

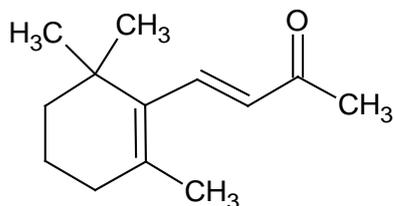
## Assessment of regulatory needs

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

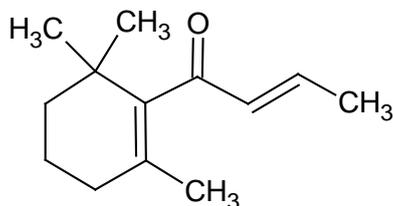
**Group Name:** Rose ketones

**General structure (molecular backbone):**

Ionone-type



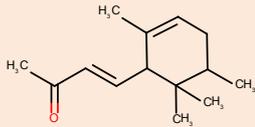
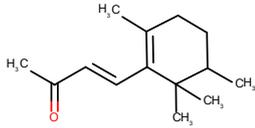
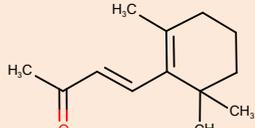
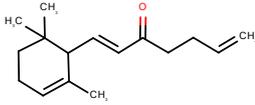
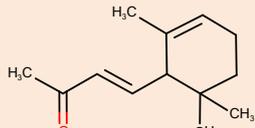
Damascone- and damascenone-type



**Revision history**

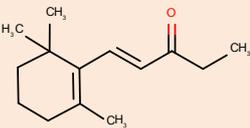
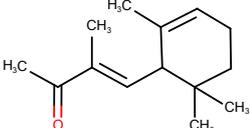
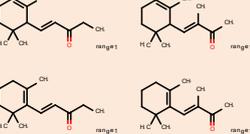
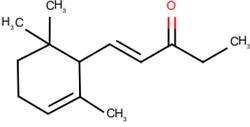
<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	21 April 2023	

## Substances within this group:

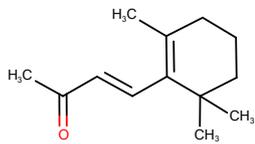
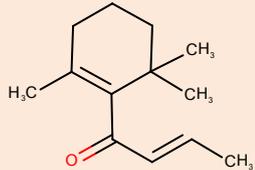
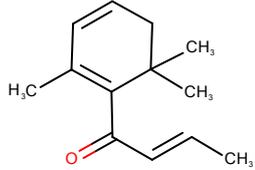
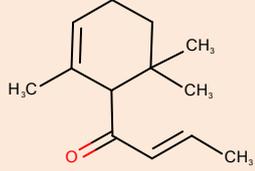
EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
201-219-6	79-69-6	4-(2,5,6,6-tetramethylcyclohex-2-enyl)but-3-en-2-one		Full, not (publicly) available
201-220-1	79-70-9	4-(2,5,6,6-tetramethyl-1-cyclohexen-1-yl)-3-buten-2-one		C&L notification
201-224-3	79-77-6	(E)-4-(2,6,6-trimethyl-1-cyclohexen-1-yl)-3-buten-2-one		Full, >1000
201-225-9	79-78-7	1-(2,6,6-trimethyl-2-cyclohexen-1-yl)hepta-1,6-dien-3-one		C&L notification
204-841-6	127-41-3	4-(2,6,6-trimethylcyclohex-2-ene-1-yl)-but-3-ene-2-one		Full, 100-1000

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

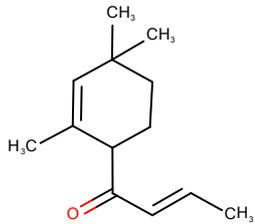
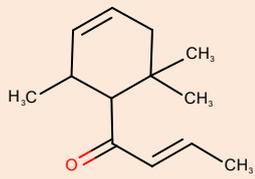
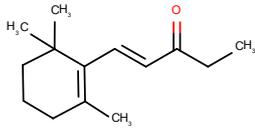
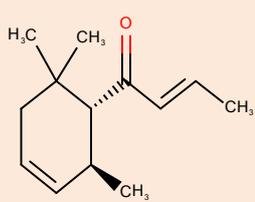
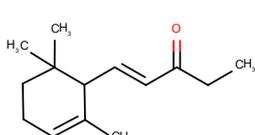
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
204-842-1	127-42-4	[R-(E)]-1-(2,6,6-trimethyl-2-cyclohexen-1-yl)pent-1-en-3-one		C&L notification
204-843-7	127-43-5	1-(2,6,6-trimethyl-1-cyclohexen-1-yl)pent-1-en-3-one		C&L notification
204-846-3	127-51-5	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one		Full, 10-100
215-635-0	1335-46-2	Ionone, methyl-		C&L notification
231-926-5	7779-30-8	1-(2,6,6-trimethyl-2-cyclohexen-1-yl)pent-1-en-3-one		C&L notification

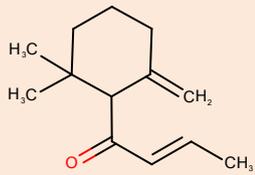
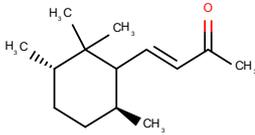
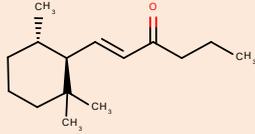
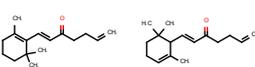
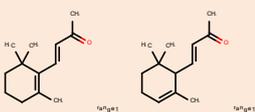
## ASSESSMENT OF REGULATORY NEEDS

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) <sup>1</sup>
232-396-8	8013-90-9	Ionone	No Structure	C&L notification
238-969-9	14901-07-6	4-(2,6,6-trimethylcyclohex-1-ene-1-yl)-but-3-ene-2-one		Full, not (publicly) available
245-842-1	23726-91-2	(E)-1-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2-buten-1-one		Full, 1-10
245-844-2	23726-93-4	(E)-1-(2,6,6-trimethyl-1,3-cyclohexadien-1-yl)-2-buten-1-one		Full, 10-100
246-430-4	24720-09-0	(E)-1-(2,6,6-trimethyl-2-cyclohexen-1-yl)-2-buten-1-one		Full, 10-100

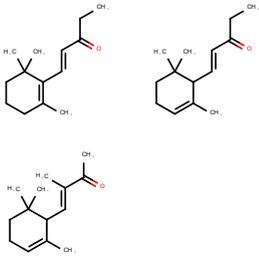
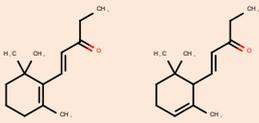
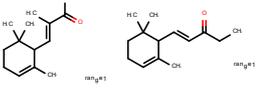
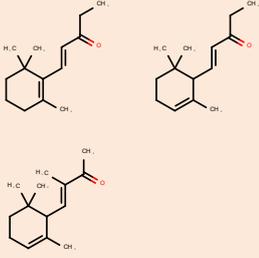
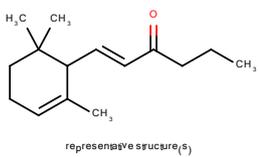
## ASSESSMENT OF REGULATORY NEEDS

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) <sup>1</sup>
254-663-8	39872-57-6	(E)-1-(2,4,4-trimethyl-2-cyclohexen-1-yl)-2-buten-1-one		Full, not (publicly) available
260-709-8	57378-68-4	1-(2,6,6-trimethyl-3-cyclohexen-1-yl)-2-buten-1-one		C&L notification
264-140-6	63429-28-7	(E)-1-(2,6,6-trimethyl-1-cyclohexen-1-yl)pent-1-en-3-one		Full, not (publicly) available
275-156-8	71048-82-3	[1α(E),2β]-1-(2,6,6-trimethylcyclohex-3-en-1-yl)but-2-en-1-one		Full, 100-1000
297-035-9	93302-56-8	(E)-1-(2,6,6-trimethyl-2-cyclohexen-1-yl)pent-1-en-3-one		Not registered

ASSESSMENT OF REGULATORY NEEDS

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) <sup>1</sup>
481-910-9	-	[No public or meaningful name is available]		NONS
482-010-9	762300-77-6	[No public or meaningful name is available]		NONS
619-053-1	94608-85-2	rel-(1E)-1-[(1R,6R)-2,2,6-trimethylcyclohexyl]hex-1-en-3-one		OSII or TII
904-551-6	-	Reaction mass of 1-(2,6,6-trimethylcyclohex-2-en-1-yl)hepta-1,6-dien-3-one and 1-(2,6,6-trimethylcyclohex-1-en-1-yl)hepta-1,6-dien-3-one		Full, 10-100
907-706-6	-	Reaction mass of 4-(2,6,6-trimethylcyclohex-2-ene-1-yl)-but-3-ene-2-one and 4-(2,6,6-trimethylcyclohex-1-ene-1-yl)-but-3-ene-2-one		Full, 100-1000

ASSESSMENT OF REGULATORY NEEDS

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) <sup>1</sup>
907-708-7(*)	-	Reaction mass of [R-(E)]-1-(2,6,6-trimethyl-2-cyclohexen-1-yl)pent-1-en-3-one and 1-(2,6,6-trimethyl-1-cyclohexen-1-yl)pent-1-en-3-one and 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one		OSII or TII
907-713-4	-	Reaction mass of 1-(2,6,6-trimethyl-1-cyclohexen-1-yl)pent-1-en-3-one and 1-(2,6,6-trimethyl-2-cyclohexen-1-yl)pent-1-en-3-one		Full, 10-100
942-741-0	-	reaction mass of 3-methyl-4-(2,6,6-trimethylcyclohex-2-en-1-yl)but-3-en-2-one and 1-(2,6,6-trimethylcyclohex-2-en-1-yl)pent-1-en-3-one		Full, >1000
943-653-5	-	Reaction mass of (E)-3-methyl-4-(2,6,6-trimethylcyclohex-2-en-1-yl)but-3-en-2-one and (E)-1-(2,6,6-trimethylcyclohex-2-en-1-yl)pent-1-en-3-one and (E)-1-(2,6,6-trimethylcyclohex-1-en-1-yl)pent-1-en-3-one		Full, not (publicly) available
943-512-8(*)	70092-19-2	1-Hexen-3-one, 1-(2,6,6-trimethyl-2-cyclohexen-1-yl)-		OSII or TII
Substance 1	Not (publicly) available	No public or meaningful name is available	Not (publicly) available	Full, not (publicly) available

## ASSESSMENT OF REGULATORY NEEDS

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

(\*) 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: List numbers 907-711-3 and 907-712-9 are not registered duplicates of 907-708-7; two possible duplicates of 943-512-8 are confidential, with one registered. In general, EC numbers take precedence over List numbers.

## Contents

<b>Foreword.....</b>	<b>11</b>
<b>Glossary .....</b>	<b>12</b>
<b>1 Overview of the group.....</b>	<b>13</b>
<b>2 Justification for the no need for regulatory risk management action at EU level .....</b>	<b>14</b>
<b>3 Conclusions and actions .....</b>	<b>17</b>
<b>Annex 1: Overview of classifications .....</b>	<b>19</b>
<b>Annex 2: Overview of uses based on information available in registration dossiers.....</b>	<b>23</b>
<b>Annex 3: Overview of completed or ongoing regulatory risk management activities .....</b>	<b>25</b>

## **DISCLAIMER**

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

## Foreword

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

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

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

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

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

For more information on Assessment of regulatory needs please consult ECHA website<sup>2</sup>.

---

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

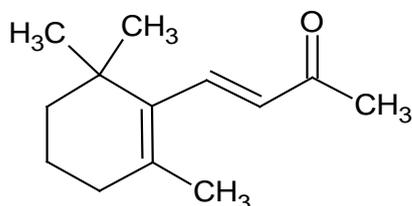
## Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
PMT/vPvM	Persistent, mobile and toxic/very persistent and very mobile
RMM	Risk management measures
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

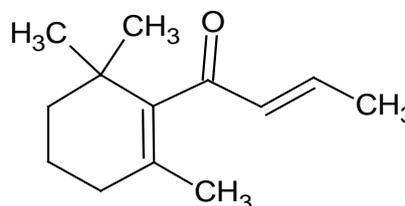
## 1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the molecular backbones shown in the figure below.

Ionone-type



Damascone- and damascenone-type



This group is called “rose ketones” due to their fragrance properties.<sup>3</sup> There are 31 substances in this group, of which 22 are registered.

They are  $\alpha,\beta$ -ketones with a trimethylcyclohexene substituent at the  $\alpha$ - or  $\gamma$ -position from the ketone group. From one group member to another the position and level of unsaturation in the cyclohexene vary, and likewise the length of the alkyl chain around the ketone group.

Based on information reported in the REACH registration dossiers, all registered substances in this group are used in cosmetics, perfumes, washing and cleaning products, air care products, polishes and waxes and biocidal products – all uses are widespread, leading to a high potential for exposure for workers and/or consumers, as well as a high potential for release to the environment. The substances are used in the mentioned applications as a fragrance.

<sup>3</sup> Williams, Alvin (2002) Rose ketones: celebrating 30 years of success. *Perfumer & Flavorist* 27(2):18-31. <https://www.perfumerflavorist.com/fragrance/ingredients/article/21860542/rose-ketones-celebrating-30-years-of-success>

**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 *a 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 all substances in the group.

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety ( $\alpha,\beta$ -ketones with a trimethylcyclohexene substituent), **most of** the substances in the group have (potentially) the following **human health hazard: skin sensitisation** (except for EC/List 201-219-6, 201-224-3, 254-663-8, 907-706-6, 942-741-0 which have negative skin sensitisation data).

This hazard is identified based on several studies with observed skin sensitisation effects from a high number of substances. Based on structural similarity the findings from the toxicity studies are extrapolated to the substances where there is limited information for this endpoint. The hazard information currently available in the registration dossiers indicates that the substances EC/List 204-846-3, 245-842-1, 245-844-2, 246-430-4, 264-140-6, 275-156-8, Substance 1, 904-551-6, 907-708-7, 907-713-4, 942-741-0 in the group are potential skin sensitisers, and they have been self-classified accordingly. In addition, several companies have submitted notifications as Skin Sens. for non-registered substances. However, the registration dossiers of EC/List 201-219-6, 201-224-3, 254-663-8, 907-706-6, 942-741-0 contain valid data showing no skin sensitisation. CCH is proposed for several substances with registration dossiers containing adaptations for skin sensitisation.

No additional potential hazards were identified for human health. These conclusions are based on available repeated dose, mutagenicity, reproductive and developmental toxicity screening studies, none of them indicating hazardous effects, including endocrine-mediated effects for the substances of the group. EC 275-156-8 showed positive results in an *in vitro* chromosomal aberration test, but

no effects were observed in an *in vivo* follow up study. Based on the repeated dose and mutagenicity study data, there are no indications of target organ effects or carcinogenicity potential. These conclusions could be extrapolated to other group members with no data available, based on common structural features.

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety, **most of** the substances in the group have (potentially) the following **environmental** hazard: **aquatic toxicity** (except EC/List 201-219-6, 204-846-3, 245-842-1, 245-844-2, 246-430-4, 254-663-8, 264-140-6, Substance 1, 907-713-4). All substances show different levels of aquatic toxicity varying from not toxic to very toxic. None of the substances in the group have a harmonised classification. One substance has a classification in registration as Aquatic Acute 1, Aquatic Chronic 1; sixteen substances have a classification in registrations as Aquatic Chronic 2; one substance has a classification in registration as Aquatic Chronic 3. However, classification in the registration of twelve substances appears to be not supported by the available data since toxicity values don't fulfil the criteria for classification set in EU Regulation 1272/2008. CCH is proposed for several substances to confirm the long-term aquatic toxicity.

The substances in this group are unlikely to fulfil the PBT/vPvB screening criteria, because they are readily biodegradable. Most of the substances (with the exception of EC/List 942-741-0, 907-713-4, 904-551-6, Substance 1, 264-140-6) are unlikely bioaccumulative. These conclusions are based on the information currently available in the registration dossiers (ready biodegradability test results, low log Kow).

Based on the above considerations on hazards and uses, a **compliance check is** proposed for some substances:

- ECs/Lists: 201-224-3, 204-841-6, 204-846-3, 238-969-9, 904-551-6, 943-653-5

to clarify skin sensitisation hazard, as well as to clarify chronic aquatic toxicity hazard (only for ECs/Lists 201-224-3, 204-841-6, 238-969-9, 904-551-6, 943-653-5).

In terms of uses, all registered substances in this group have consumer and/or professional uses in cosmetics, washing and cleaning products, biocides, perfumes, air care products and polishes and waxes. Such uses lead to a high potential for exposure for workers and/or consumers, as well as a high potential for release to the environment. Some of the substances are regulated under the Cosmetics Regulation and/or included in industry voluntary initiatives that shall, in principle, limit the concentration of the substances in the different products they are used. Additionally, some substances from this group are included in the SCCS Opinion on Fragrance Allergens in cosmetic products. <sup>4</sup>

---

<sup>4</sup> ECs 204-846-3, 245-842-1, 246-430-4, 254-663-8, 260-709-8 and 275-156-8 are listed in Annex III of Cosmetics Regulation, setting labelling requirements or maximum concentrations; ECs 204-842-1, 204-843-7, 204-846-3, 215-635-0, 231-926-5, 245-842-1, 245-844-2, 246-430-4, 254-663-8, 260-709-8, 275-156-8 are covered by IFRA Standards which define maximum concentrations for use in several product types – "[Methyl ionone, mixed isomers](#)" and "[Rose ketones](#)"; ECs 201-219-6, 201-224-3, 204-841-6, 204-846-3, 215-635-0, 232-396-8, 245-663-8, 254-663-8 and 275-156-8 are included

One substance (List 907-706-6) has declared article service life in “fabrics, textiles and apparel” for use as “cleaning agent” in washing and cleaning products (including solvent based products). The substance does not show any hazard that would require a regulatory follow-up.

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

For the skin sensitisation concern, 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 the substances from this group.

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

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

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

---

in the [“SCCS Opinion on fragrance allergens in cosmetic products”](#) and may be added to the list of known fragrance allergens, which impacts uses in cosmetics and in detergents.

### 3 Conclusions and actions

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

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
201-219-6 201-220-1 <sup>1)</sup> 201-224-3 201-225-9 <sup>1)</sup> 204-841-6 204-842-1 <sup>1)</sup> 204-843-7 <sup>1)</sup> 204-846-3 215-635-0 <sup>2)</sup> 231-926-5 <sup>1)</sup> 232-396-8 <sup>1)</sup> 238-969-9 245-842-1 245-844-2 246-430-4	Known or potential hazard for skin sensitisation (except 201-219-6, 201-224-3, 254-663-8, 907-706-6, 942-741-0)	Known or potential hazard for aquatic toxicity (except EC 201-219-6, 204-846-3, 245-842-1, 245-844-2, 246-430-4, 254-663-8, 264-140-6, Substance 1, 907-713-4 and substance 1)	Use in widespread applications (cosmetics, washing and cleaning products, air care products, polishes and waxes and biocidal products), leading to a high potential for exposure for workers and/or consumers, as well as a high potential for release to the environment.  Article service life in textiles (List 907-706-6). <sup>5)</sup>	<b>Currently no need for EU RRM</b>  <u>Justification:</u> Harmonised/self-classification followed by implementation of necessary RRM should be sufficient to ensure safe use at the workplace and for environment. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation.	CCH (ECs/Lists 201-224-3, 204-841-6, 204-846-3, 238-969-9, 904-551-6, 943-653-5)

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
254-663-8					
260-709-8 <sup>1)</sup>					
264-140-6					
275-156-8					
297-035-9 <sup>1)</sup>					
481-910-9					
482-010-9					
619-053-1					
904-551-6					
907-706-6					
907-708-7 <sup>3)</sup>					
907-713-4					
942-741-0					
943-512-8 <sup>4)</sup>					
943-653-5					
<b>Substance 1</b>					

1) C&L notification; 2) Inactive registration; 3) duplicates (not registered): 907-711-3, 907-712-9; 4) duplicates: 1 registered and 1 not registered substances; 5) as declared by the registrant

## Annex 1: Overview of classifications

Data extracted on 12/10/2022

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations <sup>5</sup>
<b>201-219-6</b>	79-69-6	4-(2,5,6,6-tetramethylcyclohex-2-enyl)but-3-en-2-one	-	Aquatic Chronic 2 H411
<b>201-220-1</b>	79-70-9	4-(2,5,6,6-tetramethyl-1-cyclohexen-1-yl)-3-buten-2-one	-	-
<b>201-224-3</b>	79-77-6	(E)-4-(2,6,6-trimethyl-1-cyclohexen-1-yl)-3-buten-2-one	-	Aquatic Acute 2 H401 Aquatic Chronic 2 H411
<b>201-225-9</b>	79-78-7	1-(2,6,6-trimethyl-2-cyclohexen-1-yl)hepta-1,6-dien-3-one	-	-
<b>204-841-6</b>	127-41-3	4-(2,6,6-trimethylcyclohex-2-ene-1-yl)-but-3-ene-2-one	-	Aquatic Chronic 2 H411
<b>204-842-1</b>	127-42-4	[R-(E)]-1-(2,6,6-trimethyl-2-cyclohexen-1-yl)pent-1-en-3-one	-	-
<b>204-843-7</b>	127-43-5	1-(2,6,6-trimethyl-1-cyclohexen-1-yl)pent-1-en-3-one	-	-
<b>204-846-3</b>	127-51-5	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	-	Skin Sens. 1B H317 Aquatic Chronic 2 H411

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

## ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations <sup>5</sup>
<b>215-635-0</b>	1335-46-2	Ionone, methyl-	-	-
<b>231-926-5</b>	7779-30-8	1-(2,6,6-trimethyl-2-cyclohexen-1-yl)pent-1-en-3-one	-	-
<b>232-396-8</b>	8013-90-9	ionone	-	-
<b>238-969-9</b>	14901-07-6	4-(2,6,6-trimethylcyclohex-1-ene-1-yl)-but-3-ene-2-one	-	Aquatic Chronic 2 H411
<b>245-842-1</b>	23726-91-2	(E)-1-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2-buten-1-one	-	Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Chronic 2 H411
<b>245-844-2</b>	23726-93-4	(E)-1-(2,6,6-trimethyl-1,3-cyclohexadien-1-yl)-2-buten-1-one	-	Skin Irrit. 2 H315 Skin Sens. 1A H317 Aquatic Chronic 2 H411
<b>246-430-4</b>	24720-09-0	(E)-1-(2,6,6-trimethyl-2-cyclohexen-1-yl)-2-buten-1-one	-	Acute Tox. 4 H302 Skin Sens. 1B H317 Aquatic Chronic 2 H411
<b>254-663-8</b>	39872-57-6	(E)-1-(2,4,4-trimethyl-2-cyclohexen-1-yl)-2-buten-1-one	-	Skin Irrit. 2 H315 Aquatic Chronic 2 H411
<b>260-709-8</b>	57378-68-4	1-(2,6,6-trimethyl-3-cyclohexen-1-yl)-2-buten-1-one	-	-
<b>264-140-6</b>	63429-28-7	(E)-1-(2,6,6-trimethyl-1-cyclohexen-1-yl)pent-1-en-3-one	-	Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Chronic 2 H411
<b>275-156-8</b>	71048-82-3	[1 $\alpha$ (E),2 $\beta$ ]-1-(2,6,6-trimethylcyclohex-3-en-1-yl)but-2-en-1-one	-	Acute Tox. 4 H302 Skin Irrit. 2 H315 Skin Sens. 1A H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410

## ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations <sup>5</sup>
<b>481-910-9</b>	-	481-910-9	-	-
<b>482-010-9</b>	-	482-010-9	-	-
<b>619-053-1</b>	94608-85-2	619-053-1	-	-
<b>Substance 1</b>	Not (publicly) available	No public or meaningful name is available	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1B H317 Aquatic Chronic 2 H411
<b>904-551-6</b>	-	Reaction mass of 1-(2,6,6-trimethyl-1-cyclohexen-1-yl)hepta-1,6-dien-3-one and 1-(2,6,6-trimethyl-2-cyclohexen-1-yl)hepta-1,6-dien-3-one	-	Skin Sens. 1B H317 Aquatic Chronic 2 H411
<b>907-706-6</b>	-	Reaction mass of 4-(2,6,6-trimethylcyclohex-1-ene-1-yl)-but-3-ene-2-one and 4-(2,6,6-trimethylcyclohex-2-ene-1-yl)-but-3-ene-2-one	-	Aquatic Chronic 3 H412
<b>907-708-7</b>	-	Reaction mass of 1-(2,6,6-trimethyl-1-cyclohexen-1-yl)pent-1-en-3-one and 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one and [R-(E)]-1-(2,6,6-trimethyl-2-cyclohexen-1-yl)pent-1-en-3-one	-	Skin Irrit. 2 H315 [intermediate (active)] Aquatic Chronic 2 H411 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)]
<b>907-713-4</b>	-	Reaction mass of 1-(2,6,6-trimethyl-1-cyclohexen-1-yl)pent-1-en-3-	-	Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Chronic 2 H411

## ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations <sup>5</sup>
		one and 1-(2,6,6-trimethyl-2-cyclohexen-1-yl)pent-1-en-3-one		
<b>942-741-0</b>	-	Reaction mass of (3E)-3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one and (E)-1-(2,6,6-trimethyl-2-cyclohexen-1-yl)pent-1-en-3-one	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1B H317 Aquatic Chronic 2 H411
<b>943-512-8</b>	-	Reaction mass of 1-Hexen-3-one, 1-(2,6,6-trimethyl-2-cyclohexen-1-yl)-, Alpha-Isomer and 1-Hexen-3-one, 1-(2,6,6-trimethyl-2-cyclohexen-1-yl)-, Beta-Isomer and 1-Hexen-3-one, 1-(2,6,6-trimethyl-2-cyclohexen-1-yl)-, Gamma-Isomer	-	-
<b>943-653-5</b>	-	Reaction mass of (E)-1-(2,6,6-trimethyl-1-cyclohexen-1-yl)pent-1-en-3-one and (E)-1-(2,6,6-trimethyl-2-cyclohexen-1-yl)pent-1-en-3-one and 695-097-5	-	Skin Irrit. 2 H315 Eye Irrit. 2B H319 Aquatic Chronic 2 H411

## Annex 2: Overview of uses based on information available in registration dossiers

Data extracted on 12/10/2022

Main types of applications structured by product or article types	201-219-6	201-224-3	204-841-6	204-846-3	238-969-9	245-842-1	245-844-2	246-430-4	254-663-8	264-140-6	275-156-8	Substance <sub>1</sub>	904-551-6	907-706-6	907-713-4	942-741-0	943-653-5
PC 35: Washing and cleaning products	F, I, P, C	I, P, C	F, 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, A	I, P, C	F, I, P, C	F, I, P, C				
PC 8: Biocidal products (e.g. disinfectants, pest control)	F, I, P, C	C	F, I, P, C	F, I, P, C	C	C	C	F, I, P, C	F, I, P, C	F, I, P, C	I, P, C	F, I, P, C	F, I, P, C				
PC 28: Perfumes, fragrances	F, C	F, C	F, I, P, C	F, C	F, I, P, C	F, C	F, C	F, C	C	F, C	F, C	F, C	F, C	F, C	F, C	F, P, C	F, C
PC 3: Air care products	F, C	F, C	F, I, P, C	F, C	F, I, P, C	C	F, C	F, C	C	C	F, C	F, C	F, C	F, P, C	C	F, P, C	F, C
PC 39: Cosmetics, personal care products	P, C	F, C	F, I, P, C	F, C	F, C	F, C	P, C	F, P, C	C	C	C	P, C	P, C	F, P, C	P, C	F, P, C	P, C
PC 29: Pharmaceuticals																C	

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	201-219-6	201-224-3	204-841-6	204-846-3	238-969-9	245-842-1	245-844-2	246-430-4	254-663-8	264-140-6	275-156-8	Substance 1	904-551-6	907-706-6	907-713-4	942-741-0	943-653-5
PC 31: Polishes and wax blends	F, P, C	F, P, C	F, I, P, C	F, P, C	F, I, P, C	P, C	F, P, C	F, P, C	P, C	P, C	P, C	F, P, C	F, P, C	F, I, P, C	P, C	F, P, C	F, P, C
PC 9c: Finger paint		C															
PC 9a: Coatings and paints, thinners, paint removes		C															
PC 18: Ink and toners		C															
PC 14: Metal surface treatment products	I		I				I	I					I	I			I
PC 21: Laboratory chemicals														F			
PC 19: Intermediate		I													I	I	

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

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

Data extracted on 26/10/2022

There are no relevant completed or ongoing regulatory risk management activities under REACH for any of the substances except for the following:

Some of the substances from this group are listed in Annex III to the Cosmetics Regulation<sup>6</sup> and, therefore subject to restrictions:

- Entries 157 to 165 – EC 204-846-3, 245-842-1, 246-430-4, 260-709-8, 275-156-8

Further, in Annex II to that regulation, 3 related but noncyclic substances are listed as prohibited (pseudomethylionone EC 247-878-3 at entry 432, pseudoionone 205-457-1 at 433, and pseudo-isomethyl ionone 214-245-8 at 449; none in this group).

---

<sup>6</sup> Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. Latest consolidated version: <http://data.europa.eu/eli/reg/2009/1223/2022-10-06>