Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Esters from linear and branched carboxylic acid and trimethylolpropane

General structure: "-"

Revision history

Version	*Date*	*Description*
1.0	19 May 2022	

Substances within this group:

EC/List no	CAS no	Substance name	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
201-089-0	78-16-0	2-ethyl-2-[[(1-oxoheptyl)oxy]methyl]propane-1,3-diyl bisheptanoate	100 - 1000; full registration
204-793-6	126-57-8	2-ethyl-2-[[(1-oxononyl)oxy]methyl]propane-1,3-diyl dinonan-1-oate	>1000; full registration
234-392-1	11138-60-6	Decanoic acid, ester with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol octanoate	no registration
246-625-4	25111-05-1	2-ethyl-2-(hydroxymethyl)-1,3-propanediyl dioleate	10 - 100; full registration
267-029-0	67762-64-5	Heptanoic acid, ester with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol pentanoate	100 - 1000; full registration
268-092-7	68002-78-8	Fatty acids, C16-18 and C18 unsatd., triesters with trimethylolpropane	100 - 1000; full registration
268-596-7	68130-53-0	Decanoic acid, mixed esters with heptanoic acid, octanoic acid and trimethylolpropane	> 1000; full registration
270-287-7	68424-27-1	Fatty acids, C16 and C18-unsatd., triesters with trimethylolpropane	> 1000; full registration
271-347-5	68541-50-4	2-ethyl-2-[[(1-oxoisooctadecyl)oxy]methyl]-1,3-propanediyl bis(isooctadecanoate)	100 - 1000; full registration
286-075-2	85186-89-6	Fatty acids, C8-18 and C18-unsatd., esters with trimethylolpropane	> 1000; full registration
287-397-6	85507-75-1	Fatty acids, C14-18 and C16-18-unsatd., mixed esters with adipic acid and trimethylolpropane	1 - 10; full registration
288-726-6	85883-76-7	Fatty acids, C8-18-branched and linear, esters with trimethylolpropane	1 - 10; full registration
292-832-8	91001-61-5	Fatty acids, C16-18 and C18-unsatd., mixed esters with adipic acid and trimethylolpropane	> 1000; full registration
293-036-3	91050-89-4	Fatty acids, C8-10, triesters with trimethylolpropane	> 1000; full registration
305-758-9	95009-31-7	Fatty acids, C8-14, triesters with trimethylolpropane	> 1000; full registration
306-085-3	95912-89-3	Fatty acids, C8-10, mixed esters with adipic acid and trimethylolpropane	100 - 1000; full registration

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

EC/List no	CAS no	Substance name	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
306-523-3	97281-24-8	Fatty acids, C8-10, mixed esters with neopentyl glycol and trimethylolpropane	10 - 100; full registration
613-848-7	65870-94-2	Hexanoic acid, 3,5,5-trimethyl-, 1,1'-[2-ethyl-2-[[(3,5,5-trimethyl-1-oxohexyl)oxy]methyl]-1,3-propanediyl] ester	Full, not (publicly) available
614-585-0	68551-65-5	Trans-esterification product of castor oil and 2-ethyl-2-(hydroxymethyl)propane-1,3-diol	Full, not (publicly) available
700-772-5	1190961-28-4	Fatty acids, coco, tetraesters with bis[2,2-bis(hydroxymethyl)butyl] adipate	Full, not (publicly) available
701-023-5	-	Fatty acids, C16-18 (even numbered) and C18-unsatd., branched and linear, di- and triesters with trimethylolpropane	Full, > 1000
701-042-9	1335202-94-2	Fatty acids, C18-unsatd., diesters and triesters with trimethylolpropane	Full, > 1000
812-652-0	-	Fatty acids, C8-10-(even numbered), diesters and triesters with trimethylolpropane	Full, > 1000
812-656-2	73947-34-9	Fatty acids, C18-unsatd., mono- and diesters with neopentylglycol and di- and triesters with trimethylolpropane	Full, not (publicly) available
812-688-7	73138-40-6	Fatty acids, coco, diesters and triesters with trimethylolpropane	Full, > 1000
815-461-0	-	Reaction product of mixed triesters of heptanoic acid (n-C7), nonanoic acid (n-C9) and trimethylolpropane (i-C7)	Full, not (publicly) available
941-376-4	147977-79-5	Fatty acids, tall-oil, esters with trimethylolpropane	Full, 100 – 1000
941-924-2	-	Carboxylic acids, C5-9, triesters with 2-ethyl-2-(hydroxymethyl)propane-1,3-diol	Full, not (publicly) available
946-440-5	-	Trimethylolpropane, mixed triesters with decanoic, heptanoic, octanoic, and 3,5,5-trimethylhexanoic acids	Full, not (publicly) available
947-835-5	-	Nonanoic acid, esters with adipic acid and trimethylolpropane	Full, not (publicly) available
Substance X	-	[No public or meaningful name is available]	Full, not (publicly) available

This table does not contain group members that are only notified under the CLP.

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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 level[3]. 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)

[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).

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 website[4].

[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 the trimethylolpropane (2-ethyl-2-(hydroxymethyl)propane-1,3-diol)moiety shown in the figure below.

This central alcohol is esterified with different aliphatic carboxylic acids with different characteristics.

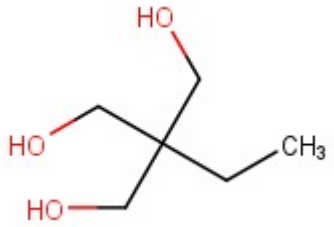

Figure 1: trimethylolpropane

The carboxylic acids present have chain lengths mainly between C5 and C20 and are linear saturated, linear unsaturated and branched saturated. In some cases bifunctional adipic acid (hexandioic acid) is also present, which is serving as “crosslinker” between two alcohol moieties. In one case 12-hydroxyoleic acid (ricinoleic acid) is present. Both complete and partial esters exist in this group.

In one extraordinary case the alcohol is a mixture of trimethylolpropane and neopentyl glycol.

There are 31 substances in the group and all of them have full registrations.

Based on information reported in the REACH registration dossiers most substances in the group have widespread uses in professional setting or consumer products where exposure to workers and consumers and/or releases to the environment can be expected.

The majority of the substances of the group have a very similar use profile. They are used as a lubricating agent, solvent, additive, fuel, functional fluid, cleaning agent, binder & release agent, intermediate, fragrance, co-formulant in a very wide range of products such as washing and cleaning products, cosmetics and personal care product, biocidal products, lubricants, greases and release products, coatings and paints, polymer preparations and compounds, fuels, fertilisers, plant protection products, explosives, construction products, textile and leather treatment products etc.

Substances used in polymers preparations and compounds, construction products as well as in textile and leather treatment products often have article service life reported.

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
201-089-0, 204-793-6, 234-392-1, 246-625-4, 267-029-0, 268-092-7, 268-596-7, 270-287-7, 271-347-5, 286-075-2, 287-397-6, 288-726-6, 292-832-8, 293-036-3, 305-758-9, 306-085-3, 306-523-3, 613-848-7, 614-585-0, 700-772-5, 701-023-5, 701-042-9,	No hazard or unlikely hazard	No hazard or unlikely hazard	Widespread uses e.g. in washing and cleaning products, cosmetics and personal care product, biocidal products, lubricants, greases and release products, coatings and paints, polymer preparations and compounds, fuels, fertilisers, plant protection products, explosives, construction products, textile and leather treatment products. Potential for exposure for workers and consumers and releases to the environment.	CCH for ECs/Lists: 286-075-2, 292-832-8, 293-036-3, 812-652-0 **Currently no need for EU RRM** <u>Justification</u>: Overall, no or unlikely hazard that would lead to concern for the reported uses.

EC / List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
812-652-0, 812-656-2, 812-688-7, 815-461-0, 941-376-4, 941-924-2, 946-440-5, 947-835-5 Substance X			EC 246-625-4 is used as intermediate and EC 234-392-1 is not registered. Low potential for exposure / release to the environment.	

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

Based on currently available information, there is no need for (further) EU regulatory risk management for the remaining substances in the group due to low potential toxicological and environmental hazard.

A majority of the substances in the group have widespread uses in professional settings or consumer products, with high exposure potential and release in the environment

The group substances are unlikely to cause skin sensitisation, mutagenicity, carcinogenicity, reproductive and developmental toxicity, endocrine disruption or target organ toxicity based on the data available which does not indicate any concern for human health as the mammalian toxicity studies are generally conducted up to limit dose.

In vitro mutagenicity studies are available for the group substances EC/List 201-089-0, 204-739-6, 234-392-1, 306-085-3, 613-848-7, 700-772-5, Substance X) (Ames studies, *in vitro* chromosomal aberration tests and *in vitro* mammalian cell gene mutation test) and are negative. Skin sensitisation studies are available for the group substances EC/List 204-793-6, 234-392-1, 268-596-7, 306-085-3, 306-523-3 and 700-772-5. Studies are negative and no functional group of concern has been identified for the group. Repeated dose toxicity are available for the group substances EC/List 204-793-6, 268-596-7, 270-287-7 and 613-848-7. Screening for reproductive/developmental toxicity studies are available for the group substances EC/List 204-793-6, 268-596-7 and 613-848-7. Developmental toxicity studies are available for the group substances EC 234-392-1 and 268-596-7. No carcinogenicity study is available, but no carcinogenic effect is expected in view of the absence of mutagenic and repeated dose toxicity hazard. Regarding a potential endocrine disruption hazard, the available data does not indicate any target organ toxicity in endocrine organs such as the thyroid or the reproductive organs. Therefore, there is no apparent hazard finding that could be linked to endocrine-mediated effects for any of the substances.

All group members will likely undergo enzyme mediated hydrolysis *in vivo* to release a carboxylic acid and trimethylolpropane (TMP) at variable rates. The majority of the carboxylic acid parts of these group members have been or are being assessed by ECHA (group on fatty acids expected to be of low toxicity and group on branched carboxylic acids, with short chain ones to be potential reproductive toxicants).

Trimethylolpropane (TMP) has a CLH intention for classification as Repr. 1B for development. In an OECD TG 443 extended one generation reproductive toxicity study, TMP caused adverse test item-related effects on target organs and reproduction. Microscopic findings in F0 and F1 animals in mid-dose group consisted of vacuolation of the gray matter of periventricular areas of the brain and in areas adjacent to the central canal of the spinal cord and cytoplasmic vacuolation of skeletal muscle myofibers. Adverse reproductive effects were observed in high-dose group Cohort 1B animals in which treatment resulted in a significantly reduced number of implantations. Developmental toxicity following treatment in high-dose group consisted of a decreased post-implantation survival

index (resulting in a decreased litter size), decreased mean combined pup weights and decreased pup viability.

There is remaining uncertainty regarding the breakdown of the group esters in body specifically regarding release of TMP, the degradation product with the most hazard potential. Enzymatic hydrolysis of the group substances is expected to be incomplete and slow based on EFSA (2010)[5]. According to the EFSA Scientific Opinion, a simulation study with a representative trimethylolpropane (TMP) tri- and di-esters mixture (not group member) demonstrated that only 10% of the substance was fully hydrolysed, 30% of the tri-esters were partially hydrolysed, and 60% remained unchanged after incubation for 4 h at 37ºC in intestinal fluid simulant. The EFSA simulation study with group substance EC 201-089-0 reported that no hydrolysis in digestive fluid simulants was observed. However, the group members are expected to enzymatically hydrolyse to generate di- and mono-esters, and the corresponding fatty acids. It is not clear based on the available information whether TMP is released from the group substances along the metabolic pathway before elimination from body.

Tri-ester group members have been tested in animal models covering the biotransformation of the parent compounds. TMP reproductive toxic effects or adverse effects to central nervous system and myofibres were not reported for the group substances tested in the screening studies, prenatal developmental toxicity studies or repeated dose toxicity studies with group tri-esters.

Currently the hazard observed with TMP is not further extrapolated to the mono-, di- and triesters group members based on the negative data available and the remaining uncertainty regarding incomplete breakdown to the alcohol and fatty acid components.

Further assessment of selected mono and di-ester group members is needed to address the remaining uncertainty.

There are **no/unlikely hazards** for the environment identified for the group members. All substances in the group are unlikely to pose *PBT/vPvB* or *aquatic toxicity* hazards.

All substances in this group are considered to be not persistent based on the results of experimental ready biodegradability studies available for half of the group members covering various structural differences present in the group and general structural similarity between group members. Hence it is unlikely that members of this group would be PBT/vPvB.

There are no fish bioaccumulation studies available for the members of the group. All substances are claimed to be not B based on various lines of evidence: QSAR predicted low bioconcentration factors values, potential for fast metabolization, hindrance of uptake due to the size of molecule, low exposure potential due to ready biodegradability and high adsorption potential. There is remaining uncertainty on bioaccumulation potential of the group members. This is due to the missing experimental data confirming low bioaccumulation potential and information from EFSA report about no enzymatic hydrolysis of trimethylolpropoane triester (EC 201-089-0) in simulation assays of a non-group member substance neopentylglycol diester (EC 272-469-1) hydrolysed in approximately 1 h.

[5] https://www.efsa.europa.eu/en/efsajournal/pub/1839

All substances (most constituents) in the group are poorly soluble in water (i.e. solubility <1 mg/l). There are long-term toxicity studies with aquatic invertebrates with 3 substances with linear C5-C10 carboxylic acid groups (EC 204-793-6, EC 268-596-7 and List 941-924-2) and long-term toxicity study with fish with 1 substance (EC 204-793-6). No toxic effects up to the water solubility limit were observed in these studies. Experimental toxicity studies with algae are available for half of the group members with C8 branched, C9 linear, C18 unsaturated and C8-C20. No effects were observed that would require classification. Based on above, it is concluded that all the member of the group are considered of low toxicity.

In addition, based on the information available on composition provided in some registration dossiers, the substances EC/List 268-092-7, 271-347-5, 286-075-2, 292-832-8, 306-085-3, 614-585-0, 700-772-5, 701-042-9 and 812-688-7 contain the substance 2-ethyl-2-(hydroxymethyl)propane-1,3-diol (TMP, EC 201-074-9) with intention for harmonised classification as Repr. 1B for development at concentration (concentration range max 1-23%) potentially above generic concentration limits under the CLP Regulation (0.3%), and if confirmed, justifying the classification of the substance itself.

Therefore, if TMP would be classified as Repr. 1B, registrants would need to update their registration dossiers and revise the classification of the substance based on impurities, as appropriate, or if technically feasible to ensure that the concentration of the impurity is below the relevant concentration limit for reproductive toxicity (Repr.1B) The safety data sheet needs to be updated accordingly.

CCH is proposed for selected group members (EC/List 286-075-2, 292-832-8, 293-036-3, 812-652-0) that contain mono- and/or di- esters to further examine among other also the potential hazard for reproductive toxicity due to potential release of trimethylpropane.

Annex 1: Overview of classifications

Data extracted on 16 November 2020.

EC/ List No	Substance name	Harmonised classification	Classification in registrations
201-089-0	2-ethyl-2-[[(1-oxoheptyl)oxy]methyl]propane-1,3-diyl bisheptanoate	-	-
204-793-6	2-ethyl-2-[[(1-oxononyl)oxy]methyl]propane-1,3-diyl dinonan-1-oate	-	-
234-392-1	Decanoic acid, ester with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol octanoate	-	-
246-625-4	2-ethyl-2-(hydroxymethyl)-1,3-propanediyl dioleate	-	-
267-029-0	Heptanoic acid, ester with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol pentanoate	-	*Asp.Tox. 1 H304*
268-092-7	Fatty acids, C16-18 and C18 unsatd., triesters with trimethylolpropane	-	-
268-596-7	Decanoic acid, mixed esters with heptanoic acid, octanoic acid and trimethylolpropane	-	-
270-287-7	Fatty acids, C16 and C18-unsatd., triesters with trimethylolpropane	-	-
271-347-5	2-ethyl-2-[[(1-oxoisooctadecyl)oxy]methyl]-1,3-propanediyl bis(isooctadecanoate)	-	-
286-075-2	Fatty acids, C8-18 and C18-unsatd., esters with trimethylolpropane	-	-
288-726-6	Fatty acids, C8-18-branched and linear, esters with trimethylolpropane	-	-
292-832-8	Fatty acids, C16-18 and C18-unsatd., mixed esters with adipic acid and trimethylolpropane	-	-
293-036-3	Fatty acids, C8-10, triesters with trimethylolpropane	-	-
305-758-9	Fatty acids, C8-14, triesters with trimethylolpropane	-	-
306-085-3	Fatty acids, C8-10, mixed esters with adipic acid and trimethylolpropane	-	-
306-523-3	Fatty acids, C8-10, mixed esters with neopentyl glycol and trimethylolpropane	-	-

EC/ List No	Substance name	Harmonised classification	Classification in registrations
700-772-5	Fatty acids, coco, tetraesters with bis[2,2-bis(hydroxymethyl)butyl] adipate	-	-
701-023-5	Fatty acids, C16-18 (even numbered) and C18-unsatd., branched and linear, di- and triesters with trimethylolpropane	-	-
701-042-9	Fatty acids, C18-unsatd., diesters and triesters with trimethylolpropane	-	-
812-652-0	Fatty acids, C8-10-(even numbered), diesters and triesters with trimethylolpropane	-	-
812-656-2	Fatty acids, C18-unsatd., mono- and diesters with neopentylglycol and di- and triesters with trimethylolpropane	-	-
812-688-7	Fatty acids, coco, diesters and triesters with trimethylolpropane	-	-
941-376-4	Carboxylic acids, C5-9, triesters with 2-ethyl-2-(hydroxymethyl)propane-1,3-diol	-	-
941-924-2	Carboxylic acids, C5-9, triesters with 2-ethyl-2-(hydroxymethyl)propane-1,3-diol	-	-
946-440-5	Trimethylolpropane, mixed triesters with decanoic, heptanoic, octanoic, and 3,5,5-trimethylhexanoic acids	-	-
613-848-7	Hexanoic acid, 3,5,5-trimethyl-, 1,1'-[2-ethyl-2-[[(3,5,5-trimethyl-1-oxohexyl)oxy]methyl]-1,3-propanediyl] ester	-	-
815-461-0	Trimethylolpropane triesters of heptanoic acid and nonanoic acid	-	-
614-585-0	Trans-esterification product of castor oil and 2-ethyl-2-(hydroxymethyl)propane-1,3-diol	-	-
287-397-6	Fatty acids, C14-18 and C16-18-unsatd., mixed esters with adipic acid and trimethylolpropane	-	-
947-835-5	Nonanoic acid, esters with adipic acid and trimethylolpropane	-	-
Substance X	No public name available	-	-

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

Data extracted on 16 November 2020.

Main types of applications structured by product or article types	201-089-0	204-793-6	267-029-0	268-092-7	268-596-7	270-287-7	271-347-5	286-075-2	287-397-6	288-726-6	292-832-8	293-036-3	305-758-9	306-085-3
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	F, I	F, I		F, I			F, I	F, I			F, I	F, I	F, I	F, I
PC 36: Water softeners	**C**	**C**		**C**			**C**	**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**	F, I, **P**			F, I, **P**,	F, I, **P**	F, I, **P**	F, I, **P**
PC 2: Adsorbents	F	F		F			F	F			F	F	F	F
PC 11: Explosives	**P**	**P**		**P**		**P**	**P**	**P**			**P**	**P**	**P**	**P**
PC 12: Fertilisers	F, I, **P**, **C**	F, I, **P**, **C**		F, I, **P**, **C**		**C**	F, I, **P**, **C**	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**	**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**	**P**, **C**			**P**, **C**	**P**, **C**	**P**, **C**	**P**, **C**
PC 35: Washing and cleaning products	F, I, **P**, **C**	F, I, **P**, **C**		F, I, **P**, **C**		F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**			F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**
PC 8: Biocidal products (e.g. disinfectants, pest control)	I, **P**, **C**	I, **P**, **C**		I, **P**, **C**		**C**	I, **P**, **C**	I, **P**, **C**			I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	I, **P**, **C**
PC 28: Perfumes, fragrances	F, **C**	F, **C**		F, **C**		F, **C**	F, **C**	F, **C**			F, **C**	F, **C**	F, **C**	F, **C**
PC 3: Air care products	**C**	**C**		**C**		**C**	**C**	**C**			**C**	**C**	**C**	**C**
PC 39: Cosmetics, personal care products	F, **P**, **C**	F, I, **P**, **C**		F, **P**, **C**		F, **C**,	F, **P**, **C**	F, **P**, **C**,			F, **P**, **C**,	F, **P**, **C**	F, **P**, **C**	F, **P**, **C**

Main types of applications structured by product or article types	201-089-0	204-793-6	267-029-0	268-092-7	268-596-7	270-287-7	271-347-5	286-075-2	287-397-6	288-726-6	292-832-8	293-036-3	305-758-9	306-085-3
PC 29: Pharmaceuticals	I, **P**	I, **P**		I, **P**			I, **P**	I, **P**			I, **P**	I, **P**	I, **P**	I, **P**
PC 31: Polishes and wax blends	**P**, **C**	**P**, **C**		**P**, **C**		**P**, **C**	**P**, **C**	**P**, **C**			**P**, **C**	**P**, **C**	**P**, **C**	**P**, **C**
PC 15: Non-metal-surface treatment products	**C**	**P**, **C**		**C**		**C**	**C**	I, **C**			**C**	**C**	**C**	**C**
PC 24: Lubricants, greases, release products	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**	I, **P**	F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**
PC 25: Metal working fluids	I, **P**, **C**	F, I, **P**, **C**	F, I, **P**	I, **P**, **C**	F, I	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**			I, **P**, **C**	F, I, **P**, **C**	I, **P**, **C**	I, **P**, **C**
PC 16: Heat transfer fluids	**C**	**C**		**C**		I, **P**, **C**	**C**	I, **P**, **C**		I, **P**	**C**	**C**	**C**	**C**
PC 17: Hydraulic fluids	I, **P**, **C**	F, I, **P**, **C**	F, I, **P**	I, **P**, **C**	F, I, **P**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**			I, **P**, **C**	F, I, **P**, **C**	I, **P**, **C**	I, **P**, **C**
PC 13: Fuels	I, **P**, **C**	I, **P**, **C**		I, **P**, **C**		I, **P**, **C**	F, I, **P**, **C**	I, **P**, **C**			I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	I, **P**, **C**
PC 32: Polymer preparations and compounds	F, I, **P**, **C**	F, I, **P**, **C**		F, I, **P**, **C**		F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**			F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**
PC 1: Adhesives, sealants	F, I, **P**, **C**	F, I, **P**, **C**		F, I, **P**, **C**		I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**			F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**
PC 9c: Finger paint	**C**	**C**		**C**		**C**	**C**	**C**			**C**	**C**	**C**	**C**
PC 9b: Fillers, putties, plasters, modelling clay	**C**	**C**		**C**		F, I, **P**, **C**	**P**, **C**	F, I, **P**, **C**			**C**	F, I, **P**, **C**	**C**	**C**
PC 9a: Coatings and paints, thinners, paint removers	F, I, **P**, **C**	F, I, **P**, **C**		F, I, **P**, **C**		F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**			F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	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, **P**, **C**	F, I, **P**, **C**			F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**

Main types of applications structured by product or article types	201-089-0	204-793-6	267-029-0	268-092-7	268-596-7	270-287-7	271-347-5	286-075-2	287-397-6	288-726-6	292-832-8	293-036-3	305-758-9	306-085-3
PC 26: Paper and board treatment products	I	I		I		F, I	I	F, I			I	I, **C**	I	I
PC 34: Textile dyes, and impregnating products	F, I, **C**, **A**	F, I, **C**, **A**		F, I, **C**, **A**		**C**	F, I, **C**, **A**	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, I, **P**, **C**	F, I, **P**, **C**		F, I, **P**, **C**		**C**	F, I, **P**, **C**	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, **P**	I	I, **P**			I	I	I	I
PC 38: Welding and soldering products, flux products														
PC 21: Laboratory chemicals	F, I, **P**	F, I, **P**, **C**		F, I, **P**		F, I, **P**	F, I, **P**	F, I, **P**			F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**
PC 19: Intermediate	I	F, I		I		I	I	I			I	I	I	I
PC 30: Photo-chemicals							F, I, **P**, **C**							
Construction chemicals	I, **P**, **C**, **A**	F, I, **P**, **C**, **A**		F, I, **P**, **C**, **A**		F, **P**, **C**,	F, **P**, **C**, **A**	**P**, **C**, **A**			F, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**
Mining chemicals	I	I		I		I,	I	I			I	I	I	I
Oil & gas field drilling	I, **P**	I, **P**		I, **P**		I, **P**	I, **P**	I, **P**			I, **P**	I, **P**	I, **P**	I, **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.

Main types of applications structured by product or article types	306-523-3	613-848-7	614-585-0	700-772-5	701-023-5	701-042-9	812-652-0	812-656-2	812-688-7	815-461-0	941-376-4	941-924-2	946-440-5	947-835-5
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	F, I				F, I	F, I, **P**, **C**	F, I			F, I	F, I			F, I
PC 36: Water softeners	**C**				**C**	**C**	**C**			**C**	**C**			I, **P**, **C**
PC 37: Water treatment chemicals	F, I, **P**				F, I, **P**	F, I, **P**, **C**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**			I, **P**, **C**
PC 2: Adsorbents	F				F	F	F			F	F			
PC 11: Explosives	**P**				**P**	**P**	**P**	**P**	**P**	**P**	**P**			**P**
PC 12: Fertilisers	F, I, **P**, **C**				F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	**C**	**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**	**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**	**P**, **C**	**P**, **C**	**P**, **C**			**P**, **C**
PC 35: Washing and cleaning products	F, I, **P**, **C**				F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**			F, I, **P**, **C**
PC 8: Biocidal products (e.g. disinfectants, pest control)	I, **P**, **C**				I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	**C**	**C**	I, **P**, **C**	I, **P**, **C**			F, I, **P**, **C**
PC 28: Perfumes, fragrances	F, **C**				F, **C**	F, **C**	F, **C**	F, **C**	F, **C**	F, **C**	F, **C**			F, **C**
PC 3: Air care products	**C**				**C**	**C**	**C**	**C**	**C**	**C**	**C**			F, **C**
PC 39: Cosmetics, personal care products	F, **P**, **C**			F, **C**	F, **P**, **C**	F, **P**, **C**	F, **P**, **C**	F, **C**	F, **C**	F, **P**, **C**	F, **P**, **C**			F, **P**, **C**
PC 29: Pharmaceuticals	I, **P**				I, **P**	I, **P**	I, **P**			I, **P**	I, **P**			
PC 31: Polishes and wax blends	**P**, **C**				**P**, **C**	**P**, **C**	**P**, **C**	**P**, **C**	**P**, **C**	**P**, **C**	**P**, **C**			F, **P**, **C**
PC 15: Non-metal-surface treatment products	**C**				**C**	**C**	**C**	**C**	F, I,**P**, **C**	**C**,	**C**,	**P**		F, I, **P**, **C**

Main types of applications structured by product or article types	306-523-3	613-848-7	614-585-0	700-772-5	701-023-5	701-042-9	812-652-0	812-656-2	812-688-7	815-461-0	941-376-4	941-924-2	946-440-5	947-835-5
PC 24: Lubricants, greases, release products	F, I, **P**, **C**	F, I, **P**			F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**	F, I, **P**, **C**
PC 25: Metal working fluids	I, **P**, **C**				F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	F, I, **P**		F, I, **P**
PC 16: Heat transfer fluids	**C**				I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	**C**	**C**			F, I, **P**, **C**
PC 17: Hydraulic fluids	I, **P**, **C**				F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	I, **P**, **C**	F, I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	F, I, **P**		I, **P**, **C**
PC 13: Fuels	I, **P**, **C**				I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	I, **P**, **C**			I, **P**, **C**
PC 32: Polymer preparations and compounds	F, I, **P**, **C**		I		F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **A**			F, I, **P**, **A**
PC 1: Adhesives, sealants	F, I, **P**, **C**		F, I, **P**		F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	I, **P**, **C**	I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**			I, **P**, **C**
PC 9c: Finger paint	**C**				**C**	**C**	**C**	**C**	**C**	**C**	**C**			**C**
PC 9b: Fillers, putties, plasters, modelling clay	**C**				**C**	F, I, **P**, **C**	**C**	**C**	**C**	**C**	**C**			**P**, **C**
PC 9a: Coatings and paints, thinners, paint removers	F, I, **P**, **C**		F, I, **P**		F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**			F, I, **P**, **C**, **A**
PC 18: Ink and toners	F, I, **P**, **C**				F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**			F, I, **P**, **C**
PC 26: Paper and board treatment products	I				F, I	F, I	F, I	F, I	F, I	I	I			F, I, **P**, **A**
PC 34: Textile dyes, and impregnating products	F, I, **C**, **A**				F, I, **C**, **A**	F, I, **C**, **A**	F, I, **C**, **A**	**C**	**C**	F, I, **C**, **A**	F, I, **C**, **A**			F, I, **C**, **A**
PC 23: Leather treatment products	F, I, **P**, **C**				F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	**C**,	**C**,	F, I, **P**, **C**	F, I, **P**, **C**			F, I, **C**, **A**

Main types of applications structured by product or article types	306-523-3	613-848-7	614-585-0	700-772-5	701-023-5	701-042-9	812-652-0	812-656-2	812-688-7	815-461-0	941-376-4	941-924-2	946-440-5	947-835-5
PC 14: Metal surface treatment products	I				I, **P**	I, **P**	I, **P**	I, **P**	F, I, **P**, **C**	I	I			I
PC 38: Welding and soldering products, flux products														**C**,
PC 21: Laboratory chemicals	F, I, **P**				F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **C**		F, I, **P**
PC 19: Intermediate	I				I	I, **P**	I	I	I	I	I	F, I		I
PC 30: Photo-chemicals														F, I, **P**, **C**,
Construction chemicals	F, I, **P**, **C**, **A**				F, **P**, **C**, **A**	I, F, **P**, **C**, **A**	I, F, **P**, **C**, **A**	**P**, **C**,	**P**, **C**,	F, I, **P**, **C**,	I, **P**, **C**,			**P**, **A**
Mining chemicals	I				I	I	I	I	I	I	I			
Oil & gas field drilling	I, **P**				I, **P**	I, **P**	I, **P**	I, **P**	I, **P**	I, **P**	I, **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 20 November 2020.

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