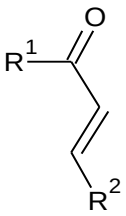
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Linear and branched α,β-unsaturated ketones

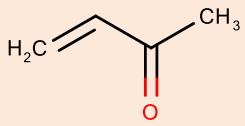
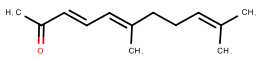
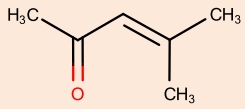
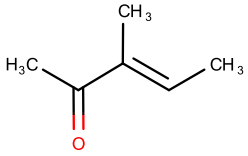
General structure:



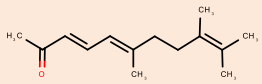
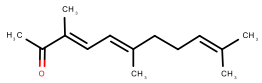
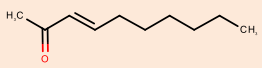
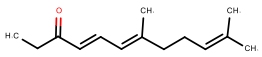
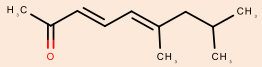
Revision history

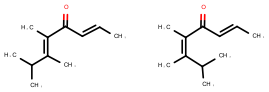
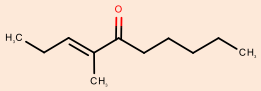
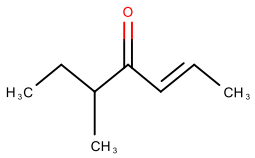
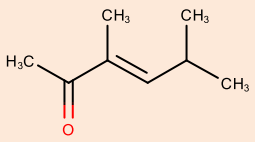
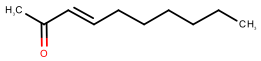
Version	Date	Description
1.0	28 November 2022	

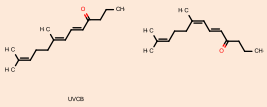
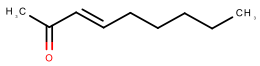
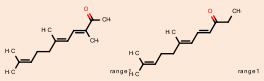
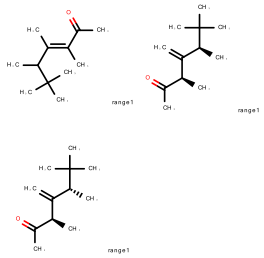
Substances within this group:

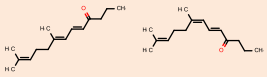
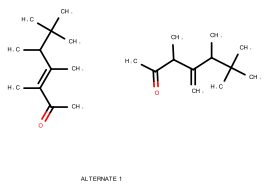
EC/List number	CAS number	Substance name	Chemical structure	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
201-160-6	78-94-4	Butenone		OSII or TII
205-457-1	141-10-6	6,10-dimethylundeca-3,5,9-trien-2-one		OSII or TII
205-502-5	141-79-7	4-methylpent-3-en-2-one		Full, not (publicly) available
209-283-7	565-62-8	3-methylpent-3-en-2-one		OSII or TII

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

EC/List number	CAS number	Substance name	Chemical structure	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
211-450-4	645-68-1	6,9,10-trimethylundeca-3,5,9-trien-2-one		OSII or TII
214-245-8	1117-41-5	3,6,10-trimethylundeca-3,5,9-trien-2-one		C&L notification
234-059-0	10519-33-2	3-decen-2-one		C&L notification
247-878-3	26651-96-7	7,11-dimethyldodeca-4,6,10-trien-3-one		OSII or TII
274-446-1	70214-76-5	6,8-dimethylnona-3,5-dien-2-one		OSII or TII

EC/List number	CAS number	Substance name	Chemical structure	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
451-330-0		Reaction mass of (2E,5Z)-5,6,7-trimethylocta-2,5-dien-4-one and (2E,5E)-5,6,7-trimethylocta-2,5-dien-4-one		Full, not (publicly) available
477-870-7	811412-48-3	3-Decen-5-one, 4-methyl-, (3E)-		Full, not (publicly) available
600-299-3	102322-83-8	2-Hepten-4-one, 5-methyl-, (2E)-		Full, not (publicly) available
606-014-9	18402-86-3	3-Decen-5-one, 4-methyl-, (3E)-		OSII or TII
701-234-2	18402-84-1	(3E)-dec-3-en-2-one		Full, not (publicly) available

EC/List number	CAS number	Substance name	Chemical structure	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
701-256-2		Reaction products of citral and pentan-2-one (base catalysed)		OSII or TII
813-141-5	18402-83-0	3-Nonen-2-one, (3E)-		OSII or TII
909-122-7		Reaction mass of 3,6,10-trimethylundeca-3,5,9-trien-2-one and 7,11-dimethyldodeca-4,6,10-trien-3-one		OSII or TII
939-627-8		Reaction mass of (3R,5R)-3,5,6,6-tetramethyl-4-methylidenehep tan-2-one and (3R,5S)-3,5,6,6-tetramethyl-4-methylidenehep tan-2-one and (E)-3,4,5,6,6-pentamethylhe pt-3-en-2-one		Full, not (publicly) available

EC/List number	CAS number	Substance name	Chemical structure	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
944-129-9		Reaction mass of (5E,7E)-8,12-dimethyltrideca-5,7,11-trien-4-one and (5E,7Z)-8,12-dimethyltrideca-5,7,11-trien-4-one		OSII or TII
946-245-5		Reaction mass of 3,5,6,6-tetramethyl-4-methylenehepta n-2-one and (E)-3,4,5,6,6-pentamethylhe pt-3-en-2-one		OSII or TII

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

Contents

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[2].

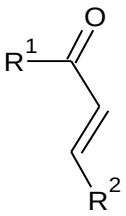
[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

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 α,β-unsaturated ketone moiety shown in the figure below.



The ketones in this group are α,β-unsaturated, i.e. enones. Keto–enol tautomerism[3] is particularly relevant for such enones, as the enol tautomer is stabilized through electron delocalisation. The typical properties of such enones include Michael addition of alcohols and amines, hetero Diels–Alder reactions, and cyclodimerization.[4]

The group consists of 20 substances, of which 6 have full registrations, 12 are registered as intermediates only, 2 are only notified under the CLP Regulation.

Based on information reported in the REACH registration dossiers, 4 of the 6 fully registered substances in the group (EC/Lists 451-330-0, 477-870-7, 600-299-3, 939-627-8) 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. EC 205-502-5 is only used in industrial settings in the production of washing and cleaning, pharmaceuticals, non-metal-surface treatment products or as a precursor in the production of other chemicals. For List 701-234-2 no identified uses are reported (full registration). Overall, high exposure potential and release in the environment can be assumed for the majority of the fully registered substances.

One substance (EC 205-502-5) has a CLH for local effects and two other substances have ongoing CLH (please refer to Annex 3). Three substances (ECs 205-457-1, 214-245-8, 247-878-3) are allergenic fragrances already restricted in cosmetics[5], toys[6] and tattoo inks[7].

[3] IUPAC. Tautomerism. In *Compendium of Chemical Terminology*, 2nd ed. (the "Gold Book"). Compiled by A. D. McNaught and A. Wilkinson. Blackwell Scientific Publications, Oxford (1997). Online version (since 2019) created by S. J. Chalk. ISBN 0-9678550-9-8. https://doi.org/10.1351/goldbook.T06252

[4] Siegel, H. and Eggersdorfer, M. (2000). Ketones. In *Ullmann's Encyclopedia of Industrial Chemistry*. https://doi.org/10.1002/14356007.a15_077 at §5.

[5] Cosmetic Product Regulation EC No 1223/2009, Annex II

[6] Directive 2009/48/EC on toy safety, Part III of Annex II

[7] REACH, Annex XVII, entry 75

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.

Based on ECHA's assessment of hazard information currently available in the registration dossiers the substances ECs/Lists 201-160-6, 205-457-1, 247-878-3, 451-330-0, 477-870-7, 600-299-3, 909-122-7, 939-627-8, 946-245-5, in the group are potential skin sensitisers, and they have been self-classified. For the substance EC 214-245-8 some companies have submitted a notification as Skin Sens. 1 or 1B according to CLP regulation. The registration dossier of EC 205-502-5 and 701-234-2 contain valid sensitisation tests showing negative results. Based on the chemical structures, it is not possible to predict which of the non-tested substances would be likely to cause 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. 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 based on common structural features.

Compliance check is suggested for List 939-627-8 to generate data on repeated dose toxicity and/or confirm the unlikely reproductive toxicity hazard for this substance.

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.

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 (CPR). Although it is not possible to predict based on the chemical structures which of the non-tested substances would be likely to cause sensitisation, potential use of other substances of the group (e.g., intermediates or C&L notified) as fragrances in cosmetics cannot be excluded. The CPR requires a safety assessment to be done prior to placing a cosmetic product on the market. The cosmetic product safety report must contain data on the exposure to the substances contained in the cosmetic product for all relevant toxicological endpoints. A particular focus on local toxicity evaluation (skin and eye irritation), skin sensitisation, and in the case of UV absorption photo-induced toxicity shall be made. As mentioned in section 1, 3 substances of the group are already restricted in cosmetics and consequently also in toys and tattoo inks, as this automatic link is set by both Directive 2009/48/EC on toy safety and REACH restriction entry 75. The same regulatory route will be followed in case restriction under CPR is pursued for other substances of the group, after a safety assessment is done.

However, there is a concern related to skin sensitisers (potentially) present in other 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 in relation to human health.

Based on ECHA’s assessment of hazard information currently available in the registration dossiers, all substances show aquatic toxicity. Due to uncertainty in the hazard data for List 939-627-8, compliance check is suggested 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, (except for List 939-627-8) have a low potential for bioaccumulation and are unlikely to fulfil the T criterion. These conclusions are based on the information currently available in the registration dossiers (ready biodegradability test results, low log Kow, and reliable QSAR data).

List 939-627-8 is potentially persistent/very persistent, based on data on ready biodegradability. Data show that the substance is not bioaccumulative and it is mobile, but not very mobile and unlikely to be toxic. Based on the available data it can be assumed that the substance is unlikely PBT/vPvB or mobile in the environment.

Compliance check on List 939-627-8 is proposed to clarify the potential persistency and mobility of the substance. However, for the time being no EU regulatory risk management is proposed for this substance until confirmation of the hazard

properties which should help identifying what the main protection goals are for this specific substance.

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.

For all the reasons above, it is proposed that there is currently no need for EU-wide regulatory risk management for this group.

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
201-160-6 **205-457-1** **214-245-8** **247-878-3** **451-330-0** **477-870-7** **600-299-3** **909-122-7** **939-627-8** **946-245-5**	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity	Few substances (ECs/ Lists 451-330-0, 477-870-7, 600-299-3 and 939-627-8) are indicated for iindustrial, widespread professional and consumer uses in washing and cleaning, perfumes, fragrances, air care products, cosmetics, personal care products, polishes and wax blends and as co-formulant in biocidal products, giving rise to the potential for exposure or release.	**Currently no need for EU RRM** <u>Justification:</u> Harmonised/self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation.	CCH for List 939-627-8
205-502-5 **209-283-7** **211-450-4**	No hazard or unlikely hazard				

EC/List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
234-059-0 **274-446-1** **606-014-9** **701-234-2** **701-256-2** **813-141-5** **944-129-9**			The other substances are used in industrial settings as intermediate with limited potential for exposure and release or have only C&L notification.		

Annex 1: Overview of classifications

Data extracted on 19.08.2022

EC/List number	CAS number	Substance name	Harmonised classification	Classification in registrations
201-160-6	78-94-4	Butenone	-	STOT Rep. Exp. 2 H373, affected organs: Nervous system, Lungs Eye Damage 1 H318 Acute Tox. 1 H330 Acute Tox. 1 H310 Aquatic Acute 1 H400 Skin Corr. 1B H314 Acute Tox. 2 H300 Flam. Liquid 2 H225 Aquatic Chronic 1 H410 Skin Sens. 1 H317
205-457-1	141-10-6	6,10-dimethylundeca-3,5,9-trien-2-one	-	Skin Sens. 1 H317 Eye Irrit. 2B H320 Aquatic Chronic 2 H411 Skin Irrit. 2 H315 Aquatic Acute 2 H401
205-502-5	141-79-7	4-methylpent-3-en-2-one	Concentration limits for acute toxicity cannot be translated into GHS from the DSD especially when minimum classifications are given; The classification for acute toxicity for this entry may be of special concern Index number: 606-009-00-1 Acute Tox. 4 Hazard Statement: H302 (Minimum classification) Acute Tox. 4 Hazard Statement: H312 (Minimum classification)	Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 4 H332 Acute Tox. 3 H331 Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT Single Exp. 3 H335, affected organs: respiratory tract

EC/List number	CAS number	Substance name	Harmonised classification	Classification in registrations
			Flam. Liq. 3 Hazard Statement: H226 Acute Tox. 4 Hazard Statement: H332 (Minimum classification)	
209-283-7	565-62-8	3-methylpent-3-en-2-one	-	Flam. Liquid 3 H226 Acute Tox. 3 H331 STOT Single Exp. 3 H335, affected organs: respiratory tract Skin Irrit. 2 H315 Acute Tox. 4 H302 Eye Irrit. 2 H319
211-450-4	645-68-1	6,9,10-trimethylundeca-3,5,9-trien-2-one	-	Aquatic Chronic 2 H411 Skin Irrit. 2 H315
214-245-8	1117-41-5	3,6,10-trimethylundeca-3,5,9-trien-2-one	-	-
234-059-0	10519-33-2	3-decen-2-one	-	-
247-878-3	26651-96-7	7,11-dimethyldodeca-4,6,10-trien-3-one	-	Skin Sens. 1B H317 Skin Irrit. 2 H315 Eye Irrit. 2 H319
274-446-1	70214-76-5	6,8-dimethylnona-3,5-dien-2-one	-	Skin Irrit. 2 H315
451-330-0		Reaction mass of (2E,5Z)-5,6,7-trimethylocta-2,5-dien-4-one and (2E,5E)-5,6,7-trimethylocta-2,5-dien-4-one	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1A H317

EC/List number	CAS number	Substance name	Harmonised classification	Classification in registrations
477-870-7	811412-48-3	3-Decen-5-one, 4-methyl-, (3E)-	-	Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
600-299-3	102322-83-8	2-Hepten-4-one, 5-methyl-, (2E)-	-	Flam. Liquid 3 H226 Acute Tox. 4 H302 Skin Irrit. 2 H315 Skin Sens. 1A H317
606-014-9	18402-86-3	3-Decen-5-one, 4-methyl-, (3E)-	-	Flam. Liquid 3 H226
701-234-2	18402-84-1	(3E)-dec-3-en-2-one	-	Acute Tox. 4 H332 Skin Irrit. 2 H315 Aquatic Chronic 2 H411
701-256-2		Reaction products of citral and pentan-2-one (base catalysed)	*Acute Tox. 4, H332; Skin Irrit. 2, H315; Skin Sens. 1, H317; Asp. Tox. 1, H304; Aquatic Chronic 2, H411	-
813-141-5	18402-83-0	3-Nonen-2-one, (3E)-	-	-
909-122-7		Reaction mass of 3,6,10-trimethylundeca-3,5,9-trien-2-one and 7,11-dimethyldodeca-4,6,10-trien-3-one	-	Skin Irrit. 2 H315 Skin Sens. 1 H317 Eye Irrit. 2 H320
939-627-8		Reaction mass of (3R,5R)-3,5,6,6-tetramethyl-4-methylideneheptan-2-one and (3R,5S)-3,5,6,6-tetramethyl-4-methylideneheptan-2-one and (E)-3,4,5,6,6-pentamethylhept-3-en-2-one	-	Skin Sens. 1B H317 Aquatic Chronic 2 H411
944-129-9		Reaction mass of (5E,7E)-8,12-dimethyltrideca-5,7,11-trien-4-one and	-	-

EC/List number	CAS number	Substance name	Harmonised classification	Classification in registrations
		(5E,7Z)-8,12-dimethyltrideca-5,7,11-trien-4-one		
946-245-5		Reaction mass of 3,5,6,6-tetramethyl-4-methyleneheptan-2-one and (E)-3,4,5,6,6-pentamethylhept-3-en-2-one	-	Skin Sens. 1B H317 Aquatic Chronic 2 H411

*Adopted RAC opinion on 18.03.2022

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

Data extracted on 19.08.2022

Main types of applications structured by product or article types	EC/ List 205-502-5	EC/ List 451-330-0	EC/ List 477-870-7	EC/ List 600-299-3	EC/ List 939-627-8
PC 35: Washing and cleaning products	F, I	F, I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	**P**, **C**
PC 8: Biocidal products (e.g. disinfectants, pest control)		F, I, **P**, **C**	**C**	**C**	**C**
PC 28: Perfumes, fragrances		F, **C**	F, **C**	**C**	F, **C**
PC 3: Air care products		F, **C**	**C**	**C**	**C**
PC 39: Cosmetics, personal care products		**P**, **C**	**P**, **C**	**C**	**C**
PC 29: Pharmaceuticals	F, I				
PC 31: Polishes and wax blends		F, **P**, **C**	**P**, **C**	**P**, **C**	**P**, **C**
PC 15: Non-metal-surface treatment products	F, I				
PC 19: Intermediate	F, 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

For List 701-234-2 no identified uses are reported. All the other substances have intermediate uses or are only notified under the CLP Regulation.

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

Data extracted on 19.08.2022

EC/List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
205-457-1				YES		Prohibited in cosmetics (Cosmetic Product Regulation EC No 1223/2009, Annex II); prohibited in toys (Part III of Annex II to Directive 2009/48/EC on toy safety).
205-502-5					YES	
214-245-8				YES		Prohibited in cosmetics (Cosmetic Product Regulation EC No 1223/2009, Annex II); prohibited in toys (Part III of Annex II to Directive 2009/48/EC on toy safety).
234-059-0					YES***	Active substance under Plant Protection Product (PPP) Regulation (EC) No 1107/2009.
247-878-3				YES		Prohibited in cosmetics (Cosmetic Product Regulation EC No 1223/2009, Annex II); prohibited in toys (Part III of Annex II to Directive 2009/48/EC on toy safety).
701-234-2					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).

**Adopted RAC opinion on 18.03.2022

***CLH intention – active substance under PPP

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