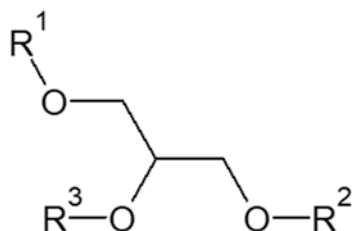


Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Esters from linear and branched carboxylic acids and glycerol

General structure:



R = alkyl chain or H
For a given substance R¹, R² and R³ may be the same or vary

Revision history

<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	18 September 2023	

ASSESSMENT OF REGULATORY NEEDS

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
203-051-9	102-76-1	Triacetin	Full, >1000 t/y
204-534-7	122-32-7	1,2,3-propanetriyl trioleate	Full, 100-1000 t/y
204-791-5	126-53-4	Propane-1,2,3-triyl trionan-1-oate	Not (publicly) available
205-526-6	142-18-7	2,3-dihydroxypropyl laurate	Full, 100-1000 t/y
208-686-5	538-23-8	Glycerol trioctanoate	Full, 10-100 t/y
209-097-6	555-43-1	Glycerol tristearate	Not (publicly) available
209-099-7	555-45-3	Glycerol trimyristate	Not (publicly) available
210-647-2	620-67-7	Propane-1,2,3-triyl trisheptanoate	Full, 100-1000 t/y
215-355-9	1323-42-8	Hydroxyoctadecanoic acid, monoester with glycerol	Not (publicly) available
228-507-4	6284-43-1	2,3-dihydroxypropyl 12-hydroxyoctadecanoate	Not (publicly) available
230-896-0	7360-38-5	Propane-1,2,3-triyl 2-ethylhexanoate	Not (publicly) available
232-292-2	8001-78-3	Castor oil, hydrogenated	Full, >1000 t/y
232-311-4	8002-50-4	Oils, menhaden	Not (publicly) available
234-398-4	11140-04-8	Octanoic acid, ester with 1,2,3-propanetriol	Not (publicly) available
247-667-6	26402-22-2	Decanoic acid, monoester with glycerol	Not (publicly) available
247-668-1	26402-26-6	Octanoic acid, monoester with glycerol	Full, 10-100 t/y
248-122-5	26942-95-0	1,2,3-propanetriyl triisooctadecanoate	Full, 100-1000 t/y
248-329-0	27214-38-6	Glycerol monomyristate	Not (publicly) available
250-097-0	30233-64-8	Docosanoic acid, monoester with glycerol	Not (publicly) available
250-379-3	30899-62-8	Lauric acid, ester with hydroxypropanediyl diacetate	Not (publicly) available
250-705-4	31566-31-1	Stearic acid, monoester with glycerol	Full, >1000 t/y
260-257-1	56554-53-1	Propane-1,2,3-triyl 3,5,5-trimethylhexanoate	Full, 100-1000 t/y
264-705-7	64147-40-6	Castor oil, dehydrated	Full, 100-1000 t/y

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	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
266-124-4	66085-00-5	Isooctadecanoic acid, monoester with glycerol	Full, 10-100 t/y
266-944-2	67701-26-2	Glycerides, C12-18	Full, >1000 t/y
266-945-8	67701-27-3	Glycerides, C14-18	OSII or TII
266-946-3	67701-28-4	Glycerides, C8-18 and C18-unsatd.	Full, >1000 t/y
266-950-5	67701-31-9	Glycerides, C8-18 and C18-unsatd. mono- and di-	OSII or TII
266-952-6	67701-33-1	Glycerides, C14-18 mono- and di-	Not (publicly) available
267-057-3	67784-87-6	Glycerides, palm-oil mono- and di-, hydrogenated	Not (publicly) available
268-083-8	68002-70-0	Glycerides, C16-22	Full, >1000 t/y
268-084-3	68002-71-1	Glycerides, C16-18	Full, >1000 t/y
270-616-4	68459-67-6	Castor oil, ester with glycerol	Not (publicly) available
271-729-1	68606-18-8	Glycerides, mixed coco, decanoyl and octanoyl	Full, 100-1000 t/y
273-607-3	68990-53-4	Glycerides, C14-22 mono-	Not (publicly) available
277-452-2	73398-61-5	Glycerides, mixed decanoyl and octanoyl	Full, >1000 t/y
278-717-5	77538-19-3	Docosanoic acid, ester with 1,2,3-propanetriol	Full, 100-1000 t/y
284-283-8	84836-98-6	Coconut oil, hydrogenated	OSII or TII
286-490-9	85251-77-0	Glycerides, C16-18 mono- and di-	Full, >1000 t/y
287-487-5	85536-06-7	Glycerides, C8-18	Not (publicly) available
287-488-0	85536-07-8	Glycerides, C8-10 mono- and di-	Full, 100-1000 t/y
293-165-5	91052-08-3	Glycerides, C18-36	Not (publicly) available
293-170-2	91052-13-0	Glycerides, C8-18 and C18-unsatd. mono- and di-, acetates	Full, >1000 t/y
293-187-5	91052-28-7	Glycerides, C14-18 and C16-18-unsatd. mono-, di- and tri-	Not (publicly) available
293-208-8	91052-47-0	Glycerides, C16-18 mono-	Full, >1000 t/y
293-209-3	91052-49-2	Glycerides, C12-18 mono- and di-	Not (publicly) available
293-214-0	91052-53-8	Glycerides, C12-18 mono-, di- and tri-	Not (publicly) available
293-215-6	91052-54-9	Glycerides, C16-18 mono-, di- and tri-	Full, 100-1000 t/y
294-571-5	91744-09-1	Glycerides, C16-18 and C18-unsatd. mono-	Full, >1000 t/y

ASSESSMENT OF REGULATORY NEEDS

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
294-582-5	91744-20-6	Glycerides, C16-18 and C18-unsatd. mono-, di and tri-	Full, >1000 t/y
294-589-3	91744-27-3	Glycerides, castor-oil mono-, di- and tri-	Not (publicly) available
294-590-9	91744-28-4	Glycerides, C12-18 di- and tri-	Not (publicly) available
294-594-0	91744-32-0	Glycerides, C8-10 mono-, di- and tri-	OSII or TII
294-661-4	91744-94-4	Glycerides, rape-oil mono-, di- and tri-, hydrogenated	OSII or TII
297-462-0	93572-32-8	Glycerides, palm-oil mono-, hydrogenated, acetates	Not (publicly) available
306-657-2	97358-80-0	Isooctadecanoic acid, mono- and diesters with glycerol	Full, 100-1000 t/y
307-031-1	97488-92-1	Glycerides, vegetable-oil mono- and di-, hydrogenated	Not (publicly) available
307-751-6	97722-02-6	Glycerides, tall-oil mono-, di-, and tri-	Full, >1000 t/y
401-020-6	-	RI 9410 Trade name)	Not (publicly) available
401-860-3	-	PDG (trade name)	Not (publicly) available
451-530-8	736150-63-3	Reaction mass of 1,3-diacetoxypropan-2-yl 12-acetoxyoctadecanoate and 2,3-diacetoxypropyl 12-acetoxyoctadecanoate	Not (publicly) available
460-300-6	-	-	Not (publicly) available
460-380-2	-	-	Not (publicly) available
918-906-8	65684-27-7	10-Undecenoic acid, monoester with 1,2,3-propanetriol	Not (publicly) available
905-964-4	-	Reaction mass of glycerol 1,3-di(acetate) and glycerol acetate and triacetin	Full, 100-1000 t/y
939-588-7	-	Dodecanoic acid, ester with 1,2,3-propanetriol, acetylated	Not (publicly) available
939-633-0	-	Decanoic acid, ester with 1,2,3-propanetriol, acetylated	Not (publicly) available
811-605-1	37318-95-9	Dodecanoic acid, ester with 1,2,3-propanetriol	Not (publicly) available
946-904-7	-	Reaction product of glycerol and octanoic acid	OSII or TII
947-787-5	-	Triglycerides, C16 and C18 (unsaturated)	Not (publicly) available
203-827-7	111-03-5	2,3-dihydroxypropyl oleate	C&L notification

ASSESSMENT OF REGULATORY NEEDS

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
204-664-4	123-94-4	Glycerol 1-stearate	C&L notification
208-687-0	538-24-9	Glycerol trilaurate	C&L notification
232-293-8 (formerly list LN 933-124-7)	8001-79-4	Castor Oil	C&L notification
232-402-9	8016-13-5	Oils, fish	C&L notification
263-131-4	61790-39-4	Fatty acids, castor-oil, hydrogenated	C&L notification
266-948-4	67701-30-8	Glycerides, C16-18 and C18-unsatd.	C&L notification
293-202-5	91052-41-4	Glycerides, C16-18 di-	C&L notification
294-606-4	91744-44-4	9-Octadecenoic acid, 12-hydroxy-, [R-(Z)]-, mono- and diester with glycerol	C&L notification
307-333-3	97593-30-1	Glycerides, C8-21 and C8-21-unsatd. mono- and di-, acetates	C&L notification
616-005-1	736150-63-3	Glycerides, castor-oil mono-, hydrogenated, acetates	C&L notification

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

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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 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
UVCB	Substance of unknown or variable composition, complex reaction products or of biological materials.

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 esters from linear and branched carboxylic acids and glycerol.

There are 81 substances in the group. 69 are registered, of these 54 are UVCBs, 13 mono-constituent substances and 2 multi-constituents.

Based on information reported in the REACH registration dossiers, the substances have widespread industrial, professional and consumer uses (including many with article service life) in many areas with high potential for exposure to both workers and consumers and release into the environment. The uses are in washing and cleaning products, cosmetics and personal care products, 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 and so on. The substances are mainly used as plasticiser, lubricating agent, cleaning agent, binding agent, emulsifier, texturiser, wetting agent, solvent, intermediate, fragrance, co-formulant and so on. Noteworthy also is that 10 substances are used in the formulation of food additives and 19 are listed as plasticisers or plastic additives, including one that is also a known alternative to phthalates (EC 203-051-9). Nine substances have only industrial use reported and six substances are registered as intermediates only.

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
260-257-1 918-906-8	Known or potential hazard for skin sensitisation	No hazard or unlikely hazard	Viscosity adjustor, emollient and solvent in cosmetics manufacturing with high exposure potential to professionals and consumers	No action <u>Justification:</u> Harmonised/self-classification (will) require company level risk management measures (RMM) for workers to be in place. Risk to consumers of skin sensitisation hazard currently controlled by other EU legislation
230-896-0 297-462-0 811-605-1	No hazard or unlikely hazard	Known or potential hazard for aquatic toxicity	Fragrant, antistatic and fixing agent including in cosmetics with high exposure potential to consumers and professionals.	No action <u>Justification:</u> 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
203-051-9	No hazard or unlikely hazard	No hazard or unlikely hazard	<p>Widespread uses in professional settings or consumer products, with high potential for exposure and release.</p> <p>ECs/List no 266-945-8, 266-950-5, 284-283-8, 294-594-0, 294-661-4, 946-904-7 are used as intermediates, potential for exposure low.</p>	<p>No action</p> <p><u>Justification:</u> Overall, no or unlikely hazard that would lead to concern for the reported uses.</p>
204-534-7				
204-791-5				
205-526-6				
208-686-5				
209-097-6				
209-099-7				
210-647-2				
215-355-9				
228-507-4				
230-896-0				
232-292-2				
232-311-4				
234-398-4				
247-667-6				
247-668-1				
248-122-5				
248-329-0				
250-097-0				
250-379-3				
250-705-4				
260-257-1				
264-705-7				
266-124-4				
266-944-2				
266-945-8				

ASSESSMENT OF REGULATORY NEEDS

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
266-946-3				
266-950-5				
266-952-6				
267-057-3				
268-083-8				
268-084-3				
270-616-4				
271-729-1				
273-607-3				
277-452-2				
278-717-5				
284-283-8				
286-490-9				
287-487-5				
287-488-0				
293-165-5				
293-170-2				
293-187-5				
293-208-8				
293-209-3				
293-214-0				
293-215-6				
294-571-5				
294-582-5				
294-589-3				
294-590-9				

ASSESSMENT OF REGULATORY NEEDS

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
294-594-0				
294-661-4				
297-462-0				
306-657-2				
307-031-1				
307-751-6				
401-020-6				
401-860-3				
451-530-8				
460-300-6				
460-380-2				
918-906-8				
905-964-4				
939-588-7				
939-633-0				
811-605-1				
946-904-7				
947-787-5				
203-827-7				
204-664-4				
208-687-0				
232-293-8				
232-402-9				
263-131-4				
266-948-4				
293-202-5				

ASSESSMENT OF REGULATORY NEEDS

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
294-606-4 307-333-3 616-005-1				

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 and environmental hazard.

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, STOT RE, PBT/vPvP, PMT/vPvM and aquatic toxicity hazards are considered unlikely for all group members except for EC 260-257-1, List no 918-906-8 that are skin sensitisers and EC 230-896-0, EC 297-462-0, List no 811-605-1 that are toxic to the aquatic environment based on the available data with the registered substances and information on their metabolites/breakdown products.

Based on the evaluations⁵ from other safety bodies, group members are expected to be rapidly hydrolysed into corresponding carboxylic acids and alcohols by carboxylesterase enzymes found in most tissues throughout the body, including the gastrointestinal tract. The resulting alcohols will be oxidised to their corresponding aldehydes and linear carboxylic acids, which will in turn be metabolised to carbon dioxide via the fatty acid pathways and the tricarboxylic acid cycle. The resulting 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 expected to be of low toxicity and group on branched carboxylic acids, with short chain ones to be potential reproductive toxicants). Furthermore, the assessment of regulatory needs of the group of aliphatic alcohols has also concluded on potential low toxicity regarding the expected alcohol metabolites from the enzymatic hydrolysis of the esters in this group.

The available experimental data indicate no potential for mutagenicity. This is based on in vitro mutagenicity studies in bacteria and mammalian cells, in vivo experimental studies on skin sensitisation, repeated dose sub-chronic and screening studies conducted on analogues, and on the low potential toxicity profile of breakdown products.

Results from repeated dose toxicity studies, including 90-day repeated dose toxicity studies conducted with the registered substances, did not show any relevant systemic or target organ toxicity at the tested doses. The absence of systemic toxicity potential is assumed to be applicable to the other substances of the group based on structural similarity.

The data available from six screening studies and the 90-day repeated dose toxicity studies do not show any relevant effects for reproductive organs or outcomes. Similarly, no evidence on developmental toxicity is seen in the available screening

⁵ JECFA, 1999 <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3169/epdf>; COM, 2003 https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out158_en.pdf; EFSA, 2013 <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3169/epdf>

studies.

Two group members (ECs 230-896-0, 260-257-1) are expected to be enzymatically hydrolysed by esterases, mostly to the corresponding fatty acids and alcohols with soluble metabolites: 2-ethylhexanoic acid (2-EHA) and 3,5,5-trimethylhexanoic acid. 2-EHA is harmonised classified as Repr.1B⁶ and 3,5,5-trimethylhexanoic acid is intended for CLH Repr.1B⁷. However, the available PNDT study with EC 230-896-0 indicates no developmental effects up to the limit dose tested, indicating that the potential for reproductive toxicity from the breakdown products is unlikely.

No carcinogenicity potential emerged from one 2-years NTP study available, and no carcinogenic effect is expected in view of the absence of mutagenic and repeated dose toxicity hazard.

Regarding a potential ED hazard, the available systemic toxicity studies from read across analogues do 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 substances in these subgroups.

However, two substances in this group (EC 260-257-1 and List no. 918-906-8) are known skin sensitisers. Self-classification for these two substances is supported by data in the respective registration dossiers, and it is not likely due to any known impurity. These positive findings are not in line with the biology of esters having no functional group that would be expected to result in skin sensitisation potential. Based on the negative skin sensitisation data for other group members it was concluded that this hazard cannot be extrapolated to other group members.

None of the substances in the group are expected to be persistent. For most of them ready biodegradability studies have been performed on the registered substance. Given the low water solubility and high adsorption potential, the substances in this group are unlikely to be significantly bioavailable to aquatic organisms. Furthermore, the substances are made of very bulky molecules and are unlikely to cross the biological membranes (e.g. through the gills). When ingested, glycerides are easily broken down to glycerol and fatty acids which then undergo fast metabolism and can be used as a source of energy for aquatic organisms. Therefore, bioaccumulation in aquatic organisms is unlikely (neither via aqueous nor dietary route) for the whole group.

For most of the substances the available short-term studies show no effects, as tests have been performed above the water solubility limit. Short-term studies are not relevant for such substances. For soluble substances no, or mild effects have been observed in short term tests. The reported effects are often attributed to physical influence of precipitated test substance (sticking to gills or decreasing an access to light for algae) rather than systemic toxicity. Three substances are classified in the registrations (EC 230-896-0, EC 297-462-0, List no. 811-605-1) and they all show mild effects resulting in classification as Aquatic Chronic 2-3.

⁶ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1435&qid=1689155759608>

⁷ <https://echa.europa.eu/fi/registry-of-clh-intentions-until-outcome/-/dislist/details/Ob0236e188116743>

ASSESSMENT OF REGULATORY NEEDS

For the two group members with skin sensitisation hazard (EC 260-257-1 and List no. 918-906-8), for industrial and professional uses, sufficient and consistent self-classification by registrants should trigger adequate risk management measures according to workplace legislation. Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing them. Current REACH registration data for ECs 260-257-1 and List no. 918-906-8 suggests exclusively uses in cosmetics. For the use of the substance(s) in cosmetics, sufficient and consistent self-classification by registrants would inform on the need or not for classification of the final product and safety assessment to be done according to Cosmetic product regulation (EC) No 1223/2009.

For ECs 230-896-0, 297-462-0 and List no. 811-605-1 that are self-classified as Aquatic Chronic 2-3, self-classification, requires company level risk management measures (RMM) for environment to be in place. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

There is remaining uncertainty regarding the breakdown of the esters, more specifically regarding the rate of hydrolysis, as the information available is mostly from literature sources and refers to the generic ability of carboxylesterases to breakdown the esters.

No further action is proposed for any group member; information from 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.

Annex 1: Overview of classifications

Data extracted on 14 September 2021.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
203-051-9	102-76-1	Triacetin	-	-
203-827-7	111-03-5	2,3-dihydroxypropyl oleate	-	-
204-534-7	122-32-7	1,2,3-propanetriyl trioleate	-	-
204-664-4	123-94-4	Glycerol 1-stearate	-	-
204-791-5	126-53-4	Propane-1,2,3-triyl trionan-1-oate	-	-
205-526-6	142-18-7	2,3-dihydroxypropyl laurate	-	-
208-686-5	538-23-8	Glycerol trioctanoate	-	-
208-687-0	538-24-9	Glycerol trilaurate	-	-
209-097-6	555-43-1	Glycerol tristearate	-	-
209-099-7	555-45-3	Glycerol trimyristate	-	-
210-647-2	620-67-7	Propane-1,2,3-triyl trisheptanoate	-	-
215-355-9	1323-42-8	Hydroxyoctadecanoic acid, monoester with glycerol	-	-
228-507-4	6284-43-1	2,3-dihydroxypropyl 12-hydroxyoctadecanoate	-	-
230-896-0	7360-38-5	Propane-1,2,3-triyl 2-ethylhexanoate	-	<i>Aquatic Chronic 3, H412</i>
232-292-2	8001-78-3	Castor oil, hydrogenated	-	-
232-311-4	8002-50-4	Oils, menhaden	-	-
232-402-9	8016-13-5	Oils, fish No Reg, no C&L	-	-
234-398-4	11140-04-8	Octanoic acid, ester with 1,2,3-propanetriol	-	-
247-667-6	26402-22-2	Decanoic acid, monoester with glycerol	-	-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
247-668-1	26402-26-6	Octanoic acid, monoester with glycerol	-	-
248-122-5	26942-95-0	1,2,3-propanetriyl triisooctadecanoate	-	-
248-329-0	27214-38-6	Glycerol monomyristate	-	-
250-097-0	30233-64-8	Docosanoic acid, monoester with glycerol	-	-
250-379-3	30899-62-8	Lauric acid, ester with hydroxypropanediyl diacetate	-	-
250-705-4	31566-31-1	Stearic acid, monoester with glycerol	-	-
260-257-1	56554-53-1	Propane-1,2,3-triyl 3,5,5-trimethylhexanoate	-	-
263-131-4	61790-39-4	Fatty acids, castor-oil, hydrogenated	-	-
264-705-7	64147-40-6	Castor oil, dehydrated	-	-
266-124-4	66085-00-5	Isooctadecanoic acid, monoester with glycerol	-	-
266-944-2	67701-26-2	Glycerides, C12-18	-	-
266-945-8	67701-27-3	Glycerides, C14-18	-	-
266-946-3	67701-28-4	Glycerides, C8-18 and C18-unsatd.	-	-
266-948-4	67701-30-8	Glycerides, C16-18 and C18-unsatd.	-	-
266-950-5	67701-31-9	Glycerides, C8-18 and C18-unsatd. mono- and di-	-	-
266-952-6	67701-33-1	Glycerides, C14-18 mono- and di-	-	-
267-057-3	67784-87-6	Glycerides, palm-oil mono- and di-, hydrogenated	-	-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
268-083-8	68002-70-0	Glycerides, C16-22	-	-
268-084-3	68002-71-1	Glycerides, C16-18	-	-
270-616-4	68459-67-6	Castor oil, ester with glycerol	-	-
271-729-1	68606-18-8	Glycerides, mixed coco, decanoyl and octanoyl	-	-
273-607-3	68990-53-4	Glycerides, C14-22 mono-	-	-
277-452-2	73398-61-5	Glycerides, mixed decanoyl and octanoyl	-	-
278-717-5	77538-19-3	Docosanoic acid, ester with 1,2,3-propanetriol	-	-
284-283-8	84836-98-6	Coconut oil, hydrogenated	-	-
286-490-9	85251-77-0	Glycerides, C16-18 mono- and di-	-	-
287-487-5	85536-06-7	Glycerides, C8-18	-	-
287-488-0	85536-07-8	Glycerides, C8-10 mono- and di-	-	-
293-165-5	91052-08-3	Glycerides, C18-36	-	-
293-170-2	91052-13-0	Glycerides, C8-18 and C18-unsatd. mono- and di-, acetates	-	-
293-187-5	91052-28-7	Glycerides, C14-18 and C16-18-unsatd. mono-, di- and tri-	-	-
293-202-5	91052-41-4	Glycerides, C16-18 di- No Reg or C&L	-	-
293-208-8	91052-47-0	Glycerides, C16-18 mono-	-	-
293-209-3	91052-49-2	Glycerides, C12-18 mono- and di-	-	-
293-214-0	91052-53-8	Glycerides, C12-18 mono-, di- and tri-	-	-
293-215-6	91052-54-9	Glycerides, C16-18 mono-, di- and tri-	-	-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
294-571-5	91744-09-1	Glycerides, C16-18 and C18-unsatd. mono-	-	-
294-582-5	91744-20-6	Glycerides, C16-18 and C18-unsatd. mono-, di and tri-	-	-
294-589-3	91744-27-3	Glycerides, castor-oil mono-, di- and tri-	-	-
294-590-9	91744-28-4	Glycerides, C12-18 di- and tri-	-	-
294-594-0	91744-32-0	Glycerides, C8-10 mono-, di- and tri-	-	-
294-606-4	91744-44-4	9-Octadecenoic acid, 12-hydroxy-, [R-(Z)]-, mono- and diester with glycerol (No Reg or C&L)	-	-
294-661-4	91744-94-4	Glycerides, rape-oil mono-, di- and tri-, hydrogenated	-	-
297-462-0	93572-32-8	Glycerides, palm-oil mono-, hydrogenated, acetates	-	<i>Aquatic Chronic 3, H412</i>
306-657-2	97358-80-0	Isooctadecanoic acid, mono- and diesters with glycerol	-	-
307-031-1	97488-92-1	Glycerides, vegetable-oil mono- and di-, hydrogenated	-	-
307-333-3	97593-30-1	Glycerides, C8-21 and C8-21-unsatd. mono- and di-, acetates - No Reg or C&L	-	-
307-751-6	97722-02-6	Glycerides, tall-oil mono-, di-, and tri-	-	-
401-020-6	-	RI 9410 – trade name - unclaimed_nons: 1-10 ton/y [1]	-	-
401-860-3	-	PDG – trade name - inactive registration	-	-
451-530-8	736150-63-3	Reaction mass of 1,3-diacetoxypropan-2-yl 12-acetoxyoctadecanoate	-	-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
		and 2,3-diacetoxypropyl 12-acetoxyoctadecanoate		
460-300-6	-	-	-	-
460-380-2	-	-	-	-
616-005-1	736150-63-3	Glycerides, castor-oil mono-, hydrogenated, acetates - No Reg or C&L	-	-
905-964-4	-	Reaction mass of glycerol 1,3-di(acetate) and glycerol acetate and triacetin	-	-
918-906-8	65684-27-7	10-Undecenoic acid, monoester with 1,2,3-propanetriol	-	-
232-293-8 (LN replaced with the EC)	8001-79-4	Castor Oil	-	-
939-588-7	-	Dodecanoic acid, ester with 1,2,3-propanetriol, acetylated	-	-
939-633-0	-	Decanoic acid, ester with 1,2,3-propanetriol, acetylated	-	-
811-605-1	37318-95-9	Dodecanoic acid, ester with 1,2,3-propanetriol	-	<i>Aquatic Chronic 2, H411</i>
946-904-7	-	Reaction product of glycerol and octanoic acid	-	-
947-787-5	-	Triglycerides, C16 and C18 (unsaturated)	-	-

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

Data extracted on 14 September 2021.

Main types of applications structured by product or article types	PC 20: Ph-regulators, flocculants, precipitants, neutralisation agents	PC 36: Water softeners	PC 37: Water treatment chemicals	PC 2: Adsorbents	PC 11: Explosives	PC 12: Fertilisers	PC 27: Plant protection products	PC 4: Anti-freeze and de-icing products	PC 35: Washing and cleaning products	PC 8: Biocidal products (e.g. disinfectants, pest control)	PC 28: Perfumes, fragrances	PC 3: Air care products	PC 39: Cosmetics, personal care products	PC 29: Pharmaceuticals	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 25: Metal working fluids
203-051-9	I, P				F, I				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	F, I, P, C	F, I, P, C	F, I, P, C
204-534-7	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	F, I, P, C
204-791-5													F, I, P, C			P	F, I, P, C	I, P
205-526-6	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
208-686-5	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
209-097-6	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
209-099-7	F, I		F, I, P		P	F, I, P, C	P, C	P, C	F, I, P, C	I, C	F, C	C	F, P, C		I, P, C	C	F, I, P, C	I, P, C
210-647-2	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
215-355-9													F, C					
228-507-4	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 20: Ph-regulators, flocculants, precipitants, neutralisation agents	PC 36: Water softeners	PC 37: Water treatment chemicals	PC 2: Adsorbents	PC 11: Explosives	PC 12: Fertilisers	PC 27: Plant protection products	PC 4: Anti-freeze and de-icing products	PC 35: Washing and cleaning products	PC 8: Biocidal products (e.g. disinfectants, pest control)	PC 28: Perfumes, fragrances	PC 3: Air care products	PC 39: Cosmetics, personal care products	PC 29: Pharmaceuticals	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 25: Metal working fluids
230-896-0													F, P, C				F, I, P, C	F, I, P
232-292-2	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C
234-398-4	F, I, P, C								F, I, P, C		F, C		F, P, C		F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C
247-667-6									F, I, P, C	F, I, C	F, I, P, C		F, I, P, C	F, I, P, C				
247-668-1	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C	P, C	C	F, I, P, C	F, I, P, C
248-122-5	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, P, C	C	F, I, P, C	F, I, P, C	I, P, C	C	F, I, P, C	I, P, C
248-329-0	F, I		F, I, P		P	F, I, P, C	P, C	P, C	F, I, P, C	I, C	F, P, C	C	F, I, P, C	F, P, C	I, P, C	C	F, I, P, C	I, P, C
250-097-0													F, C					
250-379-3	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
250-705-4	F, I	C	F, I, P		P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C	P, C	C	F, I, P, C	F, I, P, C
260-257-1													F, P, C					
264-705-7																	F, I	
266-124-4	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C	I, P, C	C	F, I, P, C	I, P, C

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 20: Ph-regulators, flocculants, precipitants, neutralisation agents	PC 36: Water softeners	PC 37: Water treatment chemicals	PC 2: Adsorbents	PC 11: Explosives	PC 12: Fertilisers	PC 27: Plant protection products	PC 4: Anti-freeze and de-icing products	PC 35: Washing and cleaning products	PC 8: Biocidal products (e.g. disinfectants, pest control)	PC 28: Perfumes, fragrances	PC 3: Air care products	PC 39: Cosmetics, personal care products	PC 29: Pharmaceuticals	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 25: Metal working fluids
266-944-2	F, I	C	F, I, P		P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C	P, C	C	F, I, P, C	F, I, P, C
266-945-8						F, I, P, C			F, I, P, C		F, I, P, C	C	F, I, P, C	F, I, P, C	P, C		F, I, P, C	F, I, P
266-946-3							F, C		C	C	C	C	F, I, P, C	C	C		C	
266-952-6	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
267-057-3	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
268-083-8						F, I, P, C	F, P, C		P, C	P, C	F, I, P, C	C	F, I, P, C	F, I, P, C	P, C		P, C	
268-084-3	F, I	C	F, I, P	F, I	P	F, I, P, C	P, C	P, C	F, I, P, C	F, I, P, C	F, P, C	F, C	F, I, P, C	I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C
270-616-4	F, I		F, I, P		P	F, I, P, C	P, C	P, C	F, I, P, C	I, C	F, C	C	F, P, C		I, P, C	C	F, I, P, C	I, P, C
271-729-1	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, I, P, C	I, P	P, C	C	F, I, P, C	I, P, C
277-452-2	F, I	C	F, I, P	F	P	F, I, P, C	F, P, C	P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, P, C	F, I, P, C	F, I, P, C	P, C	C	F, I, P, C	F, I, P, C
278-717-5	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C	P, C	C	F, I, P, C	I, P, C
286-490-9	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	F, I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C	P, C	C	F, I, P, C	F, I, P, C
287-487-5	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C

ASSESSMENT OF REGULATORY NEEDS

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287-488-0	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, I, C	F, I, C	F, I, P, C	F, I, P	F, I, P, C	C	F, I, P, C	I, P, C
293-165-5	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
293-170-2	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
293-187-5	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
293-208-8	F, I	C	F, I, P	F, I	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C	P, C	F, I, C	F, I, P, C	F, I, P, C
293-209-3	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
293-214-0													F, I					
293-215-6	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
294-571-5	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C	P, C	C	F, I, P, C	F, I, P, C
294-582-5	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C	P, C	C	F, I, P, C	F, I, P, C
294-590-9	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
306-657-2	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
307-031-1													F, P, C					

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 20: Ph-regulators, flocculants, precipitants, neutralisation agents	PC 36: Water softeners	PC 37: Water treatment chemicals	PC 2: Adsorbents	PC 11: Explosives	PC 12: Fertilisers	PC 27: Plant protection products	PC 4: Anti-freeze and de-icing products	PC 35: Washing and cleaning products	PC 8: Biocidal products (e.g. disinfectants, pest control)	PC 28: Perfumes, fragrances	PC 3: Air care products	PC 39: Cosmetics, personal care products	PC 29: Pharmaceuticals	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 25: Metal working fluids
307-751-6	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C	P, C	C	F, I, P, C	F, I, P, C
401-860-3													P, C					
451-530-8													F, C					
460-380-2													F, P, C					
811-605-1	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
905-964-4	F, I	C	F, I, P	F	P	C	C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
918-906-8													F, C					
939-588-7	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C
939-633-0	F, I	C	F, I, P	F	P	F, I, P, C	P, C	P, C	F, I, P, C	I, P, C	F, C	C	F, P, C	I, P	P, C	C	F, I, P, C	I, P, C

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

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 16: Heat transfer fluids	PC 17: Hydraulic fluids	PC 13: Fuels	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removes	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 14: Metal surface treatment products	PC 7: Base metals and alloys	PC 21: Laboratory chemicals	PC 19: Intermediate	PC41: Oil and gas exploration or production products	PC x1: Food and feed additives
203-051-9		F, I, P, C	F, I	F, I, P, C	F, I, P, C	F, I, P	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		
204-534-7	C	F, I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
204-791-5		I, P													F, I, C	I		
205-526-6	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
208-686-5	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
209-097-6	C	I, P, C	I, P, C	F, I, P, C, A	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
209-099-7	C	I, P, C	I, P, C	F, I, P, A	F, I, P, C	I, P, C	I, P, C	F, I, P, C	F, I, P, C		F, I, C, A	F, I, C	I		F, I, P	I		
210-647-2	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
228-507-4	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
230-896-0	F, I, P														F, I			
232-292-2	I, P, C	F, I, P, C	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, C	F, I, P, C	F, I, P, C	I, P, C	I	F, I, P, C	F, I, C		F
234-398-4	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					F, I, P, C	
247-668-1	I, P, C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	F, I	F, I, C, A	F, I, P, C	I, P		F, I, P	I		

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 16: Heat transfer fluids	PC 17: Hydraulic fluids	PC 13: Fuels	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removes	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 14: Metal surface treatment products	PC 7: Base metals and alloys	PC 21: Laboratory chemicals	PC 19: Intermediate	PC41: Oil and gas exploration or production products	PC x1: Food and feed additives
248-122-5	C	I, P, C	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, A	F, I, C, A	F, I, P, C	I		F, I, P	I		
248-329-0	C	I, P, C	I, P, C	F, I, P, A	F, I, P, C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	I, A	F, I, C, A	F, I, C	I		F, I, P	I		
250-097-0				F, I, A				F, I								I		
250-379-3	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
250-705-4	I, P, C	F, I, P, C	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	F, I, C, A	F, I, P, C	I, P	I	F, I, P	I		F
264-705-7				F	F			F, I, P							F, I, P	I, P		
266-124-4	C	I, P, C	I, P, C	F, I, P, A	F, I, P, C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
266-944-2	I, P, C	F, I, P, C	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	F, I, C, A	F, I, P, C	I, P	I	F, I, P	I		F
266-945-8		F, I, P		F, I, P, A	F, I, P, C		F, I, P	F, I, P, C	F, I, P				I	I	I, P	I		F
266-946-3		C	I	F	C	C	C	C		F								
266-950-5																F, I		
266-952-6	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
267-057-3	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 16: Heat transfer fluids	PC 17: Hydraulic fluids	PC 13: Fuels	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removes	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 14: Metal surface treatment products	PC 7: Base metals and alloys	PC 21: Laboratory chemicals	PC 19: Intermediate	PC41: Oil and gas exploration or production products	PC x1: Food and feed additives
268-083-8		P, C	I	F	C	P, C	P, C	P, C		F, I, A					F, I	I		
268-084-3	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	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
270-616-4	C	I, P, C	I, P, C	F, I, P, A	F, I, P, C	I, P, C	I, P, C	F, I, P, C	F, I, P, C		F, I, C, A	F, I, C	I		F, I, P	I		
271-729-1	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
273-607-3				I														
277-452-2	I, P, C	F, I, P, C	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	F, I, C, A	F, I, P, C	I, P	I	F, I, P	I		F
278-717-5	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
286-490-9	I, P, C	F, I, P, C	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, A	F, I, C, A	F, I, P, C	I, P	I	F, I, P	I		F
287-487-5	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
287-488-0	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	F, I, C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
293-165-5	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
293-170-2	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
293-187-5	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 16: Heat transfer fluids	PC 17: Hydraulic fluids	PC 13: Fuels	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removes	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 14: Metal surface treatment products	PC 7: Base metals and alloys	PC 21: Laboratory chemicals	PC 19: Intermediate	PC41: Oil and gas exploration or production products	PC x1: Food and feed additives
293-208-8	I, P, C	F, I, P, C	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, A	F, I, C, A	F, I, P, C	I, P	I	F, I, P	I		F, I
293-209-3	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
293-214-0				F, I														
293-215-6	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	F, I	F, I, C, A	F, I, P, C	I		F, I, P	I		
294-571-5	I, P, C	F, I, P, C	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	F, I, C, A	F, I, P, C	I, P	I	F, I, P	I		F
294-582-5	I, P, C	F, I, P, C	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	F, I, C, A	F, I, P, C	I, P	I	F, I, P	F, I		F
294-589-3				I, P	F, I, P, C		F	F, I, P, C	F, I, P, C						F			
294-590-9	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
294-661-4																I		
297-462-0				F, I, A				F, I								I		
306-657-2	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
307-751-6	I, P, C	F, I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	F, I, P, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I	I	F, I, P	F, I		F
451-530-8				F, I, P, A	F, I, P, C	C	C	F, I, P, C	F, I, P, A									

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 16: Heat transfer fluids	PC 17: Hydraulic fluids	PC 13: Fuels	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removes	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 14: Metal surface treatment products	PC 7: Base metals and alloys	PC 21: Laboratory chemicals	PC 19: Intermediate	PC41: Oil and gas exploration or production products	PC x1: Food and feed additives
811-605-1	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I, A	F, I, C, A	F, I, P, C	I		F, I, P	I		
905-964-4	C	I, P, C	I, P, C	F, I, P	I, C	C	I, C	F, I, P, C	F, I, P		F, I, C, A	F, I, P, C	I		F, I, P	I		
939-588-7	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
939-633-0	C	I, P, C	I, P, C	F, I, P, C	F, I, P, C	C	I, C	F, I, P, C	F, I, P, C	I	F, I, C, A	F, I, P, C	I		F, I, P	I		
947-787-5																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 9 September 2021.

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