Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Esters from linear and branched carboxylic acid and polyol ethers

General structure: “-”

Revision history

Version	*Date*	*Description*
1.0	2 May 2023	

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]
202-319-2	94-28-0	2,2'-ethylenedioxydiethyl bis(2-ethylhexanoate)	Full, > 1000
203-846-0	111-21-7	2,2'-[ethane-1,2-diylbis(oxy)]bisethyl diacetate	Full, 100 - 1000
256-367-4	49553-76-6	oleic acid, monoester with oxybis(propanediol)	Full, 100 - 1000
701-479-5	67938-21-0	di(isooctadecanoic) acid, diester with oxydi(propanediol)	Full, 100 - 1000
701-396-4	73296-86-3	Isooctadecanoic acid, ester with oxybis[propanediol]	Full, 10 - 100
285-550-1	85116-97-8	Fatty acids, C16-18, esters with diethylene glycol	Full, 10 - 100
292-947-3	91031-45-7	Fatty acids, C16-18, 1,2-ethanediylbis(oxy-2,1-ethanediyl) esters	Full, 100 - 1000
293-026-9	91050-80-5	Fatty acids, C16-18, tetraesters with 3,3'-oxybis[1,2-propanediol]	Full, 100 - 1000
305-769-9	95009-41-9	Fatty acids, vegetable-oil, esters with dipropylene glycol	Full, not (publicly) available
484-350-3	-	Radia 7838	cease manufacture
613-333-7	63705-03-3	1,2,3-Propanetriol, homopolymer, diisooctadecanoate	Full, not (publicly) available
613-583-7	64366-79-6	1,2,3-Propanetriol, homopolymer, docosanoate	Full, not (publicly) available
700-672-1	70226-26-5	Dodecanoic acid, ester with oxybis[propanediol]	Full, not (publicly) available
Substance X	-	[No public or meaningful name is available]	Full, not (publicly) available
943-350-8	-	Reaction products resulting from the esterification of C18 unsaturated fatty acid with glycerol and glycerol oligomers	Full, not (publicly) available
947-750-3	-	Reaction product of saturated palm kernel fatty acids and oxybispropanediol	Full, not (publicly) available
480-150-5	-	[No public or meaningful name is available]	NONS, not (publicly) available

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

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

Contents

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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
UVCB	Substances of unknown or variable composition, complex reaction products or 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 carboxylic acid esters derived from fatty acids and polyol ethers.

There are 17 substances in the group, of which 16 substances that have full, active REACH registrations.

The fatty acids (a) have chain lengths from 6 to 22, (b) are saturated or unsaturated, and (c) are linear or have (specific/non-specific) branching. The polyol ethers are: (a) ethylene glycols (i.e. diethylene glycol, triethylene glycol, tetraethylene glycol and hexaethylene glycol), (b) glycerol ethers (i.e. diglycerol, triglycerol, and glycerol oligomers), (c) dipropylene glycol, and (d) polypropylene glycol trimethylolpropane ether. Some of these polyol ethers are substances of UVCBs and most are well known High Production Volume[5] registered substances. Some of the substances in the group contain constituents of differing degrees of esterification, i.e. mono-, di-, tri-esters etc.

The substance EC 202-319-2 is expected to be hydrolysed into 2-ethylhexanoic acid (EC 149-57-50) which is a substance with harmonised classification Repr. 1B[6]. This substance also differs from some others in the group as (a) it has been examined by ECHA for health properties in 2 targeted compliance checks (CCH) and 2 testing proposal examinations (TPE) whereas the other substances have not been compliance checked and (b) it is a mono-constituent substance (not a UVCB).

Based on information reported in the REACH registration dossiers most of the substances in the group have widespread uses with high exposure potential both for humans and environment. Some of the substances have a high number of identified uses by industrial and professional workers and consumers and article service life is reported for 11 substances. The main uses are as solvent, emulsifier, defoamer, softener, lubricant agent, plasticiser and additive in washing and cleaning products, coatings and paints, lubricant and greases, agrochemicals, fuels, air fresheners and de-icing and anti-icing applications etc. However, two substances, EC 256-367-4 and List no. 700-672-1, are used only by industrial workers for polymer production of plastic articles. For EC 701-479-5 only formulation and consumer use of personal care products and cosmetics have been identified in the dossier. EC 203-846-0 has quite many consumer uses reported in addition to the above mentioned; use in biocidal/ plant protection products, fertilisers, metal working/ heat transfer/ hydraulic fluids, finger paints, fillers, putties, plasters, modelling clay, textile dyes, and impregnating products as well as leather treatment are reported.

[5] OECD cooperative Chemicals Assessment Programme: High production volume (HPV) chemicals.

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

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

SubEC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
202-319-2 203-846-0 256-367-4 701-479-5 701-396-4 285-550-1 292-947-3 293-026-9 305-769-9 943-350-8 Substance X	No hazard or unlikely hazard	No hazard or unlikely hazard	Industrial, professional and consumer use in washing and cleaning products, coatings and paints, lubricant and greases, agrochemicals, additive in fuel, air fresheners and de-icing and anti-icing applications, cosmetics, paper and board treatment products etc. Article service life reported for plastic, textile, paper and road construction articles, rubber goods. EC 203-846-0 is also used by consumers in biocidal/ plant protection products, fertilisers, metal working/ heat transfer/ hydraulic fluids, finger paints, fillers, putties, plasters, modelling clay, textile	Pending action for EC 202-319-2, 256-367-4, 292-947-3, 305-769-9, 701-479-5, Substance X, 943-350-8 **Currently no need for EU RRM** Justification: Overall, no or unlikely hazard that would lead to concern for the reported uses.

SubEC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
484-350-3 480-150-5			dyes, and impregnating products as well as leather treatment. Potential for exposure for workers and consumers and release to the environment.	
700-672-1 947-750-3 613-583-7 613-333-7	No hazard or unlikely hazard	Inconclusive hazard for PBT/vPvB for PMT/vPvM	Industrial, professional and/or consumer use in cosmetics and personal care products. Use in plastic articles (700-672-1, 947-750-3) and paper and board treatment products (613-583-7) reported. Potential for exposure for workers and consumers and release to the environment.	Pending action for List no. 700-672-1, 947-750-3 CCH for List no. 613-583-7 and List no. 613-333-7 **Currently not possible to assess the regulatory needs** <u>Justification</u>: Inconclusive hazard for PBT/vPvB, PMT/vPvM

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 all substances in the group due to low potential toxicological and environmental hazard.

Based on ECHA's assessment of hazard information currently available in registration dossiers, the following conclusions can be made.

All group members are unlikely CMR/ED and skin sensitisers.

Group members are expected to be hydrolysed into corresponding carboxylic acids and glycols or glycerols by carboxylesterase enzymes found in most tissues throughout the body, including the gastrointestinal tract. 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). The glycols (such as ethylene glycol, di-, tri-, tetra-ethylene glycol) have been previously screened by ECHA and are considered unlikely CMR/ED. The available studies for some of the glycerols (e.g. monoglycerol, polyglycerol) indicate they are of low toxicity and they do not possess skin sensitising or hazardous (CMR, T) properties (EFSA 2013[7], 2017[8]).

Available experimental data on mutagenicity and skin sensitisation do not indicate potential for these hazards for any group member. The available information does not indicate potential for systemic toxicity taking into account also the potential metabolites.

EC 202-319-2 is an ester with 2-ethylhexanoic acid (2-EHA). 2-EHA is harmonised classified as Repr.1B[9]. Although 2-EHA is a potential metabolite for EC 202-319-2, the available reproductive toxicity studies with the registered substance (PNDT in rat and a EOGRTs study) do not indicate potential for reproductive toxicity, while a PNDT study in rabbits is pending. At this stage the substance is considered as unlikely reproductive toxicant and the conclusion can be revisited if needed depending on the outcome of the ongoing study.

There is remaining uncertainty regarding the breakdown of the esters, more specifically regarding the rate of hydrolysis, as the information available is mostly

[7] EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2013. Scientific Opinion on the safety evaluation of the substance, polyglycerol, CAS No 25618-55-7, for use in food contact materials. EFSA Journal 2013;11 (10):3389, 8 pp. doi:10.2903/j.efsa.2013.3389

[8] European Food Safety Authority. SCIENTIFIC OPINION ADOPTED: 25 January 2017. Re-evaluation of glycerol (E 422) as a food additive. John Wiley and Sons Ltd on behalf of European Food Safety Authority. doi: 10.2903/j.efsa.2017.4720

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1435&qid=1689155759608

from literature sources and refers to the generic ability of carboxylesterases to breakdown the esters.

All group members (except List no. 700-672-1, List no. 947-750-3, List no. 613-583-7 and List no. 613-333-7) are considered unlikely PBT/vPvB, unlikely PMT/vPvM as they are considered unlikely P based on they available information on biodegradation.

These substances are claimed to be not B based only on QSAR Bioconcentration Factor (BCF) estimates. The log Kow values are generally QSAR estimates, with at least some constituents with a Log Kow >3 and mostly >4.5; However, log Kow QSAR estimate is not a relevant indicator of B potential for these surface active substances/ionising substances. Therefore, the substances are considered as inconclusive B.

All substances in the group are considered as inconclusive for M as they are surface active substances and the log Koc estimates by QSARs are not reliable.

The substances (except EC 256-367-4) are considered as inconclusive for aquatic toxicity. They are poorly water soluble and only acute aquatic toxicity studies are available therefore there is no adequate information to conclude on T. EC 256-367-4, has an algal test with 72-h ErC50 >0.125mg/l and NOEC growth rate 0.0113mg/l: hence (a) it is self-classified as aquatic chronic 2 (H414).

There is ongoing CCH for EC 202-319-2, 256-367-4, 292-947-3, 305-769-9, 701-479-5, Substance X, 943-350-8.

If the registration status changes for the substances, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

Currently not possible to suggest regulatory risk management actions for substances: List no. 700-672-1, List no. 947-750-3, List no. 613-583-7 and List no. 613-333-7

It is not possible to assess the needs for regulatory risk management for List no. 700-672-1, List no. 947-750-3, List no. 613-583-7 and List no. 613-333-7 as information on hazard is not sufficient to conclude on PBT/vPvB and PMT/vPvM. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).

List no. 613-583-7 is not readily biodegradable (OECD Guideline 301 F) and screens as P/vP. List nos. 700-672-1, 947-750-3 are inconclusive P as they do not have experimental data on ready biodegradability. List no. 613-333-7 is a complex UVCB, with (complex branching), and the available data doesn't allow to conclude on P. These substances are claimed to be not B based only on QSAR Bioconcentration Factor (BCF) estimates. The log Kow values are generally QSAR estimates, with at least some constituents with a Log Kow >3 and mostly >4.5; However, log Kow QSAR estimate is not a relevant indicator of B potential for these surfac eactive substances/ionising substances. Therefore, the substance are considered as inconclusive B. The substances are considered as inconclusive for aquatic toxicity. They are poorly water soluble and only acute aquatic toxicity studies are available therefore there is no adequate information to conclude on T.

All substances in the group are considered as inconclusive for M as they are surface active substances and the log Koc estimates by QSARs are not reliable.

The substances are considered unlikely CMR/ED and skin sensitisers as indicated above.

CCH is ongoing for List nos. 700-672-1, 947-750-3 and CCH is proposed for List no. 613-583-7 and List no. 613-333-7

Annex 1: Overview of classifications

Data extracted on 30 January 2020.

EC/ List No	Substance name	Harmonised classification	Classification in registrations
202-319-2	2,2'-ethylenedioxydiethyl bis(2-ethylhexanoate)	-	*NC*
203-846-0	2,2'-[ethane-1,2-diylbis(oxy)]bisethyl diacetate	-	-
256-367-4	oleic acid, monoester with oxybis(propanediol)	-	*Aq. Chronic 2 H411*
701-479-5	di(isooctadecanoic) acid, diester with oxydi(propanediol)	-	*NC*
701-396-4	Isooctadecanoic acid, ester with oxybis[propanediol]	-	-
285-550-1	Fatty acids, C16-18, esters with diethylene glycol	-	-
292-947-3	Fatty acids, C16-18, 1,2-ethanediylbis(oxy-2,1-ethanediyl) esters	-	*Eye Irrit. H319*
293-026-9	Fatty acids, C16-18, tetraesters with 3,3'-oxybis[1,2-propanediol]	-	-
305-769-9	Fatty acids, vegetable-oil, esters with dipropylene glycol	-	-
484-350-3	None (Radia 7838)	-	-
613-333-7	1,2,3-Propanetriol, homopolymer, diisooctadecanoate	-	-
613-583-7	1,2,3-Propanetriol, homopolymer, docosanoate	-	-
700-672-1	Dodecanoic acid, ester with oxybis[propanediol]	-	-
Substance X	No public or meaningful name is available	-	-
943-350-8	Reaction products resulting from the esterification of C18 unsaturated fatty acid with glycerol and glycerol oligomers	-	-
947-750-3	Reaction product of saturated palm kernel fatty acids and oxybispropanediol	-	-
480-150-5	[No public or meaningful name is available]	-	*sensitising (R43)*

EC / List No	Substance name	Harmonised classification	Classification in registrations
			Dangerous for the environment (R51/53)

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

Data extracted on 30 January 2020.

Main types of applications structured by product or article types	202-319-2	256-367-4	701-479-5	701-396-4	285-550-1	292-947-3	293-026-9	305-769-9	700-672-1	Substance X	943-350-8	947-750-3
Use in washing and cleaning products				F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**			I, **P, C**	
Use in coatings and paints	F, I, **P, C, A**			F, I, **P**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**		F, I, **P**	I, **C**	
Use in adhesives and sealants	F, I, **P, C**				F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**		F, I, **P**	I, **C**	
Use in lubricants and greases	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, **P, C**	
Use as fuel					F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**				
Use in agrochemicals					F, I, **P, C**	F, I, **P, C,**	F, I, **P, C**	F, I, **P, C**				
Use in road and construction applications					F, I, **P, C, A**	F, I, **P, C, A**	F, I, **P, C, A**	F, I, **P, C, A**				
Use in plastic articles	F, I, **P, C, A**	F, I, **A**							F, I, **A**			F, I, **A**
Use in rubber goods, tyres				F, I, **P, C, A**		F, I, **P, C**	F, I, **P, C**	F, I, **P, C, A**				
Use in articles (textiles, Pulp and Paper)				**A**		**A**	**A**	**P, A**				
Use in Personal care and cosmetics			F, **C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**		F, I, **P, C**		F, I, **P**		**C**
Air fresheners (aerosol and non-aerosol), candles, heated diffusers				**C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**			I, **P, C**	

Main types of applications structured by product or article types	202-319-2	256-367-4	701-479-5	701-396-4	285-550-1	292-947-3	293-026-9	305-769-9	700-672-1	Substance X	943-350-8	947-750-3
De-icing and anti-icing applications					F, I, **P, C**		F, I, **P, C**	F, I, **P, C**				
Use in medical devices				**P**			**P**	**P**				
Use in food beverage and pharmaceutical products, disinfection				I			**P, C**					
Pest control Products, PPP				**C**	**C**		**P, C**				I, **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.

Data extracted on 7 March 2023.

EC number	203-846-0	613-333-7	613-583-7
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	F, I		
PC 37: Water treatment chemicals	F, I, **P**		
PC 11: Explosives	**P**		
PC 12: Fertilisers	**C**		
PC 27: Plant protection products	**C**		
PC 4: Anti-freeze and de-icing products	**P**, **C**		
PC 35: Washing and cleaning products	I, **P**, **C**		
PC 8: Biocidal products (e.g. disinfectants, pest control)	I, **C**		
PC 28: Perfumes, fragrances	**C**		
PC 3: Air care products	**C**		
PC 39: Cosmetics, personal care products	**C**	F	
PC 31: Polishes and wax blends	**C**		
PC 15: Non-metal-surface treatment products	**C**		
PC 24: Lubricants, greases, release products	F, I, **P**, **C**		

EC number	203-846-0	613-333-7	613-583-7
PC 25: Metal working fluids	I, **P**, **C**		
PC 16: Heat transfer fluids	**C**		
PC 17: Hydraulic fluids	I, **P**, **C**		
PC 13: Fuels	I, **P**, **C**		
PC 32: Polymer preparations and compounds	F, I, **P**, **C**		
PC 1: Adhesives, sealants	F, I, **P**, **C**		
PC 9c: Finger paint	**C**		
PC 9b: Fillers, putties, plasters, modelling clay	**C**		
PC 9a: Coatings and paints, thinners, paint removes	F, I, **P**, **C**		
PC 18: Ink and toners	F, I, **P**		
PC 26: Paper and board treatment products	I		F, I, **A**
PC 34: Textile dyes, and impregnating products	F, I, **C**, **A**		
PC 23: Leather treatment products	F, I, **C**		
PC 21: Laboratory chemicals	F, I, **P**		
PC 19: Intermediate	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 22 January 2020.

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