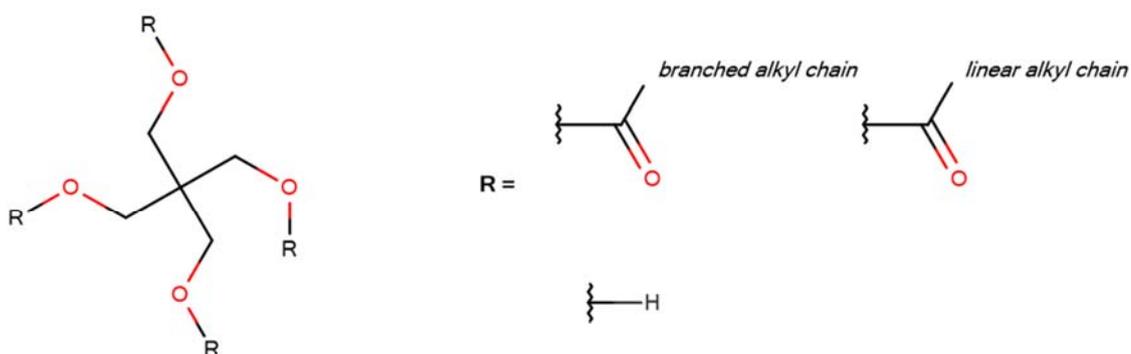


Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Esters from branched carboxylic acid and Pentaerythritol

General structure:



Revision history

Version	Date	Description
1.0	18 September 2023	

ASSESSMENT OF REGULATORY NEEDS

Substances within this group:

EC/List no	CAS no	Substance name [and Substance name acronyms]	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
230-743-8	7299-99-2	2,2-bis[[[(2-ethyl-1-oxohexyl)oxy]methyl]propane-1,3-diyl bis(2-ethylhexanoate)	Full, 100-1000
262-334-5	60623-04-3	2,2-bis[[[(2-hexyl-1-oxodecyl)oxy]methyl]-1,3-propanediyl bis(2-hexyldecanoate)	Full, not (publicly) available
263-423-1	62125-22-8	2,2-bis[[[(1-oxoisooctadecyl)oxy]methyl]-1,3-propanediyl bis(isooctadecanoate)	Full, >1000
268-582-0	68130-25-6	Decanoic acid, ester with 2,2-bis(hydroxymethyl)-1,3-propanediol 2-ethylhexanoate octanoate	Full, not (publicly) available
268-594-6	68130-51-8	Decanoic acid, mixed esters with heptanoic acid, isovaleric acid, octanoic acid and pentaerythritol	Full, not (publicly) available
270-434-5	68440-09-5	Fatty acids, lanolin, esters with pentaerythritol	Full, not (publicly) available
286-056-9	85186-72-7	Fatty acids, C14-18 and C18-unsatd., branched and linear, esters with pentaerythritol	Full, not (publicly) available
298-364-0	93803-89-5	2,2-bis[[[(1-oxoisononyl)oxy]methyl]-1,3-propanediyl diisononanoate	Full, not (publicly) available
410-830-9	-	A mixture of: pentaerythritol tetraesters with heptanoic acid and 2-ethylhexanoic acid	NONS
415-650-4	153965-54-9	Reaction mass of Pentaerythritol bis (2-ethylhexanoate) bis (3,5,5-trimethylhexanoate) and Pentaerythritol tris (2-ethylhexanoate) 3,5,5-trimethylhexanoate and Pentaerythritol 2-ethylhexanoate tris (3,5,5-trimethylhexanoate) and Pentaerythritol tetrakis(2-ethylhexanoate) and Pentaerythritol tetrakis (3,5,5-trimethylhexanoate)	Full, not (publicly) available
416-690-5	-	PRIOLUBE 1944	NONS
416-700-8	-	PRIOLUBE 1945	NONS
429-010-7	-	EMERY 2927-A	NONS
430-320-1	-	Reaction products of pentaerythritol and trimethylol propane with 2-methylbutyric acid, n-pentanoic acid, n-heptanoic acid, 3,5,5 trimethylhexanoic acid, n-octanoic acid and n-decanoic acid	Full, not (publicly) available
443-990-3	-	CETEC 2252	NONS
444-210-4	-	CETEC 2253	NONS
451-110-4	-	Not (publicly) available	NONS
451-120-9	-	Not (publicly) available	NONS
451-170-1	-	Not (publicly) available	NONS

¹ 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 no	CAS no	Substance name [and Substance name acronyms]	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
451-180-6	-	Not (publicly) available	NONS
451-200-3	-	Tetraesters from the esterification of pentaerythritol with pentanoic acid, heptanoic acid and 3,5,5-trimethylhexanoic acid	Full, >1000
451-220-2	-	Not (publicly) available	NONS
451-400-0	-	Not (publicly) available	NONS
452-180-9	-	Not (publicly) available	NONS
453-150-8	-	Not (publicly) available	NONS
484-420-3	-	Pentaerythritol, reaction product with fatty acids, C8 to 18 (even numbered) and/or branched and/or unsaturated	Full, not (publicly) available
601-553-6	118685-29-3	Heptanoic acid, mixed esters with pentaerythritol and valeric acid	C&L notification
806-879-4	1547205-02-6	Fatty acids, heptanoic, nonanoic and 2-ethylhexanoic, tetraesters with pentaerythritol	
813-120-0	1262967-45-2	Tetraesters of pentaerythritol with 2-methylpropanoic acid and 3,5,5-trimethylhexanoic acid	Full, not (publicly) available
815-460-5	-	Pentaerythritol Ester of Mixed Linear and Branched Carboxylic Acids	
817-668-1	667899-24-3	Octanoic acid, mixed tetraesters with 2-ethylhexanoic acid, heptanoic acid and pentaerythritol	Full, not (publicly) available
939-415-5	-	Monopentaerythritol tetraesters and dipentaerythritol hexaesters of 3,5,5-trimethylhexanoic, n-heptanoic, n-octanoic and n-decanoic acids	Cease manufacture
939-690-1	-	Reaction mass of 2,2-bis(hydroxymethyl)propane-1,3-diyl bis(2-ethylhexanoate) and 3-[(2-ethylhexanoyl)oxy]-2-[(2-ethylhexanoyl)oxy]methyl)-2-(hydroxymethyl)propyl 2-ethylhexanoate and 3-[(2-ethylhexanoyl)oxy]-2,2-bis{[(2-ethylhexanoyl)oxy]methyl}propyl 2-ethylhexanoate	Full, not (publicly) available
Substance 1		Tetra-esterification products of C5 -(linear and branched) , C7, C8, C9, C10 fatty acids with pentaerythritol	Full, not (publicly) available
Substance 2	-	Tetra-esterification products of C5-(branched and linear), C7, C8 and C10 fatty acids with pentaerythritol	Full, not (publicly) available
Substance 3	-	Fatty acids, C5-10 (linear and branched), mixed esters with pentaerythritol	Full, not (publicly) available
Substance 4	-	Pentaerythritol, mixed esters with linear and branched fatty acids	Full, not (publicly) available

This table contains also group members that are only notified under the CLP Regulation, however, the list is not necessarily exhaustive.

Contents

Foreword.....	6
Glossary	8
1 Overview of the group.....	9
2 Conclusions and proposed actions.....	10
3 Justification for the no need for regulatory risk management action at EU level	13
Annex 1: Overview of classifications	16
Annex 2: Overview of uses based on information available in registration dossiers.....	17
Annex 3: Overview of completed or ongoing regulatory risk management activities	21

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 assessment of regulatory needs of a group of substances is an iterative, informal process to help authorities consider the most appropriate way to address an identified concern for a group of substances or a single substance and decide whether further regulatory risk management activities are necessary.

The grouping is mainly based on structural similarity and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g. OECD categories)². These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA's grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level³. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

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

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

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

² [Working with Groups - ECHA \(europa.eu\)](https://eucha.europa.eu)

³ Regarding hazard properties the focus is for instance on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).

ASSESSMENT OF REGULATORY NEEDS

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

For more information on assessments of regulatory needs please consult ECHA's website⁴.

⁴ <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
RDT	Repeated dose toxicity
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern
TPE	Testing proposal evaluation

1 Overview of the group

Explanations on the scope of this assessment is available in the foreword to this document. Please read it carefully before going through the report.

ECHA has grouped together structurally similar substances based on the presence of linear and branched or branched carboxylic acid esters of pentaerythritol, a polyalcohol. The substances contain branched and linear carboxylic acid esters. The carboxylic acids have total carbon numbers ranging from C4 to C16 and one ester with fatty acids from lanolin (wool wax). The group includes mainly full esters, i.e. tetraesters. One substance contains also a significant amount of Di-pentaerythritols.

There are 37 substances in the group, of which 21 substances have full registrations.

Based on information reported in the REACH registration dossiers, all substances in this group are used in lubricants and that application includes at least one widespread use, leading to a high potential for exposure for workers and/or consumers, as well as a high potential for release to the environment. Additionally, five substances in this group are used in almost all product categories. For the other substances, the most common uses are as heat transfer fluids, hydraulic fluids and, to a lesser extent, cosmetics. The substances are used in these applications mostly as a lubricant or functional fluid.

2 Conclusions and proposed actions

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

Table 1: Conclusions and proposed actions

EC/List no,	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
806-879-4 939-690-1 230-743-8 262-334-5 263-423-1 268-582-0 268-594-6 270-434-5 286-056-9 298-364-0 410-830-9 415-650-4 416-690-5 416-700-8	No hazard or unlikely hazard	Known or potential hazard for aquatic toxicity for EC/List no: 230-743-8, 268-582-0, 410-830-9, 415-650-4, 416-690-5, 416-700-8, 451-120-9, 484-420-3, Substance 3, 806-879-4, 817-668-1, 939-690-1, Substance 4	Widespread uses for the registered substances in many applications fertilisers, cleaning products, perfumes, polymer preparations, paints, adhesives, textile and leather treatment products and use in articles (lubricants). Potential for exposure for workers and/or consumers, as well as release to the environment.	Currently no need for EU RRM Pending action Ongoing CCH for EC 230-743-8, Substance 3 and List No. 939-415-5 <u>Justification:</u> Overall, no or unlikely hazard that would lead to concern for the reported uses. Harmonised/self-classification (will) require company level risk management measures (RMM) for environment to be in place.

ASSESSMENT OF REGULATORY NEEDS

EC/List no,	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
429-010-7				
430-320-1				
443-990-3				
444-210-4				
451-110-4				
451-120-9				
451-170-1				
451-180-6				
451-200-3				
451-220-2				
451-400-0				
452-180-9				
453-150-8				
484-420-3				
601-553-6				
806-879-4				
813-120-0				
815-460-5				
817-668-1				
939-415-5				

ASSESSMENT OF REGULATORY NEEDS

EC/List no,	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
939-690-1 Substance 1 Substance 2 Substance 3 Substance 4				

3 Justification for the no need for regulatory risk management action at EU level

Currently no need to suggest (further) regulatory risk management actions for all substances

None of the registered substances in the group needs further EU regulatory risk management actions at the moment due to low potential toxicological hazard.

Majority/many of the substances in the group have widespread uses in professional settings or consumer products, with high exposure potential and release in the environment.

Based on currently available information, for CMR/ED, skin sensitisation and STOT RE, PBT/vPvB, PMT/vPvM hazards are considered unlikely for all substances in the group except for aquatic toxicity for some group members.

These conclusions are based on the available data on the registered substances, the hypothesis of enzymatic hydrolysis and available information on the metabolites as well as extrapolation of hazard hypothesis due to structural similarity.

Based on the evaluations from other safety bodies (JECFA, 1999; EFSA, 2013; HPV, 2006), group members might be hydrolysed into branched carboxylic acids and pentaerythritol by carboxylesterase enzymes found in most tissues throughout the body, including the gastrointestinal tract. Sequential oxidative metabolism of the four hydroxy groups of pentaerythritol is expected. The resulting branched carboxylic acids will undergo different metabolic pathways, depending on the carbon chain length and branching: beta-oxidation for short chains, omega-oxidation for long chains and alfa- and/or beta-oxidation for acids with a methyl substituent.

The majority of the carboxylic acid parts of these group members have been or are being assessed by ECHA (group on fatty acids and group on branched carboxylic acids) and are expected to be of low toxicity. Furthermore, pentaerythritol that is the common alcohol metabolite for all the esters in this group, is of low toxicity based on the information of its registration dossier (no evident systemic toxicity up to the limit dose in repeated dose toxicity, PNDD and EOGRT studies).

No systemic toxicity that would lead to classification as STOT RE is expected based on the available repeated-dose toxicity studies with the registered substances. The available information indicates no or non-significant effects up to the limit dose. One group member has self-classification as STOT RE; the data does not indicate severe systemic effects, therefore this hazard is not considered further for the purpose of the current screening.

Available experimental data on mutagenicity and skin sensitisation are negative. No carcinogenic effect is expected in view of the absence of mutagenic and repeated dose toxicity hazard.

Reproductive screening studies available (ECs 230-743-8, 268-582-0, 415-650-4, 430-320-1) do not indicate any effect up to the limit dose. For two substances also developmental toxicity studies are available indicating no effects for developmental toxicity (ECs 230-743-8 and 484-420-3). These two substances contain 2-

ASSESSMENT OF REGULATORY NEEDS

ethylhexanoic acid moiety that is harmonised classified as Repr. 1B⁵, and the available information supports the hypothesis that the concentration of the metabolite upon hydrolysis might not reach toxicity levels relevant for reproductive toxicity of the parent compound. Overall, the reproductive and developmental toxicity hazard is considered unlikely for the substances of these subgroups.

Regarding a potential endocrine disruption hazard, the available data does not indicate any target organ toxicity in endocrine organs such as the thyroid or the reproductive organs.

Some group members may upon enzymatic hydrolysis release 3,5,5-trimethylhexanoic acid which is intended for CLH Repr.1B⁶ or 2-ethylhexanoic acid that is known reproductive toxicant (Repr. 1B). The potential for enzymatic biotransformation and release of 2-ethylhexanoic acid or 3,3,5-trimethylhexanoic acid is assumed to be low taking into account the size of the parent compound. Overall, the reproductive and developmental toxicity hazard is considered unlikely for the substances of these subgroups with remaining uncertainty. This is due to the potential breakdown of the esters, more specifically regarding the rate of hydrolysis, the information available is mostly from literature sources and refers to the generic ability of carboxylesterases to breakdown the esters.

Applying the potential reproductive and developmental toxicity hazard for these group members would be a worst-case assumption, as it is not known whether the metabolites of concern resulting from their hydrolysis will be systemically available at concentrations sufficient to cause toxic effects. In general, it is assumed that the toxicity of the esters is expected to be lower than that of the corresponding carboxylic acids and alcohols since higher doses of the esters would be needed to reach equivalent toxic doses.

The substances in this group are unlikely to fulfil the PBT/vPvB, PMT/vPvM screening criteria, because they have a low potential for bioaccumulation and are not mobile.

The substances in this (sub)group are unlikely to fulfil the screening PBT/vPvB criterion, because whilst they are all potentially P/vP, they are all expected to undergo fast metabolization by aquatic organisms via enzymatic hydrolysis or eliminated via urinary excretion to corresponding free fatty acids and alcohols (literature data on metabolism available). In addition, the availability of the substances in water is reduced due to high hydrophobicity and poor solubility. All group members are expected to be not mobile in the environment based on the reported log K_{oc}.

Concerning the hazard for aquatic toxicity, the substance, EC 410-830-9 has a harmonised classification for Aquatic Chronic 4. Based on structural similarity the findings from the available aquatic studies are extrapolated to the group members EC/List no: 230-743-8, 268-582-0, 410-830-9, 415-650-4, 416-690-5, 416-700-8, 451-120-9, 484-420-3, Substance 3, 806-879-4, 817-668-1, 939-690-1, Substance 4.

The substances containing branching and linear carboxylic acid esters and/or, 3,5,5-trimethyl-hexanoate are expected to have low aquatic toxicity, based on the available long-term toxicity for the substance (List no 813-120-0) indicating low

⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1435&qid=1689155759608>

⁶ <https://echa.europa.eu/fi/registry-of-clh-intentions-until-outcome/-/dislist/details/Ob0236e188116743>

ASSESSMENT OF REGULATORY NEEDS

toxicity. Furthermore, based on the structural similarity with substances in other groups (esters from linear carboxylic acid and pentaerythritol, esters from linear and branched carboxylic acids and dipentaerythritol), it is likely that these substances show low aquatic toxicity.

Based on the information available on composition provided in (some) registration dossiers, the substance EC 230-743-8, 2,2-bis[[[(2-ethyl-1-oxohexyl)oxy]methyl]propane-1,3-diyl bis(2-ethylhexanoate) contains as constituent or impurity the substance EC 149-57-5, 2-ethylhexanoic acid with harmonised classification as Repr. 1B⁷ at concentrations above specific/generic concentration limits under the CLP Regulation, justifying the classification of the substance(s) as Repr. 1B. Registrants are invited to update their registration dossiers and revise the classification of the substance(s) based on constituents/impurities, as appropriate, or if technically feasible to ensure that the concentration of the impurity is below the relevant concentration limit for Repr. 1B. The Safety Data Sheet needs to be updated accordingly.

There is ongoing CCH for EC 230-743-8, Substance 3 and List no. 939-415-5. No further action is currently proposed for other group members at this stage. Information from the ongoing CCH as well as the potential breakdown products (acids and alcohols) ARNs and the structurally similar esters when available will further inform on their hazardous properties and the strategy can be revisited if needed.

⁷ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1435&qid=1689155759608>

Annex 1: Overview of classifications

Data extracted on 19 November 2021.

EC/ List no	CAS No	Substance name	Harmonised classification	Classification in registrations
813-120-0	1262967-45-2	Tetraesters of pentaerythritol with 2-methylpropanoic acid and 3,5,5-trimethylhexanoic acid		STOT Rep. Exp. 2 H373, affected organs: Liver and kidney
410-830-9		A mixture of: pentaerythriol tetraesters with heptanoic acid and 2-ethylhexanoic acid	Aquatic Chronic 4	

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

Data extracted on 7 December 2021.

EC number	230-743-8	262-334-5	263-423-1	268-582-0	268-594-6	270-434-5	286-056-9	298-364-0	415-650-4	430-320-1	451-200-3	484-420-3	806-879-4	813-120-0	815-460-5	817-668-1	939-415-5	939-690-1	Subst 1	Subst 2	Subst 3	Subst 4	
PC 20: Products such as ph-regulators, ...			F, I			F, I	F, I	F, I							F, I								
PC 36: Water softeners			C			C	C	C							C								
PC 37: Water treatment chemicals			F, I, P			F, I, P	F, I, P	F, I, P							F, I, P								
PC 2: Adsorbents			F			F	F	F							F								
PC 11: Explosives			P			P	P	P							P								
PC 12: Fertilisers			F, I, P, C			F, I, P, C	F, I, P, C	F, I, P, C							F, I, P, C								
PC 27: Plant protection products			P, C			P, C	P, C	P, C							P, C								
PC 4: Anti-freeze and de-icing products			P, C			P, C	P, C	P, C							P, C								
PC 35: Washing and cleaning products	I, P		F, I, P, C			F, I, P, C	F, I, P, C	F, I, P, C							F, I, P, C								
PC 8: Biocidal products			I, P, C			I, P, C	I, P, C	I, P, C							I, P, C								

ASSESSMENT OF REGULATORY NEEDS

EC number	230-743-8	262-334-5	263-423-1	268-582-0	268-594-6	270-434-5	286-056-9	298-364-0	415-650-4	430-320-1	451-200-3	484-420-3	806-879-4	813-120-0	815-460-5	817-668-1	939-415-5	939-690-1	Subst 1	Subst 2	Subst 3	Subst 4	
PC 28: Perfumes, fragrances			F, P, C			F, C	F, P, C	F, C							F, C								
PC 3: Air care products			C			C	C	C							C								
PC 39: Cosmetics, personal care products	F, C		F, I, P, C			F, P, C	F, I, P, C	F, P, C			F, C				F, P, C			F, C					
PC 29: Pharmaceuticals			F, I, P, C			I, P	F, I, P, C	I, P							I, P								
PC 31: Polishes and wax blends			P, C			P, C	P, C	P, C			C				P, C				C				
PC 15: Non-metal-surface treatment products			C			C	C	C							C								
PC 24: Lubricants, greases, release products	F, I, P, C	F, I, P	F, I, P, C	I, C, A	F, I, P, C	I, A	I, P	F, I, P, C, A	I, A	I, P	I, P	F, I, P, C	I, P	F, I, P	F, I, P, C	I, P, C	I, P	I, P	I, P	I, P			
PC 25: Metal working fluids	F	F, I, P	I, P, C		F	F, I, P, C	I, P, C	I, P, C			F, I, P				I, P, C						I, P	I, P	
PC 16: Heat transfer fluids	F, I, P		C			C	C	C	I		C				C	I, P			C	C			
PC 17: Hydraulic fluids	F, I, P		I, P, C	I, C	F, I, P	I, P, C	I, P, C	I, P, C			F, I, P, C		I, P		I, P, C				I, P, C	I, P, C	I, P		
PC 13: Fuels			I, P, C			I, P, C	I, P, C	I, P, C			I, P, C				I, P, C								

ASSESSMENT OF REGULATORY NEEDS

EC number	230-743-8	262-334-5	263-423-1	268-582-0	268-594-6	270-434-5	286-056-9	298-364-0	415-650-4	430-320-1	451-200-3	484-420-3	806-879-4	813-120-0	815-460-5	817-668-1	939-415-5	939-690-1	Subst 1	Subst 2	Subst 3	Subst 4	
PC 32: Polymer preparations and compounds			F, I, P, C, A			F, I, P, C	F, I, P, C, A	F, I, P, C			F, I, P, A				F, I, P, C								
PC 1: Adhesives, sealants			F, I, P, C			F, I, P, C	F, I, P, C	F, I, P, C			C				F, I, P, C				C				
PC 9c: Finger paint			C			C	C	C							C								
PC 9b: Fillers, putties, plasters,...			I, C			I, C	I, C	I, C			F, I, P				I, C								
PC 9a: Coatings and paints, thinners, ...	I, P		F, I, P, C			F, I, P, C	F, I, P, C	F, I, P, C			F, I				F, I, P, C								
PC 18: Ink and toners			F, I, P, C			F, I, P, C	F, I, P, C	F, I, P, C			F, I				F, I, P, C								
PC 26: Paper and board treatment products			I, A			I,	I, A	I,							I								
PC 34: Textile dyes, and impregnating products			F, I, C, A			F, I, C, A	F, I, C, A	F, I, C, A							F, I, C, A								
PC 23: Leather treatment products	F		F, I, P, C			F, I, P, C	F, I, P, C	F, I, P, C							F, I, P, C								
PC 14: Metal surface treatment products			I				I	I							I								

ASSESSMENT OF REGULATORY NEEDS

EC number	230-743-8	262-334-5	263-423-1	268-582-0	268-594-6	270-434-5	286-056-9	298-364-0	415-650-4	430-320-1	451-200-3	484-420-3	806-879-4	813-120-0	815-460-5	817-668-1	939-415-5	939-690-1	Subst 1	Subst 2	Subst 3	Subst 4	
PC 21: Laboratory chemicals	F, I		F, I, P			F, I, P	F, I, P	F, I, P			F		I, P		F, I, P			F, I					
PC 19: Intermediate			I			I	I	I							I								
PC41: Oil and gas exploration or production products		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

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

Data extracted on 11 November 2021.

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