

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Aliphatic (linear) esters from <C10 alcohols

General structure: -

Revision history

<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	4 April 2024	

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
203-425-1	106-70-7	Methyl hexanoate	Full, not (publicly) available
203-766-6	110-42-9	Methyl decanoate	Full, 10,000-100,000 t/y
662-772-0	25601-41-6	9-Decenoic acid, methyl ester	Full, not (publicly) available
203-835-0	111-11-5	Methyl octanoate	Full, 1,000-10,000 t/y
700-618-7	39202-17-0	Methyl dodec-9-enoate	Full, not (publicly) available
203-911-3	111-82-0	Methyl laurate	Full, 10,000-100,000 t/y
203-966-3	112-39-0	Methyl palmitate	Full, 1,000-10,000 t/y
203-990-4	112-61-8	Methyl stearate	Full, not (publicly) available
204-680-1	124-10-7	Methyl myristate	Full, not (publicly) available
205-472-3	141-24-2	Methyl ricinoleate	Full, 10-100 t/y
210-838-0	624-24-8	Methyl valerate	OSII or TII, not (publicly) available
267-007-0	67762-26-9	Fatty acids, C14-18 and C16-18-unsatd., Me esters	Full, 1,000,000- 10,000,000 t/y
267-014-9	67762-37-2	Fatty acids, C8-18 and C18-unsatd., Me esters	OSII or TII, not (publicly) available
267-015-4	67762-38-3	Fatty acids, C16-18 and C18-unsatd., Me esters	Full, 10,000,000-100,000,000 t/y
269-908-4	68390-63-6	Fatty acids, castor-oil, Me esters	OSII or TII, not (publicly) available
273-606-8	68990-52-3	Fatty acids, vegetable-oil, Me esters	Full, 1,000,000- 10,000,000 t/y; 71/0
287-636-4	85566-26-3	Fatty acids, C8-10, Me esters	Full, 10,000-100,000 t/y
287-824-6	85586-21-6	Fatty acids, C16-18, Me esters	Full, 100,000- 1,000,000 t/y
287-828-8	85586-25-0	Fatty acids, rape-oil, Me esters	OSII or TII, not (publicly) available
629-776-4	308065-15-8	Fatty acids, C12-14 (even numbered), methyl ester	Full, 1,000,000- 10,000,000 t/y
629-780-6	1234694-02-0	Fatty acids, C12-16 (even numbered) and C18 unsatd., Me esters	Full, 1,000-10,000 t/y
939-235-7	-	Fatty acids, C16-C18 (even numbered) and C18 (unsaturated) and Fatty acids, C16-C18 (even numbered) and C18 (unsaturated) methyl esters	Full, 10,000,000-100,000,000 t/y
942-993-1	-	Reaction mass of methyl (9E,12E,15Z)-9,12,15-octadecatrienoate and methyl (9E,12Z,15E)-9,12,15-octadecatrienoate and methyl (9Z)-9-octadecenoate and methyl (9Z,12E,15E)-9,12,15-	Full, not (publicly) available

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
		octadecatrienoate and methyl (9Z,12Z)-9,12-octadecadienoate	
273-094-6	68937-83-7	Fatty acids, C6-10, Me esters	C&L notification
203-382-9	106-30-9	Ethyl enantate	Full, not (publicly) available
204-640-3	123-66-0	Ethyl hexanoate	Full, 10-100 t/y
208-868-4	544-35-4	Ethyl linoleate	OSII or TII, not (publicly) available
253-712-0	37910-77-3	Ethyl (Z)-docos-13-enoate	OSII or TII, not (publicly) available
285-206-0	85049-36-1	Fatty acids, C16-18 and C18-unsatd., Et esters	Full, 100-1,000 t/y
293-054-1	91051-05-7	Fatty acids, essential, Et esters	Full, 10,000-100,000 t/y
293-106-3	91051-53-5	Fatty acids, safflower-oil, Et esters	Full, not (publicly) available
940-683-0	-	Fatty acids, C18 (saturated and unsaturated) ethyl esters	Full, 100-1,000 t/y
941-981-3	-	Fatty acids, C18 unsaturated, ethyl methyl esters	Full, 10-100 t/y
203-306-4	105-54-4	ethyl butyrate	Full, 1,000-10,000 t/y
208-726-1	539-82-2	ethyl valerate	OSII or TII, not (publicly) available
203-385-5	106-32-1	ethyl octanoate	Full, not (publicly) available
203-386-0	106-33-2	ethyl laurate	OSII or TII, not (publicly) available
945-734-0		Reaction mass of ethyl dodecanoate and ethyl hexadecanoate and ethyl tetradecanoate	Full, not (publicly) available
203-761-9	110-38-3	ethyl decanoate	Full, not (publicly) available
211-064-6	628-97-7	ethyl palmitate	Full, not (publicly) available
203-889-5	111-62-6	ethyl oleate	C&L notification
204-642-4	123-68-2	Allyl hexanoate	Full, 100-1,000 t/y
205-527-1	142-19-8	Allyl heptanoate	Full, 100-1,000 t/y
267-028-5	67762-63-4	Fatty acids, tall-oil, Bu esters	Full, 100-1,000 t/y
284-863-0	84988-74-9	Fatty acids, C16-18 and C18-unsatd., Bu esters	Full, 1,000-10,000 t/y
287-039-9	85408-76-0	Fatty acids, C16-18, Bu esters	Full, 1,000-10,000 t/y
209-669-5	590-01-2	Butyl propionate	Full, 100-1000 t/y
203-656-8	109-21-7	butyl butyrate	Full, not (publicly) available
944-892-8		Reaction mass of butyl palmitate and butyl oleate and butyl (9Z,12Z)-octadeca-9,12-dienoate and 482-680-2	Full, not (publicly) available
250-280-5	30673-36-0	butyl decanoate	Full, not (publicly) available
204-666-5	123-95-5	butyl stearate	C&L notification
218-528-7	2173-56-0	pentyl valerate	OSII or TII, not (publicly) available

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
222-960-1	3681-71-8	(Z)-hex-3-enyl acetate	Full, 100-1000 t/y
220-136-6	2639-63-6	hexyl butyrate	Full, 10-100 t/y
251-932-1	34316-64-8	hexyl laurate	Full, 100-1,000 t/y
228-952-4	6378-65-0	hexyl hexanoate	Full, not (publicly) available
218-980-5	2306-88-9	Octyl octanoate	Full, not (publicly) available
226-149-3	5303-24-2	Octyl laurate	Full, not (publicly) available
293-003-3	91031-98-0	Fatty acids, C8-10, octyl esters	Full, not (publicly) available
285-200-8	85049-31-6	Fatty acids, C10-18 and C12-22-unsatd., C14-18 and C16-18-unsatd. alkyl esters	Full, > 1000 t/y

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

Contents

Foreword.....	7
Glossary	9
1 Overview of the group.....	10
2 Conclusions and proposed actions.....	11
3 Justification for the no need for regulatory risk management action at EU level	14
Annex 1: Overview of classifications	17
Annex 2: Overview of uses based on information available in registration dossiers.....	20
Annex 3: Overview of completed or ongoing regulatory risk management activities	26

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 carboxylic acid esters derived from linear carboxylic acids and linear alcohols. The group consists of esters with a linear carboxylic acid chain ranging from C2 to C22 (saturated and unsaturated) and a linear alcohol chain from C1 to C8 (saturated with the exception of two substances).

There are 60 substances in the group of which 48 with full registrations and 9 intermediate registrations.

Based on information reported in the REACH registration dossiers, the substances in this group have a high potential for exposure for workers and consumers as well as for release to the environment. The substances are used in a variety of product categories (e.g. washing and cleaning, lubricants, rubber and plastics), including applications where other legislations than REACH/CLP apply (e.g. cosmetics, medical devices, fuels, plant protection products). No specific use pattern could be identified. The available information indicates that substitution within the group is likely.

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.

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
203-425-1 203-766-6 662-772-0 203-835-0 700-618-7 203-911-3 203-966-3 203-990-4 204-680-1 205-472-3 210-838-0 267-007-0 267-014-9 267-015-4 269-908-4 273-606-8 287-636-4 287-824-6 287-828-8	No hazard or unlikely hazard except for EC 210-838-0, 293-106-3, 226-149-3 that are known skin sensitisers	No hazard or unlikely hazard	Widespread uses with high potential for exposure for workers and consumers, release to environment or potential for substitution. EC 226-149-3 used in functional fluids. EC 210-838-0, 267-014-9, 269-908-4, 942-993-1 are used as intermediates. EC 293-106-3 consumer uses (e.g. as cosmetics, for washing and cleaning, biocides or air care).	Currently no need for EU RRM <u>Justification:</u> Overall, no or unlikely hazard that would lead to concern for the reported uses. For ECs 226-149-3, 210-838-0, 293-106-3 harmonised/self-classification (will) require company level risk management measures (RMM) for workers to be in place. For EC 293-106-3 the concern related to the presence of skin sensitisers in consumer mixtures is under investigation.

ASSESSMENT OF REGULATORY NEEDS

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
629-776-4				
629-780-6				
939-235-7				
942-993-1				
273-094-6				
203-382-9				
204-640-3				
208-868-4				
253-712-0				
285-206-0				
293-054-1				
293-106-3				
940-683-0				
941-981-3				
203-306-4				
208-726-1				
203-385-5				
203-386-0				
945-734-0				
203-761-9				
211-064-6				
203-889-5				
204-642-4				
205-527-1				
267-028-5				
284-863-0				

ASSESSMENT OF REGULATORY NEEDS

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
287-039-9				
209-669-5				
203-656-8				
944-892-8				
250-280-5				
204-666-5				
218-528-7				
222-960-1				
220-136-6				
251-932-1				
228-952-4				
218-980-5				
226-149-3				
293-003-3				
285-200-8				

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.

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

Based on currently available information CMR, ED, skin sensitisation, STOT RE, PBT/vPvB, PMT/vPvM hazards are considered unlikely for all group members except for ECs 226-149-3, 293-106-3, 210-838-0 that are self-classified as Skin Sens. 1.

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 evaluations⁵ from other safety bodies, group members are expected to be 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). 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.

Available experimental mutagenicity studies conducted on the registered substances are negative.

Regarding skin sensitisation, three substances (EC 226-149-3 and EC 293-106-3, EC 210-838-0) have shown positive results in an LLNA assay and are self-classified as Skin Sens. 1. 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. In addition, 17 members of the group that have experimental data on skin sensitisation showed negative results. Therefore, the skin sensitisation hazard does not apply to any of the other esters in the group on the basis of structural similarity and since there are negative results from other esters. Moreover, the

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>

ASSESSMENT OF REGULATORY NEEDS

breakdown products of esters are not skin sensitisers and there are no structural alerts from functional groups for protein binding potential.

Available systemic toxicity studies do not indicate any effect that would meet the criteria for classification as STOT RE. Similarly, reproductive and developmental toxicity data are available for some group members (screening reproductive toxicity and developmental toxicity studies) and are negative.

No carcinogenicity study is available, but no carcinogenic effect is expected in view of the absence of mutagenic and repeated dose toxicity.

Regarding a potential endocrine disruptor (ED) hazard, the available systemic toxicity studies 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.

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. Some group members upon metabolic hydrolysis can release short chain aliphatic alcohols like ethanol. The toxicity of the esters containing such alcohol moieties in their structure is expected to be lower than that of the corresponding fatty 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 are considered to be readily biodegradable and are unlikely to fulfil the T criterion. The majority of substances are considered readily biodegradable based on the available experimental data and therefore are unlikely P. The group members have low potential for bioaccumulation. Overall, although some substances in the group meet the criteria for classification as hazardous to the aquatic environment, there is no evidence of aquatic toxicity data < 0.01 mg/L. Consequently, substances in this group are not considered a concern regarding the T criterion.

For three group members that are self-classified as skin sensitisers, EC 226-149-3 is only used in functional fluids and EC 210-838-0 is only used as intermediate. Both are uses for which self-classification is expected to be sufficient to have relevant risk management in place. For EC 293-106-3 consumer uses (e.g. as cosmetics, for washing and cleaning, biocides or air care) are registered.

For industrial and professional uses, sufficient and consistent self-classification by registrants should require company level risk management measures (RMM) to be in place for workers. Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing the substance with EC 293-106-3.

However, there is a concern among authorities about presence of skin sensitisers in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern has been identified in other groups of substances. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

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

ASSESSMENT OF REGULATORY NEEDS

final product and safety assessment to be done according to Cosmetic product regulation (EC) No 1223/2009.

Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management for skin sensitisation for the substances.

Currently 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 27 April 2020.

EC/ List No	Substance name	Harmonised classification	Classification in registrations
203-382-9	ethyl enantate		Aquatic Acute 1 Aquatic Chronic 3
203-425-1	methyl hexanoate		Flam. Liquid 3
203-766-6	methyl decanoate		Aquatic Chronic 2
203-835-0	methyl octanoate		
203-911-3	methyl laurate		Aquatic Acute 1 Aquatic Chronic 2
203-966-3	methyl palmitate		
203-990-4	methyl stearate		
204-640-3	ethyl hexanoate		Flam. Liquid 3 Skin Irrit. 2
204-642-4	allyl hexanoate		Aquatic Acute 1 Aquatic Chronic 3 Acute Tox. 3 (swallowed) Acute Tox. 3 (skin) Acute Tox. 3 (inhaled)
204-680-1	methyl myristate		
205-472-3	methyl ricinoleate		
205-527-1	allyl heptanoate		Aquatic Acute 1 Aquatic Chronic 3 Acute Tox. 3 (swallowed) Acute Tox. 3 (skin)
208-868-4	ethyl linoleate		Skin Irrit. 2
209-669-5	butyl propionate	Index number: 607-029-00-3 Flam. Liq. 3 Hazard Statement: H226 Notes: C	Flam. Liquid 3 H226
210-838-0	methyl valerate		Flam. Liquid 3 Skin Sens. 1B
218-980-5	octyl octanoate		
222-960-1	(Z)-hex-3-enyl acetate		Flam. Liquid 3 H226
226-149-3	octyl laurate		Skin Sens. 1

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	Substance name	Harmonised classification	Classification in registrations
253-712-0	ethyl (Z)-docos-13-enoate		
267-007-0	Fatty acids, C14-18 and C16-18-unsatd., Me esters		
267-014-9	Fatty acids, C8-18 and C18-unsatd., Me esters		Aquatic Acute 1 Aquatic Chronic 2
267-015-4	Fatty acids, C16-18 and C18-unsatd., Me esters		
267-028-5	Fatty acids, tall-oil, Bu esters		
269-908-4	Fatty acids, castor-oil, Me esters		
273-606-8	Fatty acids, vegetable-oil, Me esters		
284-863-0	Fatty acids, C16-18 and C18-unsatd., Bu esters		
285-206-0	Fatty acids, C16-18 and C18-unsatd., Et esters		
287-039-9	Fatty acids, C16-18, Bu esters		
287-636-4	Fatty acids, C8-10, Me esters		
287-824-6	Fatty acids, C16-18, Me esters		
287-828-8	Fatty acids, rape-oil, Me esters		
293-003-3	Fatty acids, C8-10, octyl esters		
293-054-1	Fatty acids, essential, Et esters		
293-106-3	Fatty acids, safflower-oil, Et esters		Aquatic Acute 1 Aquatic Chronic 3 Skin Sens. 1 Skin Irrit. 2
629-776-4	Fatty acids, C12-14 (even numbered), methyl ester		

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	Substance name	Harmonised classification	Classification in registrations
629-780-6	Fatty acids, C12-16 (even numbered) and C18 unsatd., Me esters		
662-772-0	Methyl dec-9-enoate		
700-618-7	Methyl dodec-9-enoate		Aquatic Acute 1 H400
939-235-7	Fatty acids, C16-C18 (even numbered) and C18 (unsaturated) and Fatty acids, C16-C18 (even numbered) and C18 (unsaturated) methyl esters		Flam. Liquid 4 Acute Tox. 4 (swallowed) Acute Tox. 5 (skin) Acute Tox. 4 (inhaled)
940-683-0	Fatty acids, C18 (saturated and unsaturated) ethyl esters		
941-981-3	Fatty acids, C18 unsaturated, ethyl methyl esters		
942-993-1	Reaction mass of methyl (9E,12E,15Z)-9,12,15-octadecatrienoate and methyl (9E,12Z,15E)-9,12,15-octadecatrienoate and methyl (9Z)-9-octadecenoate and methyl (9Z,12E,15E)-9,12,15-octadecatrienoate and methyl (9Z,12Z)-9,12-octadecadienoate		

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

Data extracted on 27 April 2020 (EC 662-772-0, EC 700-618-7, EC 209-669-5 and EC 222-960-1 from 7 March 2023).

Use name	203-425-1, 203-766-6, 203-966-3, 205-472-3, 267-015-4, 287-824-6, 629-776-4	203-835-0	203-911-3	203-990-4	204-680-1	210-838-0, 267-014-9, 269-908-4, 942-993-1	267-007-0	273-606-8	287-636-4	287-828-8	629-780-6	662-772-0	700-618-7	939-235-7
Additive in polymer, plastics and resins	F, I, P, C, A	I, P	I, P		I									
Adhesives, Coatings and paints	F, I, P, C, A	I, P, C	F, I, P, C	F, I, P, C	C		F, I, P, C		F, I					
Agrochemicals	P, C	P, C	P, C											
Air care and personal care	I, C		C	C	C			C	C					
Anti-freeze and de-icing products	P, C	P	P, C											
Binder and release agents	I, P	I, P	I, P											
Biocides	I, P, C		C	F, C					I, C		P			
Building and construction	F, I, P, C, A	P	P, C											
Cleaning of food beverage	I		I	I, P				I, P	I, P		I			
Cosmetics, personal care products, pharmaceuticals	F, P, C	C	F, P, C	F, P, C	F, P, C		C	F, I, P, C	F, I, P, C		F			
Explosives	I, P	P	P											
Fertilisers	F, I, P, C													
Fuels (including additives)	F, I, P, C	I, P, C	I, P, C				F, I, P, C	F, I, P, C	I, P, C		F, I			
Hydraulic and functional fluids	I, P, C	I, P, C	I, P, C		C									
Intermediate use	I	I	I	F, I	F, I	I	I		I	I	I	I	I	I

ASSESSMENT OF REGULATORY NEEDS

Use name	203-425-1, 203-766-6, 203-966-3, 205-472-3, 267-015-4, 287-824-6, 629-776-4	203-835-0	203-911-3	203-990-4	204-680-1	210-838-0, 267-014-9, 269-908-4, 942-993-1	267-007-0	273-606-8	287-636-4	287-828-8	629-780-6	662-772-0	700-618-7	939-235-7
Laboratory use	F, I, P	F, I, P	F, I, P	F, I, P	F, I, P		I	I, P	F, I, P		I			
Lubricants, greases and metal surface treatment	F, I, P, C	I, P, C	F, I, P, C	I			F, I, P, C	I	F, I, P, C		F, I, P, C			
Non reactive processing aid	I, P		I, P											
Oil and gas field drilling, mining	I, P	I, P	I, P											
Plant protection products	F, P, C						P		F, P		C			
Rubber products	F, I, C	I	I											
Textiles and leather treatment	F, I, A						F, I, P							
Use in asphalt applications							F, P	F, I, P						
Use in medical devices	P		P	P				P	P					
Use in tyres and other rubber articles	F, I, C													
Washing, cleaning, polishes	F, I, P, C	P	F, I, P, C	F, I, P, C	I, P, C		P, C	F, I, P, C	F, I, P, C		F, I	I, P	I, P	
Water treatment	F, I, P	I, P	F, I, P	I				I	I		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.

ASSESSMENT OF REGULATORY NEEDS

Use name	204-640-3, 204-642-4, 205-527-1	208-868-4, 253-712-0, 208-726-1, 203-386-0, 250-280-5	285-206-0, 284-863-0, 287-039-9	293-054-1	203-382-9, 293-106-3	940-683-0	941-981-3	203-306-4, 203-385-5, 203-656-8	945-734-0	203-761-9, 211-064-6	250-280-5	267-028-5	203-656-8	944-892-8	209-669-5
Additive in polymer, plastics and resins			F, I, P	I, P						F, I	F, I, A	F, I, P			
Adhesives, coatings and paints			F, I, P, C	F, I, P, C				I		F, I, P, C		F, I, P, C			I, P, C
Agrochemicals			P, C	P, C								P, C			
Air care and personal care	C		I, C		C			C		C		I, C	C		F
Anti-freeze and de-icing products			P, C	P								P, C			
Binder and release agents			I, P	I, P								I, P			
Biocides	C		C		C			F, C		C		C	C		F, I, P
Building and construction			F, I, P, C, A	P								F, I, P, C, A			F, I, P
Cleaning of food beverage			I									I			
Cosmetics, personal care products, pharmaceuticals	F, P, C		F, I, P, C	C	F, P, C	A		F, I, P, C		F, P, C		F, I, P, C	C	F, I	
Explosives			P	P								P			
Fertilisers			F, I, P, C				F, I, P, C								
Food or feed additive				F, P											
Food contact											F, I, A				
Fuels (including additives)			F, I, P, C	F, I, P, C		I, A						I, P, C			
Hydraulic and functional fluids			I, P, C	I, P, C							F, I, A	I, P, C			
Intermediate use		I	I	I	I		I	F, I				I			

ASSESSMENT OF REGULATORY NEEDS

Use name	204-640-3, 204-642-4, 205-527-1	208-868-4, 253-712-0, 208-726-1, 203-386-0, 250-280-5	285-206-0, 284-863-0, 287-039-9	293-054-1	203-382-9, 293-106-3	940-683-0	941-981-3	203-306-4, 203-385-5, 203-656-8	945-734-0	203-761-9, 211-064-6	250-280-5	267-028-5	203-656-8	944-892-8	209-669-5
Laboratory use			F, I, P	F, I, P				I, P					F, I, P		F, I, P
Lubricants, greases and metal surface treatment			F, I, P, C	I, P, C	I					I			F, I, P, C		
Non reactive processing aid			I, P					I					I, P		
Oil and gas field drilling, mining			I, P	I, P									I, P		
Paper and paper products			A	F, I									F, I		
Ink and toners															I, P
Plant protection products			P, C			F, I	P, C								
Rubber products			F, I, A	I									F, I, C		
Scented articles								A							
Textiles and leather treatment			F, I, P, C, A										F, I, A		
Asphalt applications						C									
Medical devices			P										P		
Tobacco products	F, C														
Use in tyres and other rubber articles			F, I, A										F, I, C		
Washing, cleaning, polishes	I, P, C		F, I, P, C	I, P	F, I, P, C			I, P, C	I, P, C	F, I, P, C			F, I, P, C	I, P, C	F, I, P, C
Water treatment			F, I, P	I, P									F, 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.

ASSESSMENT OF REGULATORY NEEDS

Use name	218-528-7	220-136-6	228-952-4	251-932-1	218-980-5	222-960-1	226-149-3	293-003-3
Additive in polymer, plastics and resins				F, I, P				
Adhesives, Coatings and paints				F, I, P, C				
Agrochemicals				P, C				
Air care and personal care				C		P, C		
Anti-freeze and de-icing products				P, C		P		
Biocides				F, I, C		C		
Building and construction				F, I, P, C, A				
Cleaning of food beverage				I, P				
Cosmetics and personal care products, pharmaceuticals		F, C	F, C	F, C		F, P, C		
Explosives				P				
Fertilisers				F, I, P, C				
Fuels (including additives)				I, P, C				
Hydraulic and functional fluids open and closed systems)				I, P, C			F, I	
Intermediate use or use as monomer in polymer	F, I			I	I	I		I
Laboratory use				F, I, P				
Lubricants, greases and metal surface treatment				F, I, P, C		P		
Non reactive processing aid				I, P				
Oil and gas field drilling, mining				I, P				
Paper and paper products				I				

ASSESSMENT OF REGULATORY NEEDS

Use name	218-528-7	220-136-6	228-952-4	251-932-1	218-980-5	222-960-1	226-149-3	293-003-3
Pharmaceuticals						C		
Plant protection products				P, C				
Rubber products				F, I, C				
Perfumes, fragrances						F, C		
Polishes and wax blends						P, C		
Textiles and leather treatment				F, I, A				
Use in medical devices				P				
Use in tyres and other rubber articles				F, I, C				
Washing, cleaning, polishes				F, I, P, C		F, I, P, C		
Water treatment				F, 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 23 April 2020.

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