

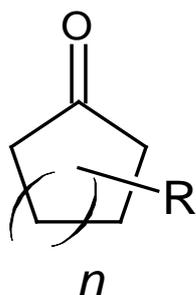
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 27.6.2022

Group Name: Unsubstituted and linear aliphatic substituted cyclic ketones

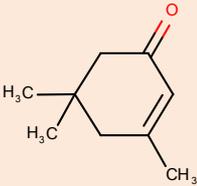
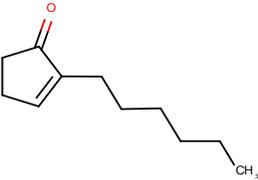
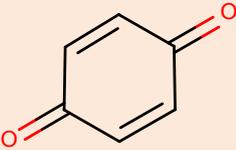
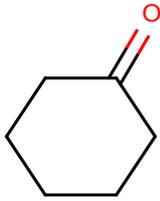
General structure:



Revision history

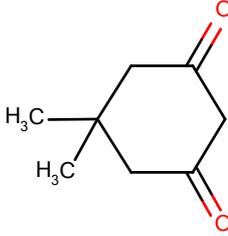
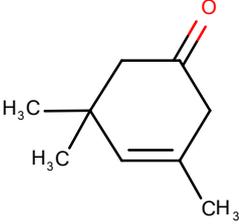
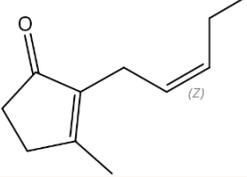
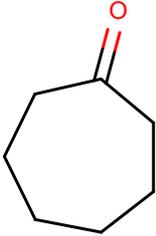
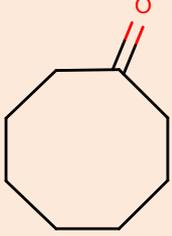
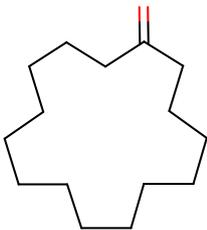
<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	20.9.2022	

Substances within this group:

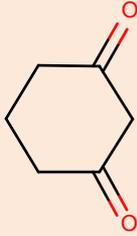
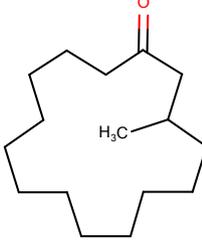
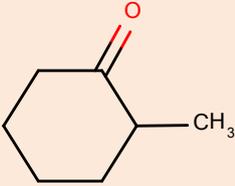
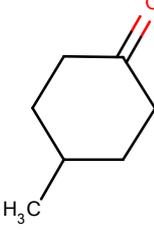
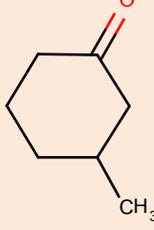
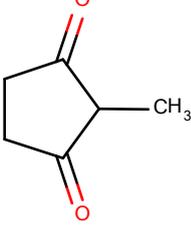
EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
201-126-0	78-59-1	3,5,5-trimethylcyclohex-2-enone		Full, 100-1000
202-417-5	95-41-0	2-hexylcyclopent-2-enone		Full, not (publicly) available
203-405-2	106-51-4	p-benzoquinone		Full, 1-10
203-631-1	108-94-1	Cyclohexanone		Full, >1000
204-435-9	120-92-3	Cyclopentanone		Full, >1000

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>

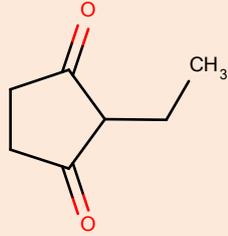
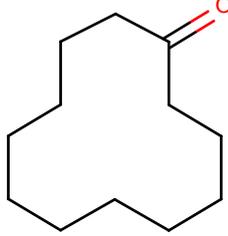
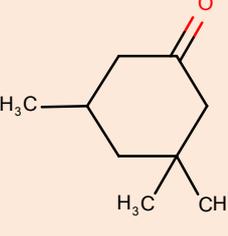
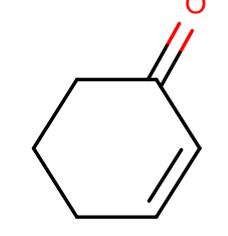
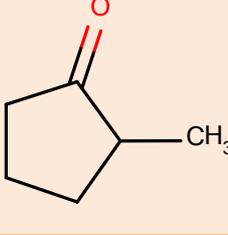
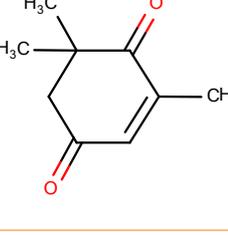
ASSESSMENT OF REGULATORY NEEDS

204-804-4	126-81-8	5,5-dimethylcyclohexane-1,3-dione		OSII or TII
205-273-1	137-03-1	2-heptylcyclopentanone		Full, 10-100
207-434-1	471-01-2	3,5,5-trimethylcyclohex-3-en-1-one		OSII or TII
207-668-4	488-10-8	3-methyl-2-pent-2-enylcyclopent-2-enone		Full, 10-100
207-937-6	502-42-1	Cycloheptanone		OSII or TII
207-940-2	502-49-8	Cyclooctanone		OSII or TII
207-951-2	502-72-7	Cyclopentadecanone		Full, not (publicly) available

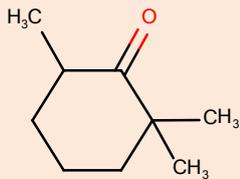
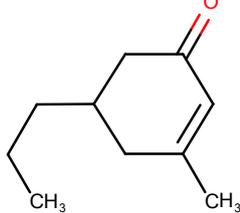
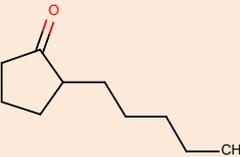
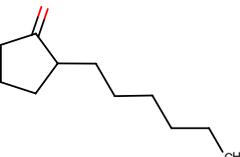
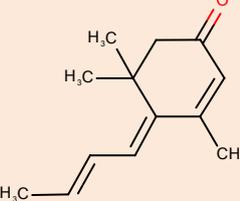
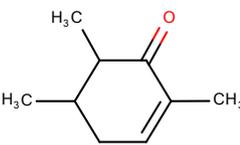
ASSESSMENT OF REGULATORY NEEDS

207-980-0	504-02-9	Cyclohexane-1,3-dione		OSII or TII
208-795-8	541-91-3	3-methylcyclopentadecan-1-one		Full, not (publicly) available
209-513-6	583-60-8	2-methylcyclohexanone		Only C&L notification
209-665-3	589-92-4	4-methylcyclohexanone		Full, 10-100
209-710-7	591-24-2	3-methylcyclohexanone		OSII or TII
212-153-2	765-69-5	2-methylcyclopentane-1,3-dione		OSII or TII

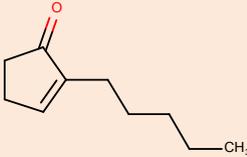
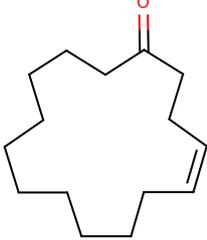
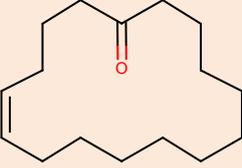
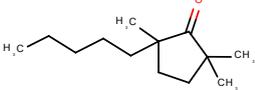
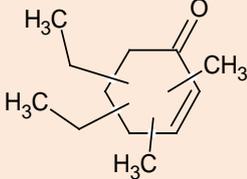
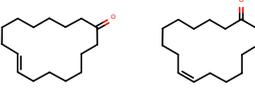
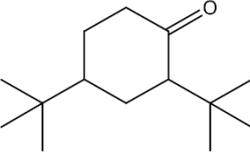
ASSESSMENT OF REGULATORY NEEDS

212-512-3	823-36-9	2-ethylcyclopentane-1,3-dione		OSII or TII
212-595-6	830-13-7	Cyclododecanone		Full, not (publicly) available
212-855-9	873-94-9	3,3,5-trimethylcyclohexan-1-one		Full, not (publicly) available
213-223-5	930-68-7	Cyclohex-2-enone		OSII or TII
214-318-4	1120-72-5	2-methylcyclopentanone		OSII or TII
214-406-2	1125-21-9	2,6,6-trimethylcyclohex-2-ene-1,4-dione		OSII or TII

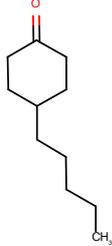
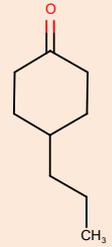
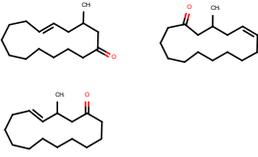
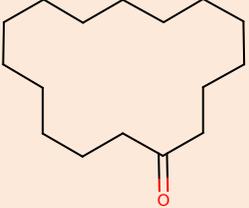
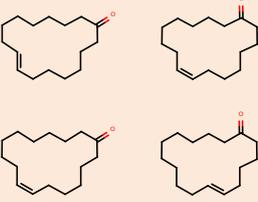
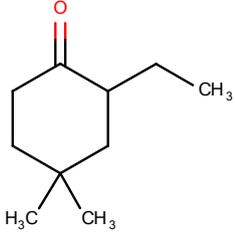
ASSESSMENT OF REGULATORY NEEDS

219-309-9	2408-37-9	2,2,6-trimethylcyclohexan-1-one		Only C&L notification
223-069-0	3720-16-9	3-methyl-5-propylcyclohex-2-enone		Full, not (publicly) available
225-392-2	4819-67-4	2-pentylcyclopentan-1-one		Full, not (publicly) available
235-970-6	13074-65-2	2-hexylcyclopentan-1-one		Full, not (publicly) available
236-187-2	13215-88-8	4-(2-butenylidene)-3,5,5-trimethylcyclohex-2-en-1-one		Full, not (publicly) available
243-473-0	20030-30-2	2,5,6-trimethylcyclohex-2-en-1-one		OSII or TII

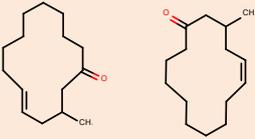
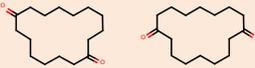
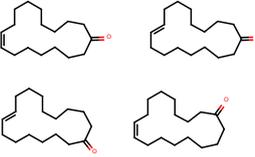
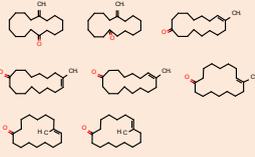
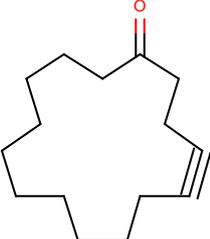
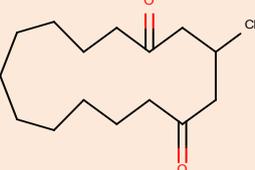
ASSESSMENT OF REGULATORY NEEDS

247-104-4	25564-22-1	2-pentylcyclopent-2-en-1-one		OSII or TII
252-692-0	35720-57-1	Cyclopentadec-4-en-1-one		Only C&L notification
253-568-9	37609-25-9	5-cyclohexadecen-1-one		Full, not (publicly) available
265-779-3	65443-14-3	2,2,5-trimethyl-5-pentylcyclopentan-1-one		Full, not (publicly) available
272-462-3	68845-36-3	Diethyldimethylcyclohex-2-en-1-one		Only C&L notification
401-700-2	3100-36-5	A mixture of cis- and trans-cyclohexadec-8-en-1-one		Full, not (publicly) available
405-340-7	13019-04-0	2,4-di-tert-butylcyclohexanone		NONS

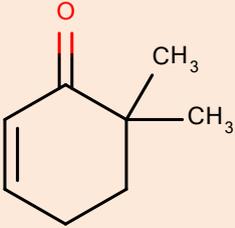
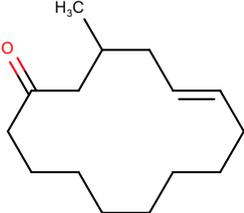
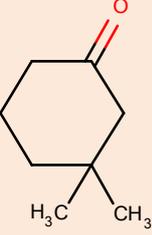
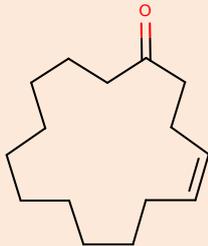
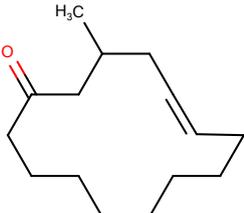
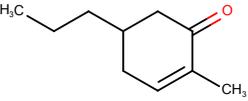
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406-670-4	61203-83-6	4-pentylcyclohexanone		Full, not (publicly) available
406-810-4	40649-36-3	4-propylcyclohexanone		OSII or TII
429-900-5	82356-51-2	(E)-3-methyl-5-cyclopentadecen-1-one		Full, not (publicly) available
438-930-8	2550-52-9	cyclohexadecanone		Full, not (publicly) available
442-550-8		LEVODION		Cease manufacture
448-300-4	88642-03-9	Cyclohexadecen-1-one		Full, not (publicly) available
451-230-7		2-ethyl-4,4-dimethylcyclohexan-1-one		Full, not (publicly) available

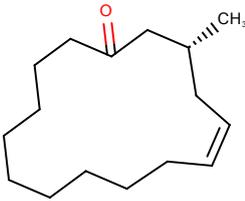
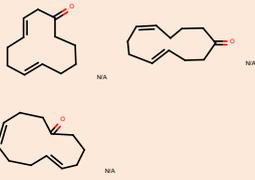
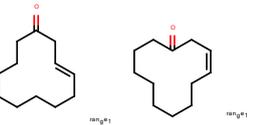
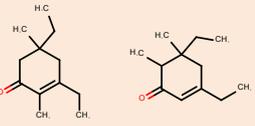
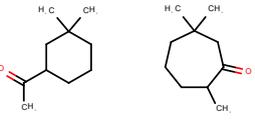
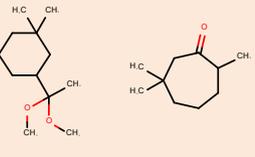
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452-280-2	259854-70-1	5-Cyclotetradecen-1-one, 3-methyl-		Full, not (publicly) available
453-530-3		Not available		NONS
454-820-2		Reaction mass of 1,8-CYCLOHEXADECANDI ON and 1,9-CYCLOHEXADECANDI ON		NONS
457-300-3		Reaction mass of cis-Cycloheptadec-8-en-1-one, trans-Cycloheptadec-8-en-1-one, cis-Cycloheptadec-9-en-1-one, trans-Cycloheptadec-9-en-1-one		NONS
458-000-5		Reaction mass of (cis,trans)-9-Methylcyclohexadec-8-en-1-one, (cis,trans)-8-Methylcyclohexadec-8-en-1-one, (cis,trans)-8-Methylcyclohexadec-7-en-1-one		NONS
604-281-6	14224-80-7	Cyclopentadec-4-yn-1-one		OSII or TII
606-859-3	21890-10-8	1,5-Cyclopentadecanedione, 3-methyl-		OSII or TII
607-739-3	2550-52-9	Cyclohexadecanone (duplicate; see 438-930-8)		Only C&L notification

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613-816-2	6553-64-6	6,6-dimethylcyclohex-2-en-1-one		OSII or TII
620-553-7	259854-70-1	5-Cyclotetradecen-1-one, 3-methyl-, (5E)-		Only C&L notification
628-905-1	2979-19-3	Cyclohexanone, 3,3-dimethyl-		OSII or TII
628-981-6	40649-36-3	4-Propylcyclohexanon (duplicate; see 406-810-4)		Only C&L notification
630-473-4	14595-54-1	4-Cyclopentadecen-1-one, (4Z)-		Full, not (publicly) available
639-113-0	259854-71-2	5-Cyclotetradecen-1-one, 3-methyl-, (5Z)-		Only C&L notification
682-338-4	61203-83-6	4-Pentylcyclohexanon (duplicate; see 406-670-4)		Only C&L notification
807-489-7	1447712-18-6	2-methyl-5-propylcyclohex-2-en-1-one		Full, not (publicly) available

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Not (publicly) available	Not (publicly) available	Not (publicly) available	Not (publicly) available	Not registered
851-742-4	464207-51-0	(3R,5Z)-3-METHYL-5-CYCLOPENTADECEN-1-ONE		Full, not (publicly) available
941-893-5	15229-79-5	4,8-Cyclododecadien-1-one		Full, not (publicly) available
942-937-6		Reaction mass of (E)-cyclododec-3-enone and (Z)-cyclododec-3-one		OSII or TII
943-554-7		Reaction mass of 3,5-diethyl-2,5-dimethylcyclohex-2-en-1-one and 3,5-diethyl-5,6-dimethylcyclohex-2-en-1-one		Full, not (publicly) available
944-298-9		Reaction mass of 1-(3,3-dimethylcyclohexyl)ethanone and 2,6,6-trimethylcycloheptanone		Full, not (publicly) available
946-194-9		Reaction mass of 2,6,6-trimethylcycloheptanone and 3-(1,1-dimethoxyethyl)-1,1-dimethylcyclohexane	 ALTERNATE 1	OSII or TII

This table contains also group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional

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search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

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DISCLAIMER

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Foreword

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

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

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

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

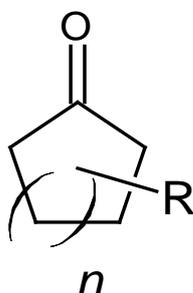
² <https://echa.europa.eu/understanding-assessment-regulatory-needs>

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 the cyclic ketone moiety shown in the figure below. In this group, there may be more than one ketone group; the substituent R is either hydrogen (i.e. unsubstituted) or linear aliphatic chain(s); and the ring may be unsaturated.



The group consists of 68 substances, out of which 32 have a full registration within REACH, 20 are intermediates, 5 are NONS, 10 are not registered and for 1 the manufacture has ceased.

Many substances in the group are present in natural oils. Beyond the use in fragrances, some are used as intermediates in organic synthesis, fungicides, solvents. Cyclohexanone (EC 203-631-1) is the most important industrial cyclic ketone, used in making nylons.³

Based on information reported in the REACH registration dossiers, 12 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, perfumes, fragrances, air care products, cosmetics, personal care products, polishes and wax blends and as co-formulant in biocidal products (e.g. disinfectants, pest control). Additional uses are reported for Cyclohexanone (EC 203-631-1) as intermediate (precursor), lubricant, hardener, laboratory chemical in various applications. Another substance having a broad use pattern is (E)-3-methyl-5-cyclopentadecen-1-one (EC 429-900-5). High exposure potential and release in the environment can be assumed for the majority of the fully registered substances in the group, with the exception of EC 212-595-6 and List 941-893-5 for which only industrial uses as intermediate are reported.

³ Hwang, Y.-L. and Bedard, T.C. (2001). Ketones. In *Kirk-Othmer Encyclopedia of Chemical Technology*. <https://doi.org/10.1002/0471238961.1105201502180109.a01.pub2> at §7.

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 (no) need for regulatory risk management action at EU level

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

The substance 3,5,5-trimethylcyclohex-2-enone (isophorone; EC 201-126-0) has a harmonised classification as Carc. 2 and it has recently been evaluated under SEv to clarify reproductive and ED effects. Some indications of hazards (delay in preputial separation, reduced testosterone levels, reduced seminal vesicle weight) were earlier reported in a Pubertal Development and Thyroid function assay in male rats. An Extended one-generation reproductive toxicity study (EOGRTS) has recently been conducted and is currently under evaluation. As the final EOGRTS report was not yet available at the time of the SEv conclusion, the outcome of the SEv was that no conclusion can for the moment be reached regarding reproductive toxicity and endocrine disruption (concern unresolved). The currently available information on hazard is not sufficient to conclude on reproductive toxicity and ED hazard for this substance, therefore it is proposed to wait until the ongoing processes are concluded.

For industrial and professional uses of isophorone, it is expected that based on the harmonised classification as Carc. 2 registrants have recommended necessary RMMs to ensure safe use at the workplace. The substance 3,5,5-trimethylcyclohex-3-en-1-one (EC 207-434-1) is structurally very similar to isophorone and is self-classified as Carc. 2. Since only intermediate uses are reported for this substance, limited exposure potential and release in the environment can be assumed for that and sufficient and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management for these two substances.

The remaining substances have no data indicating a potential hazard for carcinogenicity. All substances in the group (except one) are unlikely to be mutagenic and based on repeated dose toxicity studies conducted on 18 of the substances, there is no specific concern for target organ effects. In addition, chronic studies showing no carcinogenicity have been conducted with rats and mice with one substance (cyclohexanone, EC 203-631-1). Whilst there are seven substances with a structure similar to that of isophorone (unsaturated, linear alkyl 6-membered rings), they are all registered at low tonnage / intermediate / not registered, so there is no repeated dose toxicity data available on these, and relevant data generation under evaluation may be difficult.

The substance cyclohexanone (EC 203-631-1) was evaluated under SEv in 2017, where it was concluded that *"Following analysis the eMSCA considered that the available information is sufficient for classification of cyclohexanone as Muta. Cat. 2"*⁴. However, so far, no formal intention for CLH has been submitted. It is noted that this conclusion was drawn based on data in one *in vivo* micronucleus test published in a scientific journal. After SEv was concluded, a new *in vivo* micronucleus test (OECD TG 474, GLP) was conducted in 2020. A robust study summary is included in the REACH registration dossier of the substance. No genotoxicity was reported in this study. As also several other *in vitro* and *in vivo* studies showed negative results for mutagenicity, it is considered that mutagenicity

⁴ [Substance evaluation conclusion](#)

is unlikely, and the classification criteria as Muta. 2 would not be fulfilled. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management. Based on the available information, the substance might show some level of aquatic toxicity, but this has to be confirmed through data generation.

The substance p-benzoquinone (EC 203-405-2) is self-classified as Muta 2 based on positive in vitro tests. This substance is structurally different from the other group members, as it is the only quinone. Other quinones have also been classified as mutagens. In vitro and/or in vivo studies, showing no mutagenicity, are available on 22 of the registered substances. Based on this, mutagenicity is considered unlikely for the rest of the group.

Ten substances in the group are known skin sensitisers, with either harmonised classification as Skin Sens. 1B (EC 429-900-5) or self-classification as Skin Sens. 1 or 1B (see details in Annex I). 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 substances EC/List 807-489-7, 236-187-2, 429-900-5, 452-280-2.

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.

Studies showing no skin sensitisation are available on 20 of the substances with full REACH registrations. Based on the chemical structures, it is not possible to predict which of the non-tested substances would be likely to cause sensitisation.

Reproductive/developmental toxicity studies have been conducted on eight of the substances, none of them indicating hazardous effects (except isophorone; see above). Regarding a potential endocrine disruption hazard, the available data does not indicate any target organ toxicity in endocrine organs such as the thyroid or the reproductive organs. Therefore, there is no apparent hazard finding that could be linked to endocrine-mediated effects for the substances.

Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management in relation to human health.

All substances show different levels of aquatic toxicity varying from not toxic to moderate to very toxic. The cyclic ketones with large rings (cycles with $\geq C_{12}$) show high aquatic toxicity. This is clear from the experimental data in the registration dossiers and from the self classification for most of them (Aquatic acute 1 and Aquatic chronic 1). Some of these substances have only short-term data which due to their poor water solubility (<1 mg/L) is considered not valid. Five substances of the group with large rings (ECs 207-951-2, 208-795-8, 253-568-9, 438-930-8, 448-300-4) are poorly water soluble and expected to be classified (or change the self-classification) as toxic to the aquatic environment after data generation, while the substance EC 203-631-1 might show moderate levels of aquatic toxicity, to be confirmed through data generation.

The current classification for the following substances are 207-951-2 (Aquatic Acute 1, Aquatic Chronic 1), 253-568-9 (Aquatic Acute 1, Aquatic Chronic 1), 438-930-8 (CLH Aquatic Chronic 4).

All other substances show different levels of aquatic toxicity. It is not possible to indicate a clear trend, however it looks that the substances with long alkyl chain substituents and/or multiple short-chain substituents show higher aquatic toxicity.

Data generation under CCH will be used to confirm aquatic toxicity for a representative group of substances (mainly those containing cycles with \geq C12). 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.

Uncertainty

Based on the available information on uses reported in the registration dossier, the substance EC 429-900-5 is widely used in a variety of applications leading to exposure to workers and consumers and release to the environment. Industry should update their registration dossiers and clarify whether or not the uses reported for this substance are supported. In the next iteration to this assessment of regulatory needs, if no update of the registration dossiers has been submitted, those uses will be considered to be of relevance and if the potential hazard properties confirmed, then further regulatory risk management will be considered.

3 Conclusions and actions

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

EC/List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
201-126-0	Known or potential hazard for carcinogenicity (CLH Carc. 2), Inconclusive hazard for reproductive toxicity and ED	No hazard or unlikely hazard for aquatic toxicity for PBT/vPvB Inconclusive hazard for ED	Mainly used in industrial settings as intermediate with limited potential for exposure and release, with the exception of professional use in plant protection products with potential for worker exposure and release in the environment.	Currently no need for EU RRM <u>Justification:</u> based on the harmonised classification as Carc. 2 registrants have recommended necessary RMMs to ensure safe use at the workplace.	Await completion of on-going processes
203-631-1 207-951-2 208-795-8 253-568-9 438-930-8 448-300-4	No hazard or unlikely hazard	Known or potential hazard for aquatic toxicity	Industrial, widespread professional and consumer uses as fragrance/odour agent in washing and cleaning products, perfumes, fragrances, air care	Currently no need for EU RRM <u>Justification:</u> Harmonised/self classification followed by implementation of necessary RMMs should be sufficient	CCH

ASSESSMENT OF REGULATORY NEEDS

EC/List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			<p>products, cosmetics, personal care products, polishes and wax blends. Potential for worker exposure and release in the environment.</p> <p>EC 208-795-8: intermediate use in industrial setting, with limited exposure potential and release in the environment.</p>	to ensure safe use for environment	
<p>203-405-2 214-406-2 (intermediate) 236-187-2 247-104-4 (intermediate)406-810-4 429-900-5 452-280-2 807-489-7 851-742-4 941-893-5</p>	<p>Known or potential hazard for skin sensitisation for mutagenicity (EC 203-405-2)</p>	<p>Known or potential hazard for aquatic toxicity</p>	<p>Industrial, widespread professional and consumer uses as fragrance/odour agent in washing and cleaning products, perfumes, fragrances, air care products, cosmetics, personal care products, polishes and wax blends. Potential for worker exposure and</p>	<p>Currently no need for EU RRM</p> <p><u>Justification:</u></p> <p>Harmonised/self-classification followed by implementation of necessary RRM should be sufficient to ensure safe use at the workplace. The concern related to the presence of skin sensitisers in</p>	<p>No action</p>

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EC/List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			release in the environment.	consumer mixtures is under investigation.	
<p>All the other substances in the group</p> <p>Fully registered:</p> <p>202-417-5 204-435-9 205-273-1 207-668-4 209-665-3 212-595-6 212-855-9 223-069-0 225-392-2 235-970-6 265-779-3 272-462-3 401-700-2 442-550-8 (Cease manufacture) 451-230-7 630-473-4 943-554-7 944-298-9</p>	<p>No hazard or unlikely hazard</p> <p>Known or potential hazard for carcinogenicity (EC 207-434-1)</p>	<p>Known or potential hazard for aquatic toxicity</p> <p>Except EC/List: 204-435-9, 207-434-1, 207-668-4, 212-855-9, 214-318-4, 219-309-9, 628-905-1</p>	<p>Fully registered substances:</p> <p>Industrial, widespread professional and consumer uses as fragrance/odour agent in washing and cleaning products, perfumes, fragrances, air care products, cosmetics, personal care products, polishes and wax blends. Potential for worker exposure and release in the environment. For ECs 204-435-9 and 212-855-9: mainly intermediate use in industrial settings with limited exposure and release in the environment.</p>	<p>Currently no need for EU RRM</p> <p><u>Justification:</u> Overall, no or unlikely hazard that would lead to concern for the reported uses.</p> <p>For the substances where some level of aquatic toxicity is expected, Harmonised/self classification followed by implementation of necessary RRM should be sufficient to ensure safe use for environment</p>	No action

ASSESSMENT OF REGULATORY NEEDS

EC/List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
<p>NONS:</p> <p>405-340-7 453-530-3 454-820-2 457-300-3 458-000-5</p> <p>Intermediates:</p> <p>204-804-4 207-434-1 207-937-6 207-940-2 207-980-0 209-710-7 212-153-2 212-512-3 213-223-5 214-318-4 243-473-0 406-810-4 604-281-6 606-859-3 613-816-2 628-905-1 942-937-6 946-194-9</p> <p>Not registered:</p>			<p>No information is available for the other substances</p>		

ASSESSMENT OF REGULATORY NEEDS

EC/List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
209-513-6 219-309-9 252-692-0 607-739-3 620-553-7 628-981-6 639-113-0 682-338-4 824-106-9					

Annex 1: Overview of classifications

Data extracted on 9 February 2022

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
201-126-0	78-59-1	3,5,5-trimethylcyclohex-2-enone	Carc. 2 Acute Tox. 4 * Acute Tox. 4 * STOT SE 3 Eye Irrit. 2	Carc. 2 H351 Acute Tox. 4 H302 Acute Tox. 4 H312 Eye Irrit. 2 H319 STOT Single Exp. 3 H335, affected organs: respiratory tract, specific concentration: >=10 STOT Single Exp. 3 H335, affected organs: respiratory system, specific concentration: >=10
202-417-5	95-41-0	2-hexylcyclopent-2-enone		Skin Irrit. 2 H315
203-405-2	106-51-4	p-benzoquinone	Acute Tox. 3 * Acute Tox. 3 * STOT SE 3 Skin Irrit. 2 Eye Irrit. 2 Aquatic Acute 1	Aquatic Acute 1 H400 [STOT Single Exp. 3 H335, affected organs: respiratory tract Skin Irrit. 2 H315 Eye Irrit. 2 H319 Muta. 2 H341 Flam. Solid 1 H228 Acute Tox. 3 H301 Acute Tox. 3 H331 Skin Corr. 1 H314 Eye Damage 1 H318

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EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
				Skin Sens. 1 H317 Aquatic Acute 1 H400, M-factor: 10.00 STOT Single Exp. 3 H335, affected organs: Respiratory system Aquatic Chronic 1 H410
203- 631- 1	108-94-1	cyclohexanone	Flam. Liq. 3 Acute Tox. 4 *	Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Damage 1 H318 STOT Single Exp. 3 H335, affected organs: Respiratory tract
204- 435- 9	120-92-3	cyclopentanone	Flam. Liq. 3 Skin Irrit. 2 Eye Irrit. 2	Flam. Liquid 3 H226 Skin Irrit. 2 H315 Eye Irrit. 2 H319
204- 804- 4	126-81-8	5,5-dimethylcyclohexane-1,3-dione		-
205- 273- 1	137-03-1	2-heptylcyclopentanone		Skin Irrit. 2 H315
207- 434- 1	471-01-2	3,5,5-trimethylcyclohex-3-en-1-one		Carc. 2 H351 Acute Tox. 4 H302 STOT Single Exp. 3 H335, affected organs: Respiratory tract

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EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
				Acute Tox. 4 H312 Eye Irrit. 2A H319 Acute Tox. 3 H331
207- 668- 4	488-10-8	3-methyl-2-pent-2- enylcyclopent-2-enone		Skin Irrit. 2 H315 Eye Irrit. 2 H320 Eye Irrit. 2 H319
207- 937- 6	502-42-1	cycloheptanone		Flam. Liquid 3 H226 Eye Damage 1 H318 Acute Tox. 4 H302
207- 940- 2	502-49-8	cyclooctanone		Eye Damage 1 H318 Skin Corr. 1C H314
207- 951- 2	502-72-7	cyclopentadecanone		Aquatic Acute 1 H400 Aquatic Chronic 1 H410
207- 980- 0	504-02-9	cyclohexane-1,3-dione		Eye Damage 1 H318 Aquatic Chronic 3 H412 STOT Single Exp. 3 H335, affected organs: resp tract Acute Tox. 4 H302
208- 795- 8	541-91-3	3-methylcyclopentadecan-1- one		-
209- 513- 6	583-60-8	2-methylcyclohexanone		-
209- 665- 3	589-92-4	4-methylcyclohexanone		Flam. Liquid 3 H226 Acute Tox. 4 H302 Skin Corr. 1B H314

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NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
				Eye Damage 1 H318
209-710-7	591-24-2	3-methylcyclohexanone		Flam. Liquid 3 H226 STOT Single Exp. 3 H335, affected organs: Respiratory system Skin Irrit. 2 H315 Eye Irrit. 2 H319
212-153-2	765-69-5	2-methylcyclopentane-1,3-dione		Aquatic Chronic 3 H412 Aquatic Acute 3 H402 Eye Irrit. 2B H320
212-512-3	823-36-9	2-ethylcyclopentane-1,3-dione		Eye Irrit. 2B H320 Aquatic Acute 3 H402
212-595-6	830-13-7	cyclododecanone		Aquatic Chronic 2 H411
212-855-9	873-94-9	3,3,5-trimethylcyclohexan-1-one		Eye Irrit. 2 H319 STOT Single Exp. 3 H335, affected organs: respiratory tract STOT Single Exp. 3 H335, affected organs: Respiratory tract Acute Tox. 4 H332 Skin Irrit. 2 H315
213-223-5	930-68-7	cyclohex-2-enone		Acute Tox. 3 H301 Flam. Liquid 3 H226 Acute Tox. 2 H310 Acute Tox. 1 H330

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NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
214-318-4	1120-72-5	2-methylcyclopentanone		Flam. Liquid 3 H226
214-406-2	1125-21-9	2,6,6-trimethylcyclohex-2-ene-1,4-dione		Skin Sens. 1 H317 Skin Sens. 1B H317
219-309-9	2408-37-9	2,2,6-trimethylcyclohexan-1-one		-
223-069-0	3720-16-9	3-methyl-5-propylcyclohex-2-enone		Aquatic Chronic 3 H412
225-392-2	4819-67-4	2-pentylcyclopentan-1-one		-
235-970-6	13074-65-2	2-hexylcyclopentan-1-one		-
236-187-2	13215-88-8	4-(2-butenylidene)-3,5,5-trimethylcyclohex-2-en-1-one		Acute Tox. 4 H302 Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Chronic 3 H412
243-473-0	20030-30-2	2,5,6-trimethylcyclohex-2-en-1-one		Skin Irrit. 2 H315 Acute Tox. 4 H302 Aquatic Chronic 3 H412
247-104-4	25564-22-1	2-pentylcyclopent-2-en-1-one		Skin Irrit. 2 H316 Skin Sens. 1B H317 Eye Irrit. 2 H320
252-692-0	35720-57-1	cyclopentadec-4-en-1-one		-

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NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
253- 568- 9	37609- 25-9	5-cyclohexadecen-1-one		Aquatic Acute 1 H400 Aquatic Chronic 1 H410
265- 779- 3	65443- 14-3	2,2,5-trimethyl-5- pentylcyclopentan-1-one		Aquatic Chronic 2 H411
272- 462- 3	68845- 36-3	diethyldimethylcyclohex-2-en- 1-one		-
401- 700- 2	3100-36- 5	A mixture of cis- and trans- cyclohexadec-8-en-1-one	Aquatic Acute 1 Aquatic Chronic 1	Aquatic Acute 1 H400 Aquatic Chronic 1 H410
406- 670- 4	-	4-pentylcyclohexanone	Skin Irrit. 2 Aquatic Chronic 2	Aquatic Chronic 2 H411
406- 810- 4	-	4-propylcyclohexanone	Aquatic Chronic 2	Skin Sens. 1B H317 Skin Irrit. 2 H315 Aquatic Chronic 3 H412
429- 900- 5	-	429-900-5	Skin Irrit. 2 Aquatic Chronic 3	Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
438- 930- 8	2550-52- 9	438-930-8	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	Aquatic Chronic 4 H413
442- 550- 8	-	442-550-8	Aquatic Chronic 4	-
448- 300- 4	-	448-300-4		Skin Irrit. 2 H315 Aquatic Acute 1 H400

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NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
451-230-7	-	451-230-7		STOT Single Exp. 3 H336, affected organs: Central Nervous System Aquatic Chronic 3 H412
452-280-2	-	452-280-2		Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
454-820-2	-	454-820-2		-
457-300-3	-	457-300-3		-
458-000-5	-	458-000-5		-
604-281-6	14224-80-7	604-281-6		-
606-859-3	21890-10-8	606-859-3		Flam. Solid 1 H228
607-739-3	-	607-739-3		-
613-816-2	6553-64-6	6,6-dimethylcyclohex-2-en-1-one		Flam. Liquid 3 H226 Acute Tox. 4 H302 Skin Corr. 1B H314
620-553-7	259854-70-1	620-553-7		-

ASSESSMENT OF REGULATORY
NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
628-905-1	2979-19-3	3,3-dimethylcyclohexanone		Flam. Liquid 3 H226
628-981-6	40649-36-3	628-981-6	Skin Irrit. 2 Aquatic Chronic 3	-
630-473-4	14595-54-1	630-473-4		Aquatic Acute 1 H400 Aquatic Chronic 1 H410
639-113-0	259854-71-2	639-113-0		-
682-338-4	61203-83-6	682-338-4	Aquatic Chronic 2	-
807-489-7	1447712-18-6	2-methyl-5-propylcyclohex-2-en-1-one		Skin Irrit. 2 H315 Skin Sens. 1 H317
851-742-4	464207-51-0	(3R,5Z)-3-methylcyclopentadec-5-en-1-one		Skin Sens. 1B H317 Aquatic Chronic 3 H412
906-627-4	-	Reaction mass of cyclohexanol and cyclohexanone		Acute Tox. 4 H332 Skin Irrit. 2 H315 Acute Tox. 4 H302 Eye Irrit. 2 H319 Acute Tox. 4 H312 Aquatic Chronic 3 H412 STOT Single Exp. 3 H335, affected organs: respiratory tract Flam. Liquid 3 H226
909-034-9	-	Reaction mass of cyclododecanol and cyclododecanone		Aquatic Chronic 2 H411

ASSESSMENT OF REGULATORY
NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
941- 893- 5	-	Reaction mass of (4E,8Z)-cyclododeca-4,8-dien-1-one and (4Z,8E)-cyclododeca-4,8-dien-1-one and (4E,8E)-cyclododeca-4,8-dien-1-one		Skin Sens. 1B H317 STOT Single Exp. 3 H336, affected organs: Central nervous system
942- 937- 6	-	942-937-6		-
943- 554- 7	-	Reaction mass of 3,5-diethyl-2,5-dimethyl-cyclohex-2-en-1-one and 3,5-diethyl-5,6-dimethylcyclohex-2-en-1-one		Skin Irrit. 2 H315 Aquatic Chronic 3 H412
944- 298- 9	-	Reaction mass of 1-(3,3-dimethylcyclohexyl)ethanone and 2,6,6-trimethylcycloheptanone		Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Chronic 2 H411
946- 194- 9	-	Reaction mass of 3-(1,1-dimethoxyethyl)-1,1-dimethylcyclohexane and 2,6,6-trimethylcycloheptanone		Flam. Liquid 3 H226

(*) 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 3: Overview of completed or ongoing regulatory risk management activities

Data extracted on 14 March 2022

EC/List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
201-126-0					Yes	
203-405-2					Yes	
203-631-1					Yes	
204-435-9					Yes	
401-700-2					Yes	NONS
405-340-7						NONS
406-670-4					Yes	NONS
406-810-4					Yes	NONS
429-900-5					Yes	NONS
438-930-8					Yes	NONS
442-550-8					Yes	NONS
448-300-4						NONS
451-230-7						NONS
452-280-2						NONS
453-530-3						NONS
454-820-2						NONS
457-300-3						NONS
458-000-5						NONS
628-981-6					Yes	
682-338-4					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 on the other substances.