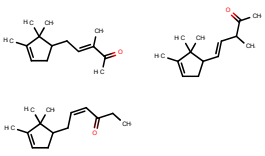
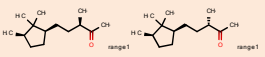
EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
260-486-7	56973-85-4	1-(5,5-dimethyl-1-cyclohexen-1-yl)pent-4-en-1-one		Full, not (publicly) available
260-772-1	57499-57-7	1-[1,6-dimethyl-4-(4-methylpent-3-enyl)-3-cyclohexen-1-yl]ethan-1-one		OSII or TII
265-450-4	65113-95-3	3-methyl-5-(2,2,3-trimethyl-3-cyclopenten-1-yl)pent-3-en-2-one		OSII or TII
267-135-7	67801-15-4	3-methyl-5-(2,2,3-trimethyl-3-cyclopenten-1-yl)pent-4-en-2-one		OSII or TII
415-570-1	30925-48-5	5-Hexen-3-one, 2-[(2S,5R)-5-ethenyltetrahydro-5-methyl-2-furanyl]-4,4-dimethyl-, (2S)-		NONS

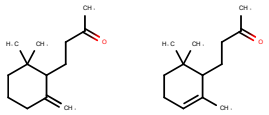
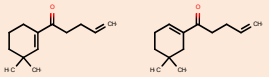
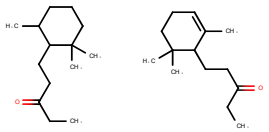
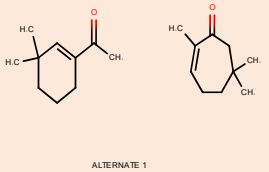
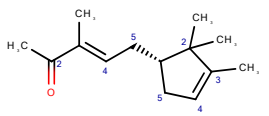
EC / List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
422-330-8 [2]		1-(3,3-dimethylcyclohexyl)pent-4-en-1-one		Full, not (publicly) available
438-060-9	224031-70-3	4-Penten-1-one, 1-spiro[4.5]dec-7-en-7-yl-		Full, not (publicly) available
441-580-9	313973-37-4	1,6-Heptadien-3-one, 2-cyclohexyl-		Full, not (publicly) available
466-270-0	17339-74-1	Ethanone, 1-(1-cycloocten-1-yl)-		NONS

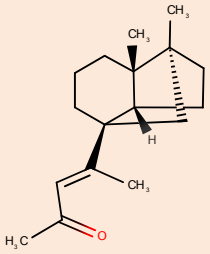
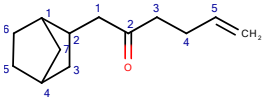
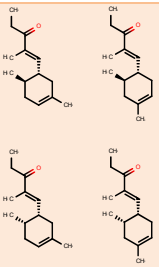
[2] When a dossier is submitted without EC number, REACH-IT automatically assigns a List number to the dossier. Sometimes, due to IT technical limitations, duplicate List numbers are created. In this Group the following are considered duplicate entries: EC 422-330-8 and List nr 687-590-9. In general EC numbers take precedence over List numbers.

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]
472-300-3	854737-10-3	Ethanone, 1-(2,3-dimethylbicyclo[2.2.1]hept-2-yl)-		NONS
482-330-9	144020-22-4	Reaction products of acetic anhydride and 1,5,10-trimethyl-1,5,9-cyclodecatriene		Full, 10-100
620-555-8	224031-70-3	4-Penten-1-one, 1-Spirodec-7-en-7-yl		C&L notification
639-250-6	224031-71-4	1-spiro[4.5]dec-6-en-7-yl-4-Penten-1-one		C&L notification
687-590-9[3]	56973-87-6	1-(3,3-dimethylcyclohexyl)pent-4-en-1-one		C&L notification

3 When a dossier is submitted without EC number, REACH-IT automatically assigns a List number to the dossier. Sometimes, due to IT technical limitations, duplicate List numbers are created. In this Group the following are considered duplicate entries: EC 422-330-8 and List nr 687-590-9. In general EC numbers take precedence over List numbers.

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]
800-278-0	41435-93-2	Ethanone, 1-[(1R,2S)-2,6,6-trimethyl-3-cyclohexen-1-yl]-, rel-		OSII or TII
807-612-4	1393645-32-3	1-(5-ethyl-5-methylcyclohex-1-en-1-yl)pent-4-en-1-one		Full, not (publicly) available
900-069-5		Reaction mass of 1-(3,3-dimethylcyclohex-1-en-1-yl)ethanone and 1-(5,5-dimethylcyclohex-1-en-1-yl)ethanone and 2,6,6-trimethylcyclohept-2-en-1-one		OSII or TII
939-720-3		Reaction products of (2,2,3-trimethylcyclopent-3-en-1-yl)acetaldehyde and butan-2-one		OSII or TII
942-532-4		Reaction mass of (3R)-3-Methyl-5-((1R,3R)-2,2,3-trimethylcyclopentyl)pentan-2-one and (3S)-3-Methyl-5-((1R,3R)-2,2,3-trimethylcyclopentyl)pentan-2-one		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]
943-896-7		multi constituent - Reaction mass of (E)-6,10-dimethylundeca-5,9-dien-2-one and (Z)-6,10-dimethylundeca-5,9-dien-2-one and 4-(2,2-dimethyl-6-methylenecyclohexyl)butan-2-one and 4-(2,6,6-trimethyl-2-cyclohexen-1-yl)butan-2-one		Cease manufacture
944-482-9		Reaction mass of 1-(3,3-dimethylcyclohex-1-en-1-yl)pent-4-en-1-one and 1-(5,5-dimethylcyclohex-1-en-1-yl)pent-4-en-1-one		Full, 10-100
945-940-0		Reaction mass of 1-(2,6,6-trimethylcyclohex-2-en-1-yl)pentan-3-one and 1-(2,2,6-trimethylcyclohexyl)pentan-3-one		OSII or TII
945-947-9		reaction mass of 1-(3,3-dimethylcyclohex-1-en-1-yl)ethanone and 2,6,6-trimethylcyclohept-2-en-1-one		OSII or TII
948-348-0	208034-56-4	(3E)-3-methyl-5-[(1R)-2,2,3-trimethylcyclopent-3-en-1-yl]pent-3-en-2-one		OSII or TII

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]
948-498-7	143785-33-5	(3E)-4-[(1S,3aS,4R,7aS)-1,7a-dimethyloctahydro-4H-1,4-methanoinden-4-yl]pent-3-en-2-one		Full, not (publicly) available
950-588-6	1352216-91-1	1-(3-bicyclo[2.2.1]heptanyl)hex-5-en-2-one		Full, not (publicly) available
950-718-1		Reaction mass of (E)-1-(3,6-dimethylcyclohex-3-en-1-yl)-2-methylpent-1-en-3-one and (E)-1-(4,6-dimethylcyclohex-3-en-1-yl)-2-methylpent-1-en-3-one		Full, not (publicly) available

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)[4]. 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[5]. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

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

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

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

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

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

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

For more information on assessments of regulatory needs please consult ECHA's website[6].

[6] 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
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 are available in the foreword to this document. Please read it carefully before going through the report.

ECHA has grouped together structurally similar substances based on the presence of:

- the "**ketone**" functional group
- and the "**alicyclic**" moieties

The status of the 36 substances is as such:

- **15** substances with full registrations
- **14** intermediates
- **3** NONS
- **4** not registered

Based on information reported in the REACH registration dossiers, most (13/15) substances that have full REACH registrations within the group have professional and/or consumer uses, in addition to any industrial uses. These uses include use in products categories such as washing and cleaning products, perfumes and fragrances, cosmetics and personal care products, air care products, polishes and wax blends, and biocidal products. In addition, one substance (EC 942-532-4) has consumer uses in finger paints, filler and putties, as well as coatings, paints, thinners and paint removers and inks and toners. The substances are mainly used as odour agents or fragrances. There is only a limited number of substances that have any article service life uses (one substance with two ASL uses). Given this use information, there is a high potential for exposure to these substances.

2 Conclusions and actions

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

Table 1: Conclusions and proposed actions

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Table 2: Conclusions and proposed actions
251-020-3[7] 293-297-3	Known or potential hazard for reproductive toxicity; for ED; and for skin sensitisation	Known or potential hazard for aquatic toxicity; for PBT/vPvB; and for ED	Consumer and professional uses in washing, and cleaning products, cosmetics and personal care products as well as polishes and wax blends. Consumer uses as biocidal products, perfumes and fragrances, air care products leading	**First step:** CCH **Potential next steps (if hazard confirmed after data generation):** CLH; (or SVHC identification); followed by Restriction; **Potential last action:** **Restriction** <u>Justification:</u> The harmonised classification as Repr. 1B would trigger the restriction entry 30 and by that ensure that the substances are

[7] Due to its sensitising potential, EC 251-020-3, has to be declared on the ingredient list (INCI) when the following applies: concentration greater than 0,001 % in leave-on products and 0,01 % in rinse-off products (Cosmetic Product Regulation (EC) No 1223/2009, Annex III/ 327).

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Table 2: Conclusions and proposed actions
			to potential for consumer exposure.	not included in consumer mixtures above the limits specified in that entry. 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.
438-060-9 441-580-9 482-330-9 807-612-4	Known or potential hazard for ED, skin sens (438-060-9, 482-330-9 and 807-612-4)	Known or potential hazard for aquatic toxicity and for ED	Consumer and professional uses in washing, and cleaning products, cosmetics and personal care products (only EC 438-060-9), biocidal products, as well as polishes and wax blends. Consumer uses as perfumes and fragrances, air care products leading to potential for consumer exposure.	**First step:** CCH; Substance evaluation for ED properties **Potential next steps (if hazard confirmed after data generation):** CLH or SVHC identification followed by Restriction **Potential last action:** **Restriction** <u>Justification:</u> 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. 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.

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Table 2: Conclusions and proposed actions
				Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses. Industrial uses to be considered as part of the restriction.
942-532-4 948-498-7 950-718-1	Inconclusive hazard for reproductive toxicity Known or potential hazard for skin sensitisation for EC 942-532-4 No hazard or unlikely hazard for other hazards	Known or potential hazard for PBT/vPvB;	Consumer and professional uses in washing, and cleaning products, cosmetics and personal care products, biocidal products, as well as polishes and wax blends. Consumer uses as perfumes and fragrances, air care products leading to potential for consumer exposure.	**First step:** CCH; Substance evaluation for PBT **Potential next steps (if hazard confirmed after data generation):** SVHC identification or CLH **Potential last action:** **Restriction** <u>Justification:</u> 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. 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.

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Table 2: Conclusions and proposed actions
260-486-7 944-482-9	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity	Consumer and professional uses in washing, and cleaning products, cosmetics and personal care products, biocidal products, as well as polishes and wax blends. Consumer uses as perfumes and fragrances, air care products leading to potential for consumer exposure.	**First step:** CCH **Potential next steps (after data generation):** No action **Potential last action:** **Currently no need for EU RRM** <u>Justification:</u> Self-classification, (aquatic chronic 2) requires company level risk management measures (RMM) for environment to be in place. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.
All other substances	Known or potential hazard for skin sensitisation for EC 260-486-7, EC and EC 950-588-6 Inconclusive hazard	No hazard or unlikely hazard	Consumer and professional uses in washing, and cleaning products, cosmetics and personal care products, biocidal products, as well as polishes and wax blends. Consumer uses as finger paints, fillers and putties, , coatings and paints,	No action **Potential last action:** **Currently no need for EU RRM** <u>Justification:</u> Overall, no or unlikely hazard that would lead to concern for the reported uses. For substances exhibiting skin sensitising properties, all substances are self classified as skin sens. 1B, and therefore no EU RRM is proposed. Harmonised/self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace. The

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Table 2: Conclusions and proposed actions
	for skin sensitisation for EC 225-767-0, 259-173-8, 260-772-1, 415-570-1, 466-270-0, 472-300-3, 800-278-0 Inconclusive hazard for reproductive toxicity for EC 225-767-0, 259-173-8, 422-330-8, 950-588-6 Inconclusive hazard for ED for EC 225-562-6, 241-318-1,		inks and toners, perfumes and fragrances, air care products leading to potential for consumer exposure.	concern related to the presence of skin sensitisers in consumer mixtures is under investigation. For inconclusive hazards, no possibility to generate data at the moment to clarify the hazards

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Table 2: Conclusions and proposed actions
	and 950-588-6			

3 Justification for the need for regulatory risk management action at EU level (if hazards confirmed)

Suggested regulatory risk management action for the following substances and hazards if the hazards are confirmed:

- for reproductive toxicity, ED, PBT/vPvB, aquatic toxicity hazards due to the potential for release/exposure of the substances EC 251-020-3 and EC 293-297-3,

- for ED hazards for human health and environment due to the potential for release/exposure of EC 438-060-9, EC 441-580-9, 482-330-9 and EC 807-612-4, and

- for PBT hazards due to the potential for release/exposure of EC 942-532-4, EC 948-498-7 and EC 950-718-1.

Based on ECHA's assessment of currently available hazard information, potential hazards were identified for human health. The available information indicates potential for reproductive toxicity and endocrine disrupting properties due to findings in a 90-day repeated dose toxicity study for EC 251-020-3. The substance showed effects on thyroids, as well as animals' testis, epididymis, and prostate. The findings are observed with EC 251-020-3, and can be extrapolated to EC 293-297-3 based on the presence of common constituents (EC 251-020-3 is a constituent of EC 293-297-3). These ED findings are also relevant to environmental concerns.

Additionally, based on ECHA's assessment of currently available hazard information, substances EC 251-020-3 and EC 293-297-3 fulfil the PBT/vPvB screening criteria[8]. Further data to assess these hazards is not available on EC 293-297-3, however, data and conclusions for EC 251-020-3 can be extrapolated to assess the properties of EC 293-297-3, because EC 251-020-3 is a constituent of EC 293-297-3:

- these substances are potentially persistent or very persistent (P/vP) as they are not readily biodegradable (i.e., <60/70% degradation in an OECD 301F);
- these substances are potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - they screen for B/vB (lowKow 5.6 – 5.97); and
  - they may meet the criteria B as set out in Annex XIII (*i.e.* BCF > 2 000);
- these substances are potentially toxic (T) as the substances show reprotoxic effects in a 90-day study and may require classification as reprotoxic, category 1B.

In addition, three substances EC 942-532-4, 948-498-7 and 950-718-1 have screening level information to indicate potential PBT/vPvB hazards based on ready

[8] As defined in REACH Annex XIII and R11 Guidance on PBT assessment https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

biodegradation test results and log Kow values >4.5. However, there is no higher tier degradation simulation or bioaccumulation information to data to conclude on the hazards.

Therefore, the substances are considered as potential PBT/vPvB substances. The data to assess these PBT properties is under follow up to dossier evaluation, and further data generation may be required to confirm the hazards. The other substances listed above are unlikely to fulfil the PBT/vPvB screening criteria because they are either readily biodegradable or unlikely bioaccumulative.

The first step of the regulatory risk management action proposed for EC 251-020-3 and EC 293-297-3, should the hazards exist, is the confirmation of hazard via SVHC identification as PBT and ED and via harmonised classification (CLH) as reprotoxic category 1B. Alternatively, CLH may be pursued for all endpoints[9]. The harmonised classification and labelling can also be used to address the concern for aquatic toxicity together with the reprotoxic category 1B. The sequence of action (CLH or SVHC identification) may depend on which hazard(s) are confirmed first via CCH.

Additionally, the available information indicates potential for endocrine disrupting properties due to findings in short-term repeated dose toxicity studies for EC 438-060-9, EC 441-580-9, 482-330-9, and EC 807-612-4 showing effects on the thyroid. Confirmation of the hazard is needed before proceeding with EU regulatory risk management measures for ED. Substance evaluation (SEV) is proposed as it is the only potential approach to clarify the ED hazard for these substances. Dossier evaluation should be considered as a first step prior to launching SEV for these cases. The SEV process should define the appropriate studies needed to address the concern, as well as evaluate the proportionality of any requests for these substances.

Furthermore, for EC 942-532-4, 948-498-7 and 950-718-1 SEV is required as the initial step in order to confirm the hazard. Confirmation of the PBT hazard is required before proceeding with EU regulatory risk management measures for these substances.

For EC 438-060-9, EC 441-580-9, 482-330-9 and EC 807-612-4, the first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via SVHC identification as ED and for EC 942-532-4, 948-498-7, 950-718-1 as PBT . Alternatively, CLH may be pursued (see above).

SVHC identification or CLH are highly recommended as a step prior to restriction. In addition, SVHC identification brings immediate obligations for suppliers of the substances such as (i) supplying a safety data sheet and communicating on the safe use of the substances, (ii) responding to consumer requests within 45 days and (iii) notifying ECHA if the article they produce contains the substance above regulatory threshold.

CLH i) will require company level risk management measures (RMM) under the OSH legislation for workers to be in place, and ii) is needed or highly recommended in support of further regulatory processes under REACH; would lead to generic restriction of the substance(s) in consumer mixtures by means of restriction entry 30.

[9] The hazard classes PBT/vPvB, PMT/vPvM, ED have been introduced in CLP. Therefore, instead of SVHC identification under REACH, these hazards may be confirmed via CLH. It is not clear when to use which legal route (SVHC under REACH or CLH under CLP) during the period that both legal options are available. However, in this case, since CLH is proposed for other hazards it is recommended for addressing all these hazards.

Confirmation of the hazard properties via SVHC identification and/or CLH is not considered sufficient to minimise potential releases of the substances in the environment. Potential for release and exposure is expected in particular from consumer uses (e.g. washing and cleaning products) where releases to the environment cannot be avoided.

Furthermore, EC 438-060-9 and 441-580-9 both have additional uses (cosmetics, personal care products, polishes and wax blends, as well as biocidal products) that can lead to widespread exposure. No use information is available for 807-612-4, however, publicly available information indicate that the substance may be used in fragrances, as with other substances in this group. Therefore, in order to avoid the potential for regrettable substitution, a similar plans for regulatory risk management should be followed (pending the confirmation of the hazard in SEV).

The professional uses in washing and cleaning products are expected to be widespread (at many sites and by many users) and typically non-contained and non-automated leading to releases to the environment and with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration leading to potential workers' exposure. In addition, professional users may be self-employed and therefore not covered by OSH legislation.

Consumers may be co-exposed to the substances used by professionals (in washing and cleaning products).

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

In addition, the use of the most harmful substances (e.g. PBT/vPvB, CMR) by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[10].

Currently no need to suggest (further) regulatory risk management actions for the remaining substances in the group.

It is not possible to clarify the potential hazards of substances EC 225-767-0, 259-173-8, 260-772-1, 415-570-1, 466-270-0, 472-300-3 and 800-278-0 for reproductive toxicity, and for substances 225-562-6, 241-318-1, and 950-588-6 for ED properties. 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.

Based on ECHA's assessment of currently available hazard information, no potential hazards were identified for human health for these substances. These conclusions are based on based on a general absence of toxicity in the available repeated dose toxicity studies and if toxicity is observed it is above the classification thresholds (therefore no STOT-SE or STOT-RE), absence of mutagenicity as all remaining substances (and all substances within the group) are unlikely to be mutagenic based on the available in vitro assays on 16 substances, and absence of data suggesting reproductive toxicity (apart from the substances addressed above). Some of the substances do exhibit skin sensitising

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

properties, specifically, EC 260-486-7, EC 482-330-9, and EC 950-588-6, however all three substances are self-classified as Skin Sens 1B, which provides adequate risk management measures for professional users. In addition, there is high uncertainty for the conclusions for skin sensitisation for eight substances (EC 225-767-0, 259-173-8, 260-772-1, 415-570-1, 466-270-0, 472-300-3, 800-278-0) due to lack of data and absence of structural similarity, for reproductive toxicity for most of these substances due to lack of data as well as for ED HH hazard also due to lack of data.

For industrial and professional uses, sufficient and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation. Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing substance x.

For the use of the substance(s) 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.

These remaining substances are unlikely to fulfil the PBT/vPvB criteria, because they are either readily biodegradable or unlikely bioaccumulative (based on low LogKow). Substances in EC 241-318-1, EC 250-657-4, EC 943-896-7, and EC 945-940-0 are unlikely to have PBT/vPvB hazards. Data on EC 241-318-1 indicates that the substance is readily biodegradable in the screening test and this outcome can be extrapolated to EC 250-657-4, 943-896-7, 945-940-0 because they are structurally very similar.

Similarly, substances 620-555-8 and 639-250-6 are unlikely to have PBT/vPvB hazards. EC 620-555-8, 639-250-6 do not have data but structural similarity to EC 438-060-9 allow to consider similar unlikely PBT/vPvB hazards for these substances.

Substances EC 265-450-4, 267-135-7, 939-720-3, 948-348-0 are unlikely to have PBT/vPvB hazards. The submitted logKow for EC 267-135-7 indicates borderline B potential. Structural similarity to EC 267-135-7 allow to consider similar unlikely PBT/vPvB hazards for these substances across the subgroup.

Four remaining substances EC 212-146-4, 225-562-6, 472-300-3, 950-588-6 are unlikely to have PBT/vPvB hazards. The substances are not readily biodegradable, but their bioaccumulation potential is expected to be low. EC 212-146-4, 225-562-6, and 950-588-6 have logKow <4.5, and 472-300-3 has higher logKow but bioaccumulation higher tier data indicates low B potential.

Annex 1: Overview of classifications

Data extracted on 11 October 2022

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
204-336-0	119-60-8	dicyclohexyl ketone	-	Eye Irrit. 2 H319 [intermediate (inactive)]	Acute Tox. 4 H302 [1 out of 2]
212-146-4	765-43-5	cyclopropyl methyl ketone	-	Acute Tox. 4 H302 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] Flam. Liquid 2 H225 [intermediate (active)]	Acute Tox. 3 H301 [5 out of 11] Skin Irrit. 2 H315 [4 out of 11] Eye Irrit. 2 H319 [5 out of 11] Eye Damage 1 H318 [1 out of 11]
225-562-6	4927-39-3	4-cyclohexyl-4-methylpentan-2-one	-	Skin Irrit. 2 H315 Aquatic Chronic 2 H411	-
225-767-0	5063-03-6	methyl (8,9,10-trinorborn-5-en-2-yl) ketone	-	Acute Tox. 4 H302 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Aquatic Chronic 3 H412 [intermediate (active)]	Skin Irrit. 2 H315 [1 out of 49]
241-318-1	17283-81-7	4-(2,6,6-trimethyl-1-cyclohexen-1-yl)butan-2-one	-	Aquatic Acute 2 H401 Aquatic Chronic 2 H411	Skin Irrit. 2 H315 [4 out of 22] Eye Irrit. 2 H319 [3 out of 22] Aquatic Chronic 2 H411 [4 out of 22]
246-799-1	25304-14-7	1-(3,3-dimethylcyclohexyl)ethan-1-one	-	-	STOT Single Exp. 3 H335 [1 out of 20] Eye Irrit. 2 H319 [1 out of 20] Skin Irrit. 2 H315 [1 out of 20]
250-657-4	31499-72-6	4-(2,6,6-trimethyl-2-cyclohexen-1-yl)butan-2-one	-	-	Aquatic Chronic 2 H411 [1 out of 131] Skin Sens. 1 H317 [81 out of 131]
251-020-3	32388-55-9	[3R-(3α,3aβ,7β,8aα)]-1-(2,3,4,7,8,8a-hexahydro-3,6,8,8-tetramethyl-1H-3a,7-	-	Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	-

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
		methanoazulen-5-yl)ethan-1-one			
259-173-8	54464-54-9	1-[1,6-dimethyl-3-(4-methylpent-3-enyl)-3-cyclohexen-1-yl]ethan-1-one	-	-	Skin Irrit. 2 H315 [1 out of 41] Aquatic Chronic 3 H412 [1 out of 41] Skin Sens. 1 H317 [29 out of 41]
260-486-7	56973-85-4	1-(5,5-dimethyl-1-cyclohexen-1-yl)pent-4-en-1-one	-	Skin Sens. 1B H317 Aquatic Chronic 2 H411	-
260-772-1	57499-57-7	1-[1,6-dimethyl-4-(4-methylpent-3-enyl)-3-cyclohexen-1-yl]ethan-1-one	-	-	-
265-450-4	65113-95-3	3-methyl-5-(2,2,3-trimethyl-3-cyclopenten-1-yl)pent-3-en-2-one	-	Aquatic Chronic 2 H411 [intermediate (active)]	-
267-135-7	67801-15-4	3-methyl-5-(2,2,3-trimethyl-3-cyclopenten-1-yl)pent-4-en-2-one	-	Aquatic Chronic 2 H411 [intermediate (active)]	-
293-297-3	91053-33-7	Juniper, Juniperus mexicana, ext., isomerized, acetylated	-	Skin Sens. 1B H317 Asp. Tox. 1 H304 Aquatic Chronic 2 H411	Skin Sens. 1 H317 [6 out of 6] Aquatic Chronic 1 H410 [6 out of 6]
422-330-8	-	1-(3,3-dimethylcyclohexyl)pent-4-en-1-one	-	Aquatic Chronic 2 H411	Aquatic Chronic 1 H410 [1 out of 4] Eye Damage 1 H318 [1 out of 4]
438-060-9	-	438-060-9	-	Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 2 H411	Skin Sens. 1 H317 [4 out of 4] Skin Irrit. 2 H315 [4 out of 4]
441-580-9	-	441-580-9	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Acute 1 H400 Aquatic Chronic 3 H412	Aquatic Chronic 4 H413 [1 out of 1]

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
466-270-0	-	466-270-0	-	-	Skin Sens. 1B H317 [2 out of 11] Skin Sens. 1 H317 [9 out of 11] Aquatic Chronic 2 H411 [1 out of 11] Aquatic Chronic 1 H410 [10 out of 11] Aquatic Acute 1 H400 [10 out of 11]
472-300-3	-	472-300-3	-	-	Aquatic Chronic 1 H410 [1 out of 10] Aquatic Chronic 2 H411 [2 out of 10] Aquatic Acute 1 H400 [9 out of 10] Skin Sens. 1 H317 [8 out of 10] Skin Sens. 1B H317 [2 out of 10]
482-330-9	144020-22-4	482-330-9	-	Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	Skin Irrit. 2 H315 [1 out of 2] Aquatic Chronic 2 H411 [1 out of 2]
620-555-8	224031-70-3	620-555-8	-	-	-
639-250-6	224031-71-4	639-250-6	-	-	-
687-590-9	56973-87-6	687-590-9	Index number: 606-086-00-1 Aquatic Chronic 2 Statement: H411	-	-
800-278-0	41435-93-2	800-278-0	-	-	-
807-612-4	1393645-32-3	1-(5-ethyl-5-methylcyclohex-1-en-1-yl)pent-4-en-1-one	-	Acute Tox. 4 H302 Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	-

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
900-069-5	-	900-069-5	-	Flam. Liquid 2 H225 [intermediate (active)]	-
939-720-3	-	Reaction products of (2,2,3-trimethylcyclopent-3-en-1-yl)acetaldehyde and butan-2-one	-	-	-
942-532-4	-	Reaction mass of (3R)-3-methyl-5-[(1R,3R)-2,2,3-trimethylcyclopentyl]pentan-2-one and (3S)-3-methyl-5-[(1R,3R)-2,2,3-trimethylcyclopentyl]pentan-2-one	-	Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	-
943-896-7	-	Reaction mass of (E)-6,10-dimethylundeca-5,9-dien-2-one and 4-(2,2-dimethyl-6-methylenecyclohexyl)butan-2-one and 4-(2,6,6-trimethyl-2-cyclohexen-1-yl)butan-2-one and 626-253-2	-	Aquatic Chronic 3 H412 [intermediate (inactive)]	-
944-482-9	-	Reaction mass of 1-(3,3-dimethylcyclohex-1-en-1-yl)pent-4-en-1-one and 1-(5,5-dimethyl-1-cyclohexen-1-yl)pent-4-en-1-one	-	Skin Sens. 1B H317 Aquatic Chronic 2 H411	-
945-940-0	-	Reaction mass of 1-(2,6,6-trimethylcyclohex-2-en-1-yl)pentan-3-one and 1-(2,2,6-trimethylcyclohexyl)pentan-3-one	-	-	

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
945-947-9	-	reaction mass of 1-(3,3-dimethylcyclohex-1-en-1-yl)ethanone and 2,6,6-trimethylcyclohept-2-en-1-one	-	-	
948-348-0	208034-56-4	(3E)-3-methyl-5-[(1R)-2,2,3-trimethylcyclopent-3-en-1-yl]pent-3-en-2-one	-	-	
948-498-7	143785-33-5	(3E)-4-[(1S,3aS,4R,7aS)-1,7a-dimethyloctahydro-4H-1,4-methanoinden-4-yl]pent-3-en-2-one	-	Aquatic Acute 1 H400 Aquatic Chronic 1 H410	
950-588-6	1352216-91-1	1-(bicyclo[2.2.1]heptan-2-yl)hex-5-en-2-one	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1B H317 Aquatic Chronic 2 H411	
950-718-1	-	Reaction mass of (1E)-1-(3,6-dimethylcyclohex-3-en-1-yl)-2-methylpent-1-en-3-one and (1E)-1-(4,6-dimethylcyclohex-3-en-1-yl)-2-methylpent-1-en-3-one	-	Acute Tox. 4 H302 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	

(*) 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 11 October 2022

EC number	225-562-6	241-318-1	251-020-3	260-486-7	293-297-3	422-330-8	438-060-9	441-580-9	482-330-9	807-612-4	942-532-4	944-482-9	948-498-7	950-588-6	950-718-1
Main types of applications by product or article types	Annex VII	Annex VII	Annex IX	Annex VIII	Annex VII	Annex VII	Annex VII	Annex VII	Annex VIII	Annex VII	Annex VII	Annex VIII	Annex VII	Annex VII	Annex VII
PC 35: Washing and cleaning products	I, **P**, **C**	F, I, **P**, **C**	I, **P**, **C**	I, **P**, **C**		I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**		F, I, **P**, **C**	F, I, **P**, **C**	I, **P**, **C**		I, **P**, **C**

PC 8: Biocidal products (e.g. disinfectants, pest control)	**C**	F, I, **P**, **C**	**C**	**C**		**C**	F, I, **P**, **C**	F, I, **P**, **C**	**C**		F, **C**	F, I, **P**, **C**	**C**		**C**
PC 28: Perfumes, fragrances	**C**	F, **C**	F, **C**	F, **C**		F, **C**	F, **C**	F, **C**	F, **C**		F, **C**	F, **C**			F, **C**
PC 3: Air care products	**C**	F, **C**	**C**	**C**		**C**	F, **C**	F, **C**	**C**		F, **C**	F, **C**	**C**		**C**
PC 39: Cosmetics, personal care products	**C**	**P**, **C**	**C**	**C**		**C**	**P**, **C**	**P**, **C**	F, **C**		F, **C**	**P**, **C**	**C**		**P**, **C**

PC 31: Polishes and wax blends	**P, C**	F, **P, C**	**P, C**	**P, C**		**P, C**	F, **P, C**	F, **P, C**	**P, C**		**P, C**	F, **P, C**	**P, C**		**P, C**
PC 13: Fuels											**C**				
PC 32: Polymer preparations and compounds						**A**									
PC 9c: Finger paint											**C**				
PC 9b: Fillers, putties, plasters, modelling clay											**C**				

PC 9a: Coatings and paints, thinners, paint removes											**C**				
PC 18: Ink and toners											**C**				
PC 26: Paper and board treatment products						**A**									
PC 14: Metal surface treatment products		I										I			

PC 19: Intermediate															

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

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

Data extracted on 25/10/2022

EC / List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
687-590-9					YES	

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

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