

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)



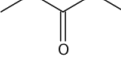
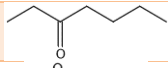
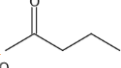
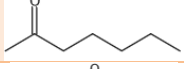
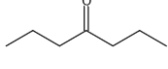
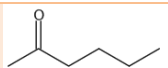
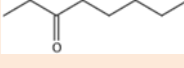
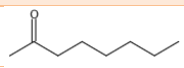
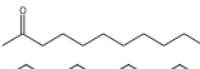
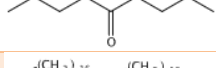
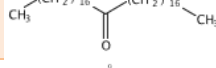
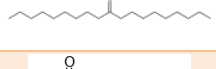
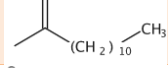
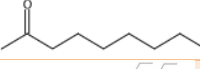
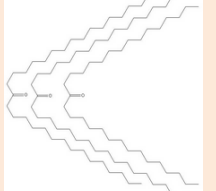
Date: 31 January 2021

Group Name: Linear aliphatic ketones

Revision history

<i>Version</i>	<i>Revision Date</i>	<i>Description</i>
1.0	31 January 2021	

Substances within this group:

EC/List number	CAS number	Substance name	Chemical structures [and/ or] Substance name acronyms	Registration type (full/OSI/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
Subgroup 1 – substances with carbon chain length C₃ to C₇				
200-662-2	67-64-1	Acetone		Full, > 1000
201-159-0	78-93-3	Butanone		Full, > 1000
202-490-3	96-22-0	Pentan-3-one		Full, not (publicly) available
203-388-1	106-35-4	Heptan-3-one		C&L notified
203-528-1	107-87-9	Pentan-2-one		Full, 100 - 1000
203-767-1	110-43-0	Heptan-2-one		Full, 100 - 1000
204-608-9	123-19-3	Heptan-4-one		OSI/TII, not (publicly) available
209-731-1	591-78-6	Hexan-2-one		C&L notified
Subgroup 2 – substances with carbon chain length C₈ to C₃₅				
203-423-0	106-68-3	Octan-3-one		Full, not (publicly) available
203-837-1	111-13-7	Octan-2-one		Full, 10 - 100
203-937-5	112-12-9	Undecan-2-one		Full, 1 - 10
207-946-5	502-56-7	Nonan-5-one		C&L notified
207-993-1	504-53-0	Pentatriacontan-18-one		Full, 1 - 10
207-994-7	504-57-4	Nonadecan-10-one		C&L notified
209-784-0	593-08-8	Tridecan-2-one		C&L notified
212-480-0	821-55-6	Nonan-2-one		Full, 1 - 10
946-252-3	none	Reaction mass of Hentriacontan-16-one and Pentatriacontan-18-one and Tritriacontan-16-one		Full, not (publicly) available

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

ASSESSMENT OF REGULATORY NEEDS

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 will 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.

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DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessments 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 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

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 linear aliphatic ketones.

The group is composed of 17 substances, with the simplest being EC 200-662-2 (acetone, $\text{CH}_3(\text{C}=\text{O})\text{CH}_3$) and the most complex being EC 946-252-3 (a reaction mass of three ketones $\text{C}_{15}\text{H}_{31}(\text{C}=\text{O})\text{C}_{15}\text{H}_{31}$, $\text{C}_{15}\text{H}_{31}(\text{C}=\text{O})\text{C}_{17}\text{H}_{35}$, and $\text{C}_{17}\text{H}_{35}(\text{C}=\text{O})\text{C}_{17}\text{H}_{35}$). The group is split by chain length into two subgroups: (1) subgroup 1 covering all shorter-chain members (C_3 to C_7) and (2) subgroup 2 covering all longer-chain members (C_8 to C_{35}).

A number of short-chain members have harmonised classification for specific target organ toxicity (including STOT SE 3). Among the long-chain substances showing aquatic toxicity, undecan-2-one was approved as a biocidal active substance and a CLH by Spain for aquatic acute 1 and aquatic chronic 1 endpoints is ongoing.

Based on information reported in the REACH registration dossiers, the substances have a wide variety of uses, with a general trend of the number of uses decreasing as carbon number increases; some substances, e.g. acetone (EC 200-662-2), butanone (EC 201-159-0) and heptan-2-one (EC 203-767-1) each have numerous registered uses primarily as solvents. Most common products across the group include washing and cleaning products, polishes and waxes, air care products, coatings, paints, inks, cosmetics, personal care products and biocides. Solvent, cleaning and odour agent appear to be the most common functionalities of these ketones.

For the vast majority of registered uses, there is potential for exposure of professional workers and/or consumers as well as for releases to the environment. The overlap in uses (particularly evident in the case of butanone, acetone and heptan-2-one which share numerous common uses) would suggest possibility for potential substitution of one sub-group member by another.

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 a need for (further) EU regulatory risk management – Restriction for specific professional applications in combination with EU-wide exposure limit for workers under Occupational Health and Safety (OSH) legislation or REACH due to potential reprotoxicity and exposure for all **subgroup 1** substances (substances with carbon chain length C3 to C7).

All short chain substances in subgroup 1 (except EC 203-528-1 and EC 204-608-9) have harmonised classification for specific target organ toxicity (STOT SE3; H336 – May cause drowsiness or dizziness). The representative substance of this subgroup is butanone (EC 201-159-0), a neurotoxicant currently under substance evaluation to address concern for developmental neurotoxicity (DNT). Therefore, based on information available in the registration dossiers, the ongoing SEv, the fact that most substances are already classified as STOT SE3 and structural similarity across the substances, all substances in subgroup 1 may have reproductive toxicity properties (assumed Repr 1 B). The potential for reprotoxicity needs to be first confirmed via substance evaluation for butanone and then re-assessed for all the other subgroup 1 substances.

Registered short-chain aliphatic ketone substances in the subgroup have a wide variety of uses as explained in section 1 with high potential for professional and consumer exposure via both the inhalation and dermal route, for example, washing and cleaning products, polishes and waxes, air care products, coatings and paints, thinners and paint removers, cosmetics and personal care products.

If the substances in subgroup 1 are confirmed as being reprotoxic, the first step will be to confirm the classification as Repr. 1B via harmonised classification and labelling. Consumer exposure will be addressed by downstream measures stemming from a Repr 1B harmonised classification for sub-group members. Following CLH as Repr 1B, subgroup 1 ketones and mixtures containing them at concentrations above 0.3% (mixtures classified as Repr 1B, unless substance specific concentration limit is decided), will be covered by the generic restriction of the consumer uses under entry 30 of REACH Annex XVII. In addition, harmonised classification as Repr 1B would render certain sub-group members unacceptable co-formulants in plant protection products (EC 200-662-2, 201-159-0, 203-767-1) and would also affect the authorisation of biocidal products containing several of the sub-group members, if present at concentrations above 0.3% (NB. no information on concentrations is available).

To address the exposure of professional workers restriction (ban with a concentration limit) is considered as the best option at this point in time. The choice of the restriction for professional uses over other regulatory management options is in line with the policy recently proposed by the European Commission³ under the Chemical Strategy for Sustainability that expresses the need to extend *the level of protection granted under REACH to consumers also to professional users*. Furthermore, the possibility to establish OELs have been considered however, adherence to OELs is generally poorer for professional uses and OELs do not apply to self-employed workers. Therefore, a restriction will be considered for specific professional applications once the hazard is confirmed and further assessment of the uses done.

³ European Commission, Chemical Strategy for Sustainability Towards a Toxic-Free Environment, 14.10.20 Ref to paragraph 2.2.1, <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

Worker exposure in industrial applications will be addressed considering the establishment of EU-wide exposure limit values being either OELs through OSH route, or via restriction under REACH. First step will be to consider current OELs⁴ available for five members of the subgroup 1, and make an analysis of their validity to mitigate exposure to such Repr 1 B substances, revisiting the current values, if needed, and establishing iOELs for the other substances.

Finally, in relation to articles, the only relevant use is the use of acetone as a foam blowing agent. Within the scope of this analysis, it has not been possible to assess whether exposure to the blowing agent over foreseeable conditions of use would be a realistic scenario but, in principle, exposure either of workers or end users (exposed to the residual amount) cannot definitely be precluded. The use of acetone as a foam blowing agent could be considered with a view to assess whether the substance in articles poses a risk to human health that is not adequately controlled and, if necessary, prepare a restriction to manage such risk. This will be looked at after confirmation of hazard.

Based on currently available information, there is no need for (further) EU regulatory risk management for substances of the **subgroup 2** (substances with a carbon chain length C8-C35).

All substances in that subgroup have low toxicological and environmental hazard based on information available in the registration dossiers. Substance EC 203-937-5 is under CLH as Aqua Acute 1, Aqua Chronic 1, and is approved as biocidal active substance. It is used in indoor spraying by non-professionals to discourage dogs from fouling and has been found to pose no potential risk to non-professional users through dermal and inhalation routes of exposure and the release to the environment is assumed to be very limited. The proposed classification should trigger adequate safety measures. For all the reasons above, no need for further EU regulatory risk management currently arises.

⁴ IOEL (EU, 8h) for EC 201-159-0 (Butanone) is 600mg/m³, 200 ppm; for EC 200-662-2 (Acetone) is 1210 mg/m³, 500 ppm; for EC 203-767-1 (Heptan-2-one) is 238 mg/m³, 50 ppm; for EC 203-388-1 (Heptan-3-one) is 95 mg/m³, 20ppm; National OELs for EC 209-731-1 (Hexan-2-one) 4-200 mg/m³, 1-50 ppm

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. (NB. substances marked with an asterisk (*) are substances only notified to the C&L inventory).

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Subgroup 1 – substances with full registrations and carbon chain length C₃ to C₇ 201-159-0 Butanone plus 200-662-2 Acetone 202-490-3 Pentan-3-one 203-528-1 Pentan-2-one 203-767-1	Known or potential hazard for reproductive toxicity	No hazard or unlikely hazard for aquatic toxicity No hazard or unlikely hazard for PBT/vPvB	Solvents, process regulators, cleaning agents and several other functionalities in wide range of uses with potential for professional and consumer exposure (widest range of uses for EC 200-662-2, 201-159-0 and 203-767-1)	Need for EU RRM – Restriction for specific professional applications in combination with EU-wide exposure limit for workers under Occupational Health and Safety (OSH) legislation or REACH <u>Justification:</u> if the Repr. 1B hazard is confirmed, for professional exposure the restriction route is proposed to ensure same level of	First step: Wait for SEv conclusion for butanone to propose further generation of hazard data. Next steps (if hazard confirmed): <ul style="list-style-type: none"> • CLH Repr 1B for butanone. • SEv for remaining substances to be initiated in parallel to the CLH for butanone.

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Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Heptan-2-one 204-608-9 Heptan-4-one *203-388-1 Heptan-3-one *209-731-1 Hexan-2-one				protection to professional users as to consumers (reference to CSS ²). For worker exposure in industrial applications considering the establishment of OELs through OSH route, or via restriction is proposed.	<ul style="list-style-type: none"> • CLH Repr 1B for remaining substances. • EU wide exposure limit (via OSH or REACH restriction) for industrial uses and restriction for specific professional uses (possibly in parallel to the CLH).
<i>Subgroup 2 – substances with a carbon chain length C₈ to C₃₅:</i> 203-423-0 Octan-3-one 203-837-1 Octan-2-one 203-937-5 Undecan-2-one *207-946-5	No hazard or unlikely hazard based on the available data	Known or potential hazard for aquatic toxicity No hazard or unlikely hazard for PBT/vPvB	Mostly odour agents and fragrances but also biocidal products (203-937-5), waxes (207-993-1) and plasticiser in printer inks (946-252-3); uses with potential for professional and consumer exposure	Currently no need for EU RRM <u>Justification:</u> Overall, no or unlikely hazard. For EC 203-937-5, currently under CLH for aquatic toxicity, the use in biocidal products poses no risk for humans and a limited release to the environment is assumed.	No action

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Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Nonan-5-one 207-993-1 Pentatriacontan-18-one *207-994-7 Nonadecan-10-one *209-784-0 Tridecan-2-one 212-480-0 Nonan-2-one 946-252-3 Reaction mass of Hentriacontan-16-one and Pentatriacontan-18-one and Tritriacontan-16-one					

Annex 1: Harmonised and self-classifications

Data extracted on 31 August 2020

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
200-662-2	67-64-1	Acetone	Flam. Liq. 2 H225 Eye Irrit. 2 H319 STOT SE 3 H336	Flam. Liquid 2 H225 Eye Irrit. 2 H319 STOT Single Exp. 3 H336	Flam. Liquid 3 H226 Eye Irrit. 2A H319 STOT Single Exp. 3 H335
201-159-0	78-93-3	Butanone	Flam. Liq. 2 H225 Eye Irrit. 2 H319 STOT SE 3 H336	Flam. Liquid 2 H225 Eye Irrit. 2 H319 STOT Single Exp. 3 H336	Skin Irrit. 2 H315 STOT Single Exp. 3 H335
202-490-3	96-22-0	Pentan-3-one	Flam. Liq. 2 H225 STOT SE 3 H335 STOT SE 3 H336	Flam. Liquid 2 H225 Eye Irrit. 2 H319 STOT Single Exp. 3 H336 STOT Single Exp. 3 H335	Skin Irrit. 2 H315
203-388-1	106-35-4	Heptan-3-one	Flam. Liq. 3 H226 Eye Irrit. 2 H319 Acute Tox. 4 H332	-	Flam. Liquid 3 H226 Acute Tox. 4 H332 Eye Irrit. 2 H319
203-423-0	106-68-3	Octan-3-one	-	Flam. Liquid 3 H226 Skin Irrit. 2 H315	Eye Irrit. 2 H319 STOT Single Exp. 3 H335
203-528-1	107-87-9	Pentan-2-one	-	Flam. Liquid 2 H225 Acute Tox. 4 H302 Eye Irrit. 2 H319	Acute Tox. 3 H331 Skin Irrit. 2 H315 Skin Corr. 1B H314 STOT Single Exp. 3 H335 STOT Single Exp. 3 H336
203-767-1	110-43-0	Heptan-2-one	Flam. Liq. 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H332	Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H332 STOT Single Exp. 3 H336	Skin Irrit. 2 H315 STOT Single Exp. 3 H335
203-837-1	111-13-7	Octan-2-one	-	Flam. Liquid 3 H226 Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Chronic 3 H412	Acute Tox. 4 H312
203-937-5	112-12-9	Undecan-2-one	-	Skin Irrit. 2 H315 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	Aquatic Chronic 2 H411 Aquatic Chronic 3 H412

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EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
204-608-9	123-19-3	Heptan-4-one	Flam. Liq. 3 H226 Acute Tox. 4 H332	Flam. Liquid 3 H226 Acute Tox. 4 H332	-
207-946-5	502-56-7	Nonan-5-one	-	-	Flam. Liquid 3 H226 Eye Irrit. 2 H319 STOT Rep. Exp. 1 H372 STOT Single Exp. 3 H336 STOT Single Exp. 3 H335
207-993-1	504-53-0	Pentatriacontan-18-one	-	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT Single Exp. 3 H335
207-994-7	504-57-4	Nonadecan-10-one	-	-	Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2A H319 STOT Single Exp. 3 H335
209-731-1	591-78-6	Hexan-2-one	Flam. Liq. 3 H226 STOT SE 3 H336 STOT RE 1 H372 Repr. 2 H361f	-	Repr. 2 H361, specific effect: f Flam. Liquid 3 H226 Acute Tox. 4 H332 Eye Irrit. 2 H319 STOT Rep. Exp. 1 H372 STOT Single Exp. 3 H336 STOT Single Exp. 3 H335
209-784-0	593-08-8	Tridecan-2-one	-	-	Aquatic Acute 1 H400 Aquatic Chronic 1 H410
212-480-0	821-55-6	Nonan-2-one	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Chronic 3 H412	STOT Single Exp. 3 H335
946-252-3	none	Reaction mass of hentriacontan-16-one and pentatriacontan-18-one and tritriacontan-16-one	-	-	-

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

Data extracted on 31 August 2020

Main types of applications structured by product or article types	EC/List 200-662-2	EC/List 201-159-0	EC/List 202-490-3	EC/List 203-423-0	EC/List 203-528-1	EC/List 203-767-1	EC/List 203-837-1	EC/List 203-937-5	EC/List 207-993-1	EC/List 212-480-0	EC/List 946-252-3
PC 0: other - tobacco products				F, C				F, C			
PC 1: Adhesives, sealants	I, F, P, C	I, P, C		C	C	I, P, C					
PC 2: Adsorbents	I										
PC 3: Air care products	I, F, P, C	C		C		C	F, C	C		C	
PC 4: Anti-freeze and de-icing products	I, F, P, C	P, C									
PC 8: Biocidal products (e.g. disinfectants, pest control)	I, F, P, C	C		C		C	C	C		C	
PC 9a: Coatings and paints, thinners, paint removers	I, F, P, C	I, F, P, C			I, F, P, C	I, F, P, C	F, C		C	F	
PC 9b: Fillers, putties, plasters, modelling clay	I, F, P, C	I, F, P, C			C	C	F, C			F	
PC 9c: Finger paints	I, F, P, C	C							C		
PC 11: Explosives	I, P	P									
PC 12: Fertilisers	I, F, P	C				P					
PC 13: Fuels	I, P, C	I, P, C									
PC 14: Metal surface treatment products	I, P, C	I, P									
PC 15: Non-metal-surface treatment products	I, F, P, C	P, C									
PC 16: Heat transfer fluids	P, C	P, C									
PC 17: Hydraulic fluids	P, C	P, C									

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	EC/List 200-662-2	EC/List 201-159-0	EC/List 202-490-3	EC/List 203-423-0	EC/List 203-528-1	EC/List 203-767-1	EC/List 203-837-1	EC/List 203-937-5	EC/List 207-993-1	EC/List 212-480-0	EC/List 946-252-3
PC 18: Ink and toners	I, F, P, C	I, F, P, C				I, P	F		C	F	I, P
PC 19: Intermediate	I, F	I	I		I, P					I	
PC 20: Products such as pH-regulators, flocculants, precipitants, neutralisation agents	I, P	I, P			I						
PC 21: Laboratory chemicals	I, F, P	F, P	F, P		I, P	I, F, P				I	
PC 23: Leather treatment products		C									
PC 24: Lubricants, greases, release products	I, F, P, C	I, F, P, C			I, F, P, C						
PC 25: Metal working fluids		I									
PC 26: Paper and board treatment products	P, C								A		
PC 27: Plant protection products	I, F, P, C	P, C				P, C					
PC 28: Perfumes, fragrances		C		F, C		F, C	F, C	F, C		F, C	
PC 29: Pharmaceuticals	I, F, P, C										
PC 30: Photo-chemicals	I, F, P	F				I					
PC 31: Polishes and wax blends	I, F, P, C	C		P, C		P, C	F, P, C	P, C	C	P, C	
PC 32: Polymer preparations and compounds	I, F, P, A	I				I, F, P					
PC 33: Semiconductors						I					
PC 34: Textile dyes, and impregnating products		C									
PC 35: Washing and cleaning products	I, F, P, C	I, F, P, C	P	I, P, C	I, F, P, C	I, P, C	I, F, P, C	I, F, P, C		I, P, C	
PC 37: Water treatment		I, F, P									
PC 38: Welding and soldering products, flux products	I, F, P, C	C									

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	EC/List 200-662-2	EC/List 201-159-0	EC/List 202-490-3	EC/List 203-423-0	EC/List 203-528-1	EC/List 203-767-1	EC/List 203-837-1	EC/List 203-937-5	EC/List 207-993-1	EC/List 212-480-0	EC/List 946-252-3
PC 39: Cosmetics, personal care products	I, F, P, C	C		C		P, C	F, C	C		C	
PC 40: Extraction agents	I, P										
PC 41: Oil and gas exploration or production products	P										
PC x1: Food and feed additives	I				I, F, P						

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 August 2020

EC/List number	Other processes	RMOA	Authorisation		Restriction*	CLH	Other or previous legislation
			Candidate list	Annex XIV			
203-937-5						YES	BPR

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

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