

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 21/11/2023

Group Name: Branched carboxylic acids and their salts

Revision history

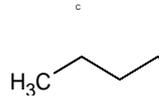
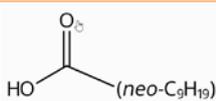
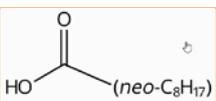
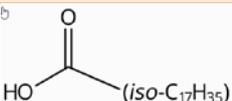
<i>Version</i>	<i>Date</i>	<i>Description</i>
1	10/01/2023	
1.1	24/11/2023	Corrigendum

Substances within this group:

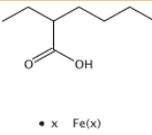
EC/List number	CAS number	Substance name and/ or Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
Branched carboxylic acids				
Subgroup 1: Well-defined carboxylic acids <C12				
200-922-5	75-98-9	pivalic acid	O	Full, not (publicly) available
201-195-7	79-31-2	isobutyric acid	O	Full, >1000
201-796-4	88-09-5	2-ethylbutyric acid	O	Intermediate
202-594-9	97-61-0	2-methylvaleric acid	O	Intermediate
202-777-3	99-66-1	2-propylvaleric acid	O	Intermediate
204-145-2	116-53-0	2-methylbutyric acid	O	Full, 1-10
205-743-6	149-57-5	2-ethylhexanoic acid	O	Full, >1000
207-975-3	503-74-2	isovaleric acid	O	Full, not (publicly) available
209-865-0	595-37-9	2,2-dimethylbutyric acid	O	Intermediate

¹Note that the total aggregated tonnage band may be available on ECHA's webpage at <https://echa.europa.eu/information-on-chemicals/registered-substances>

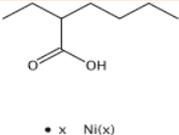
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EC/List number	CAS number	Substance name and/ or Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
211-464-0	646-07-1	4-methylvaleric acid		Intermediate
221-975-0	3302-10-1	3,5,5-trimethylhexanoic acid		Full, >1000
243-402-3	19889-37-3	2-ethyl-2-methylbutyric acid		C&L notification
246-885-9	25354-97-6	2-hexyldecanoic acid		Full, not (publicly) available
248-570-1	27610-92-0	2-butyloctanoic acid		Full, not (publicly) available
298-190-5	93778-52-0	2-decyltetradecanoic acid		Full, not (publicly) available
941-570-9	-	Reaction mass of 2-butylheptanoic acid and 2-ethylnonanoic acid and 2-methyldecanoic acid and 2-propyloctanoic acid		Cease manufacture
Subgroup 2: UVCB neo-carboxylic acids ≤ C10				
248-093-9	26896-20-8	neodecanoic acid		Full, >1000
261-716-9	59354-78-8	neononanoic acid		Full, not (publicly) available
Subgroup 3: UVCB neo-carboxylic acids > C10				
273-114-3	68938-07-8	Fatty acids, C9-13-neo-	-	Full, >1000
285-549-6	85116-96-7	Fatty acids, C10-20-neo-	-	Full, not (publicly) available
Subgroup 4: Branched fatty acids				
250-178-0	30399-84-9	isooctadecanoic acid		1Full, >1000
269-214-1	68201-37-6	Octadecanoic acid, branched and linear	-	Full, not (publicly) available

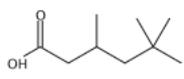
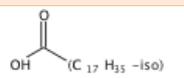
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273-295-9	68955-98-6	Fatty acids, C16-18 and C18-unsatd., branched and linear	-	Full, >1000
Salts of branched carboxylic acids				
Subgroup 5: 2-Ethylhexanoic acid (EHA) salts				
205-249-0	136-51-6	calcium bis(2-ethylhexanoate)	Ca	Full, 100-1000
205-251-1	136-53-8	zinc bis(2-ethylhexanoate)	Zn	Full, 100-1000
243-283-8	19766-89-3	sodium 2-ethylhexanoate	O	Full, 100-1000
221-625-7	3164-85-0	potassium 2-ethylhexanoate	O	Full, 100-1000
286-272-3	85203-81-2	Hexanoic acid, 2-ethyl-, zinc salt, basic	Zn	Full, 100-1000
413-670-8	-	nitrilotriethyleneammon iopropane-2-ol 2-ethylhexanoate (published ELINCS name)	O	NONS
219-536-3	2457-02-5	strontium bis(2-ethylhexanoate)	Sr	Full, 100-1000
243-169-8	19583-54-1	2-ethylhexanoic acid, iron salt (published EINECS name)		Full, 10-100

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230-794-6	7321-53-1	iron tris(2-ethylhexanoate)	°	Full, not (publicly) available
224-699-9	4454-16-4	nickel bis(2-ethylhexanoate)	Ni	Full, 10-100
239-685-8	15602-15-0	magnesium 2-ethylhexanoate	Mg	Full, not (publicly) available
263-502-0	62314-22-1	(2-hydroxypropyl)trimethylammonium 2-ethylhexanoate	N	Full, not (publicly) available
278-031-6	74931-55-8	2-ethylhexanoic acid, compound with 2-aminoethanol (1:1) (published EINECS name)	°	Full, not (publicly) available
231-480-1	7580-31-6	2-ethylhexanoic acid, nickel salt (published EINECS name)	 <p>• x Ni(x)</p>	C&L notification
437-360-7	-	No published name in ELINCS	N	NONS
Subgroup 6: Salts of well-defined carboxylic acids				
220-169-6	2650-30-8	sodium 3,5,5-trimethylhexanoate	°	Full, not (publicly) available
299-890-3	93918-10-6	potassium 3,5,5-trimethylhexanoate	°	Full, not (publicly) available

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264-731-9	64216-15-5	calcium 3,5,5-trimethylhexanoate	o	Full, 100-1000
283-563-7	84682-03-1	zinc 3,5,5-trimethylhexanoate	o	Full, not (publicly) available
243-077-8	19455-20-0	potassium isobutyrate	O	Full, 1-10
213-961-8	1069-66-5	sodium valproate	Na	OSII or TII
421-140-2	-	No published name in ELINCS	o	Full, not (publicly) available
700-021-1	79992-76-0	magnesium bis(2-ethylbutanoate); Butanoic acid, 2-ethyl-, magnesium salt (2:1)	o	Full, not (publicly) available
Subgroup 7: Salts of branched carboxylic acids				
258-901-1	53988-05-9	calcium isononanoate	 <p>• 1/2 Ca</p>	C&L notification
261-999-9	59963-30-3	calcium isooctadecanoate		Full, not (publicly) available
266-369-7	66469-15-6	potassium isooctadecanoate	 <p>• K</p>	Full, not (publicly) available

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EC/List number	CAS number	Substance name and/ or Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
812-724-1	106705-37-7	Strontium decanoate, branched; Strontium neodecanoate	<p>• 1/2 Sr</p>	Full, not (publicly) available
248-374-6	27253-32-3	manganese neodecanoate	<p>• x Mn(x)</p>	Full, 100-1000
260-742-8	57453-97-1	magnesium neodecanoate	<p>• 1/2 Mg</p>	Full, 10-100
248-370-4	27253-29-8	zinc neodecanoate	<p>• 1/2 Zn</p>	Full, 100-1000
282-780-4	84418-68-8	Neodecanoic acid, zinc salt, basic	<p>• 1/2 Zn</p>	Full, 100-1000
248-375-1	27253-33-4	calcium neodecanoate	<p>• 1/2 Ca</p>	Full, 10-100
247-978-7	26761-42-2	potassium neodecanoate	<p>• K</p>	Full, 10-100
257-446-6	51818-55-4	neodecanoic acid, iron salt		Full, 10-100
Subgroup 8: Salts of branched fatty acids				
270-296-6	68424-35-1	Fatty acids, C9-13-neo-, calcium salts	-	Cease manufacture
295-362-1	92044-83-2	Fatty acids, C9-13-neo-, potassium salts	-	Full, not (publicly) available

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EC/List number	CAS number	Substance name and/ or Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
270-064-4	68409-80-3	Fatty acids, C6-19-branched, calcium salts	-	Full, not (publicly) available
940-217-6	-	Fatty acids, C10-20-neo, potassium salts	-	Full, not (publicly) available
271-378-4	68551-44-0	Fatty acids, C6-19-branched, zinc salts	-	Full, 100-1000
295-363-7	92044-84-3	Fatty acids, C9-13-neo-, zinc salts	-	Full, 100-1000

This table contains also group members that are only notified under the CLP Regulation. However, the list is not necessarily exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

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Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, *i.e.*, the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (*e.g.*, harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, *i.e.*, any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on a different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, a more extensive set of information can be available, *e.g.*, assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (*e.g.*, further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process, but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website².

² <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
EOGRTS	Extended one-generation reproductive toxicity study
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
PNDT	Prenatal developmental toxicity
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

1 Overview of the group

ECHA has grouped together 63 structurally similar substances based on the presence of a carboxylic functional group attached to branched aliphatic carbon chains and/or their salts, as shown in the figure below:

O

where R¹, R² and R³ are alkyl and/or hydrogen (excluding formic acid, acetic acid, propionic acid, and butyric acid).

The branched carboxylic acids ($\geq C_4$) consist of 23 registered carboxylic acid substances of which nearly half are registered at 1000+tpa. The group contains only one functional group (*i.e.*, the carboxylic group) with different chain lengths and presence of branching. The registration status of the substances is the following: 17 with full (Article 10) registrations and 6 intermediate registrations.

The branched carboxylic acid salts consist of 40 substances. The registration status of the substances is the following: 35 with full (Article 10) registrations, 1 with C&L notifications, 1 intermediate registration and 2 non-updated NONS.

A few group members were manually screened for initial reproductive and/or developmental toxicity concern and some regulatory actions were taken. 2-ethylhexanoic acid (EC 205-743-6) was assessed under substance evaluation between 2012-2017 and RAC has adopted an opinion on a CLH group entry as Repr. 1B H360D for 2-ethylhexanoic acid and its salts³, now translated in the 18th ATP to the CLP Regulation⁴. 3,5,5-trimethylhexanoic acid (EC 221-975-0) was initially planned to be evaluated under substance evaluation as well based on a developmental toxicity concern but it was withdrawn from the CoRAP list in March 2022 as new OECD TG 414 (in a 2nd species) and OECD TG 443 studies were requested under compliance check and considered sufficient to clarify the initial concern. A number of additional group members are currently undergoing compliance check or testing proposal evaluation to clarify their reproductive and/or developmental toxicity potential.

Based on information reported in the REACH registration dossiers, the substances in the group are mainly used in the following ways:

- Acids: used in washing/cleaning products, air care products, lubricants, metal working fluids, coatings, pharmaceuticals.
- Salts: used in coatings, lubricants, inks/toners, polymer preparations, also some are used in washing/cleaning products

In addition, there are 3 acids (ECs: 250-178-0, 269-214-1 and 273-295-9) that have all the uses indicated above, and are additionally used as pH regulators, water

³ see <https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e181d2af93>

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0692&from=EN>

softeners, or in fertilisers, fuels, adhesives, fillers, textile dyes etc. (almost all Process Categories (PCs) are indicated in their registrations).

Ten of the acids and five of the salts have only industrial uses, but for the majority of substances in the group the registrants indicate professional, consumer and article uses across several product categories. So, there is a significant potential for exposure for humans and the environment for the majority of the substances (both acids and salts).

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is 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 table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (*e.g.*, neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release/exposure is generally considered high for "widespread" uses, *i.e.*, professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted, and no quantitative exposure assessment is performed at this stage.

2 Justification for the need for regulatory risk management action at EU level

The leading hazard identified for this group is reproductive and developmental toxicity. A few group members are known to be reproductive and/or developmental toxicants based on their classification and some findings in the available studies. In particular, 2-propylvaleric acid (EC 202-777-3) is a known teratogenic substance in humans and is self-classified as Repr. 1A for developmental effects. In addition, RAC has adopted an opinion on 2-ethylhexanoic acid (EC 205-743-6) and its salts for a CLH group entry as Repr. 1B H360D⁵, now translated in the 18th ATP to the CLP Regulation⁶.

Based on structural similarity with 2-propylvaleric acid and some findings in the available studies, all short carbon chain acids and salts (*i.e.*, with a length of the main carbon chain <C9) are likely reproductive and developmental toxicants, warranting classification as Repr. 1B as worst case. Some salts in this subgroup

⁵ see <https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e181d2af93>

⁶ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0692&from=EN>

also present a reproductive and developmental toxicity due to the cation specific properties, e.g. nickel, manganese and strontium compounds.

Long carbon chain acids and salts (i.e., with length of the main carbon chain $\geq C9$) are generally assumed to be less toxic than short carbon chain substances as bioavailability may be lower. However, experimental data with long carbon chain substances are limited and read-across with the corresponding acids or cations, or with shorter carbon chain substances, is largely used. Most of these substances are UVCBs and specific effects of some short carbon chain constituents or toxicity related to the cation cannot be excluded from the available data. Further investigation is needed to confirm the reproductive and developmental toxicity potential of those long carbon chain substances.

Regarding other human health hazards, skin sensitisation, mutagenicity, repeated dose toxicity, carcinogenicity and endocrine disruption are considered unlikely for this group based on available data and the structure and functional groups of the acid moiety of the substances. In particular, the assessment of the known reproductive and developmental toxicants in the group, including the RAC opinion on 2-ethylhexanoic acid, did not identify endocrine disruption properties for these substances.

Most cations in the group are metals whose influence on the overall toxicity of the salts is considered limited based on the outcome of the assessment of the group of inorganic carboxylates. However, cation-specific toxicity was shown for a few exceptions, such as nickel compounds (harmonised classifications as Repr. 1B for developmental effects, Carc. 1A, STOT RE 1, Muta. 2, Skin Sens. 1, Resp. Sens. 1, Aquatic Acute 1, Aquatic Chronic 1), manganese compounds (self-classification as STOT RE 2 for neurotoxicity, developmental effects that may warrant classification as Repr. 1B), strontium compounds (developmental effects that may warrant classification as Repr. 1B).

Based on currently available information, there is a need for (further) EU regulatory risk management – Restriction for reproductive toxicity hazards due to the potential for release/ exposure from industrial, professional, consumer and article uses of **2-ethylhexanoic acid (EC 205-743-6) and its salts** (Subgroup 5), **3,5,5-trimethylhexanoic acid (EC 221-975-0) and its salts** (EC 220-169-6, 258-901-1, 264-731-9, 283-563-7, 299-890-3 and EC 258-901-1⁷), and **EC 200-922-5⁸, 248-093-9, 248-570-1, 246-885-9, 201-195-7, 250-178-0, 261-716-9, 266-369-7, 285-549-6, 421-140-2, 700-021-1, 812-724-1 and 940-217-6** (plus 12 UVCB salts that read-across to them: **247-978-7, 248-370-4, 248-374-6, 248-375-1, 257-446-6, 260-742-8, 282-780-4, 270-064-4, 270-296-6, 271-378-4, 295-362-1 and 295-363-7**).

2-ethylhexanoic acid (EC 205-743-6) and its salts

2-ethylhexanoic acid (EC 205-743-6) and its salts are subject to a group harmonised classification which has been published in CLP Annex VI via the 18th

⁷ With a C&L notification, EC 258-901-1 is not registered but is proposed to be subject to the same restriction.

⁸ Listed in the database BfR Recommendations on Food Contact Materials (https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp?filter=clear) in the section XXXVI and section XV, respectively. Therefore, oral exposure is likely.

ATP to the CLP Regulation⁹. The opinion of RAC¹⁰ is that the substances are reprotoxic category 1B based on developmental toxicity. EC 413-670-8 is a 2-EHA salt with a separate entry in Annex VI to CLP and would need to go through the standard procedure to update the entry (with a dossier etc.). Its current registration status is as a non-updated NONS with only industrial uses indicated in the registration, and with no information about its substitution potential for the other substances in the subgroup. Therefore while in principle it would merit an update to its entry to indicate Repr 1B CLH, such a CLH entry update would be considered of low priority due to the low exposure potential.

Of note, there are two nickel salts in this subgroup 5, nickel bis(2-ethylhexanoate) (EC 224-699-9) and 2-ethylhexanoic acid, nickel salt (EC 231-480-1), for which self-classification as Repr. 1B (and also CLH as Carc. 1A, STOT RE 1, Muta. 2, Skin Sens. 1, Resp. Sens. 1, Aquatic Acute 1, Aquatic Chronic 1) is already applied.

There is also one strontium salt in this subgroup (Strontium bis(2-ethylhexanoate) (EC 219-536-3)), which is under testing proposal evaluation. While data on the analogue substance strontium chloride hexahydrate (List 600-046-7) could support a CLH proposal for strontium compounds as Repr. 1B for developmental effects, EC 219-536-3 is already self-classified as Repr. 2 and should adopt the revised harmonised classification as Repr. 1B due to the 2-ethylhexanoic acid moiety.

For four of these substances, registrants indicate only industrial uses (ECs EC 230-794-6, 278-031-6, 413-670-8 and 437-360-7, the latter two being non-updated NONs). The registrants of the other substances also indicate industrial uses and in addition professional uses and article service life for the majority, with a small number indicating consumer uses (4 substances: ECs: 205-249-0, 219-536-3, 243-169-8 and 243-283-8). In addition EC 205-743-6 is listed in the German Printing Inks Ordinance¹¹, which amends the German Consumer Goods Ordinance, as well as in the Swiss Ordinance of the Federal Department of Home Affairs on materials and articles intended to come into contact with foodstuffs. Therefore oral exposure cannot be excluded.

3,5,5-trimethylhexanoic acid (EC 221-975-0) and its salts

Compliance check is ongoing for EC 221-975-0 but results from the requested extended one generation toxicity study (EOGRTS) indicate the substance may warrant a Reprotoxic 1B H360FD classification. Once completed, a group harmonised classification is proposed for the substance and its salts. All the substances indicate industrial and professional uses in their registrations, with EC 264-731-9 additional having consumer uses (as a coating) and EC 264-731-9 and 283-563-7 indicating article service life.

Remaining substances with reproductive toxicity hazards with the potential for release/exposure from industrial, professional, consumer and article uses of the substances.

There is an ongoing compliance check for 3 of the substances (2 short-chain acids EC 200-922-5, 248-570-1, and one long-chain acid EC 248-093-9) where various

⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0692&from=EN>

¹⁰ <https://www.echa.europa.eu/web/guest/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e181d2af93>

¹¹

[https://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&start=/*\[@attr_id=%27bgbl121s5068.pdf%27\]#_bgbl_%2F%2F*%5B%40attr_id%3D%27bgbl121s5068.pdf%27%5D_1649399235305](https://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&start=/*[@attr_id=%27bgbl121s5068.pdf%27]#_bgbl_%2F%2F*%5B%40attr_id%3D%27bgbl121s5068.pdf%27%5D_1649399235305)

higher-tier repeated-dose and reproductive and developmental toxicity studies have been requested to clarify the suspected hazards. Most of the other substances (EC/List 246-885-9, 250-178-0, 261-716-9, 266-369-7, 285-549-6, 421-140-2, 700-021-1, 812-724-1, 940-217-6 and 201-195-7) are UVCBs and long chain acids and salts and read-across to the above substances is used (in particular pivalic acid (EC 200-922-5) and neodecanoic acid (EC 248-093-9)). The preliminary data on pivalic acid (EC 200-922-5) show some developmental effects in a prenatal developmental toxicity (PNDT) study in rats in the presence of maternal toxicity but a PNDT study in a second species and the EOGRTS study are still missing to conclude on this endpoint. The requested OECD TG 414 studies with neodecanoic acid (EC 248-093-9) do not seem to show any effects either in rats or rabbits up to ca. 900 mg/kg bw/d (through feed) but the evaluation is still ongoing. The registrant used an exposure-based adaptation for the EOGRTS study, which also needs to be assessed. Depending on the outcome of the ongoing compliance checks on the source substances, compliance checks could be opened on the other substances to clarify their reproductive and developmental toxicity potential and/or check the read-across validity for repeated dose toxicity (RTD) and reproductive and developmental toxicity.

Of note, strontium decanoate, branched (List 812-724-1) is under testing proposal evaluation and the requested OECD TG 414 study in rats with the source substance strontium chloride hexahydrate (List 600-046-7) showed reduced embryo-foetal survival and skeletal variations and malformations that warrant classification as Repr. 1B for developmental effects. This could already support a CLH proposal for strontium compounds, including List 812-724-1.

Moreover, manganese neodecanoate (EC 248-374-6) is the only manganese compound in the group. Based on the conclusions of the group on simple manganese compounds, there are strong indications that soluble salts and oxides of manganese induce severe adverse effects on sexual function and fertility and on development, warranting classification as Repr. 1B, which could be confirmed for EC 248-374-6 under compliance check.

Registrants of the substances indicate industrial uses, with the registrants of EC 200-922-5 only indicating intermediate uses although the substance is listed in the database BfR Recommendations on Food Contact Materials indicating that oral exposure is likely. The registrants of the remaining substances also indicate professional and consumer uses, and article service life.

The reported professional uses (as lubricants, heat transfer fluids, metal working fluids, hydraulic fluids and in polymer preparations, coatings, fillers, adhesives and inks) are expected to be widespread (at many sites and by many users). Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation. Therefore, a restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals is suggested after CLH for reproductive toxicity. The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Reprotox. 1A/B.

CLH [Reprotox. 1A/B] i) will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 30. In addition upon CLH cat 1B, EFSA (on its own initiative or following a request from a Member State or the Commission) shall re-evaluate their authorisation for EC 200-922-5 for use as a food contact material.

CLH is also a prerequisite to restrict the presence of the substances in clothing, other textiles, and footwear articles, by means of the restriction entry 72 of REACH Annex XVII (this would require addition of the relevant substances to Appendix 12 by the Commission through Article 68(2)).

CLH will also support regulatory action under other regulations. For instance, in this specific case:

- harmonised classification as CMR cat. 1 will trigger regulatory action under the Cosmetic products regulation (EC) No 1223/2009 for uses as fragrance, since CMR cat. 1 are restricted by this regulation.
- harmonised classification as CMR cat. 1 will trigger regulatory action under the biocidal product regulation (EU) 528/2012, which does not allow the use by the general public of a product containing substances above the concentration limit leading to classification of the mixture as CMR cat 1.
- harmonised classification as CMR cat 1 would render the substances unacceptable co-formulants in plant protection products

Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability¹² which aims to extend to professional users under REACH the level of protection granted to consumers.

Moreover, restricting substances in articles used by professionals or consumers¹³ as should be considered due to the potential for exposure from articles. Registrants have indicated a wide range of article service life for the substances including in polymer preparations, adhesives, coatings and paints, inks and toners, paper and board treatment products, textile dyes and impregnating products, and leather treatment products. The registrants have also described the article service life as "low release" and mainly used in industrial and professional settings (except for consumer uses of leather articles).

The restriction may also address industrial uses, but in case that is not possible then authorisation can be considered for the industrial uses.

Based on currently available information, there is a need for (further) EU regulatory risk management – harmonised classification for aquatic toxicity hazards due to the potential for release/ exposure of the substances EC 205-251-1¹⁴, 286-272-3, 283-563-7, 248-370-4, 271-378-4, 282-780-4, and 295-363-7. The hazards for these substances are quite clear based on the toxicity of available zinc data but transformation is incorrectly assessed, the most conservative zinc data is not uniformly applied, and the CLP criteria are incorrectly applied across the

¹² European Commission, Chemical Strategy for Sustainability Towards a Toxic-Free Environment, available at <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

¹³ Reported for substances EC 205-249-0, 205-251-1, 219-536-3, 221-625-7, 239-685-8, 243-169-8, 243-283-8, 286-272-3, 264-731-9, 283-563-7, 250-178-0, 421-140-2, 700-021-1, 812-724-1, 247-978-7, 248-370-4, 248-374-6, 248-375-1, 260-742-8, 282-780-4, 270-296-6, 271-378-4, 295-362-1 and 295-363-7.

¹⁴ Listed in the database BfR Recommendations on Food Contact Materials (https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp?filter=clear) in the section XXXVI and section XV, respectively. Therefore, oral exposure is likely.

zinc salts. Consequently, current self-classifications under-estimate aquatic hazards.

Based on currently available information, it is not possible to assess need for regulatory risk management as information on hazard is not sufficient to conclude on PBT hazards. Consequently, ECHA recommends CCH for PBT hazards due to the potential for release/exposure from industrial, professional, consumer and article uses of the substances: **EC 940-217-6 and EC 243-169-8** and the industrial use of **EC 230-794-6** (the latter two are also a 2-ethylhexanoic acid salts and thus Reprotoxic 1B according to the RAC opinion).

EC 230-794-6: P and B assessments lack reliable information to reach a conclusion. T is confirmed based on Repr 1B for 2-EHA. CCH is recommended to generate data and clarify the considerable uncertainties.

EC 243-169-8: is a UVCB contain 2-EHA salts of Fe¹⁺, Fe²⁺, and Fe³⁺. If EC 230-794-6 is not PBT, no CCH is needed as no concern for PBT.

EC 940-217-6: The registrant assesses the substance as not P but the argumentation is not convincing as test data for the respective acid indicates 0% degradation after 28 days. No B assessment is presented but the Log know for this salt is > 4.5, whereas the acid (285-549-6) is assessed as not B based on RA to 248-093-9 (BCF 225). T appears to be fulfilled based on Repr classification. CCH is recommended to generate data and clarify the considerable uncertainties.

Based on currently available information, there is no need for (further) EU regulatory risk management for reproductive toxicity hazards due to the low potential for release/ exposure from industrial intermediate uses of the substances: **273-114-3 and 285-549-6**. The substances are not classified as Repr. 1B but information from these substances is read-across to substances that are potential reproductive toxicants. While at the same time their registrations only indicate industrial/intermediate uses, the reproductive and developmental hazard could be clarified for these two substances under compliance check.

Based on currently available information, there is no need for (further) EU regulatory risk management for the remaining substances in the group mainly due to the low hazard potential (aquatic toxicity, where toxicity data indicates low/no hazards) or low concern (reproductive and developmental hazard but with limited exposure): 201-796-4, 202-594-9, 202-777-3, 204-145-2, 207-975-3, 209-865-0, 211-464-0, 243-402-3, 298-190-5, 941-570-9, 269-214-1, 273-295-9, 213-961-8.

Based on ECHA's assessment of currently available hazard information, no potential concerns were identified for human health. A few substances in this subgroup are known developmental toxicants (2-propylvaleric acid EC 202-777-3 self-classified as Repr 1A and its salt sodium valproate EC 213-961-8) and based on structural similarity the hazard is suspected for the other short-chain acids and salts. However, they are not proposed for further action regarding reproductive and developmental toxicity as either:

- their registration is inactive (EC/List 243-402-3 and 941-570-9),
- they are only used as intermediates (EC 201-796-4, 202-594-9, 202-777-3, 213-961-8, 209-865-0, 211-464-0), or
- they are only registered at Annex VII with no possibility to request further data under compliance check and lower priority for substance evaluation due to low tonnage (EC 204-145-2 and 207-975-3).

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In addition, a few acids in this subgroup have a long carbon chain or are composed of long carbon chain constituents only (EC 269-214-1, 273-295-9, 298-190-5). Although read-across validity would need to be formally checked, these substances are considered as less likely to be reproductive or developmental toxicants based on carbon chain length and may have a lower priority for further investigation.

The remaining substances are also unlikely to fulfil the PBT/vPvB screening criteria, because they are readily biodegradable, unlikely to be bioaccumulative, or unlikely to fulfil the T criterion.

There is no evidence for substitution potential since there is a wide variety of uses and a variety of functional groups in the structures.

Note, 700-021-1 indicates 'data lacking' for chronic aquatic hazards but warrants classification as Aquatic Chronic 3 based on the surrogate approach. However, as this substance is Annex VII and low hazard it is not recommended for CLH.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. 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 will be updated and conclusions and actions revisited

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
2-ethylhexanoic acid and salts (Subgroup 5) 205-743-6 205-249-0 205-251-1 219-536-3 221-625-7 224-699-9 230-794-6 231-480-1 239-685-8 243-169-8 243-283-8 263-502-0 278-031-6 286-272-3	Known or potential hazard for reproductive toxicity For all substances Known or potential hazard for skin sensitisation for mutagenicity for carcinogenicity for STOT RE For EC 224-699-9 and 231-480-1	Known or potential hazard for aquatic toxicity EC 205-251-1, 224-699-9, 286-272-3, Inconclusive hazard for PBT/vPvB: EC 230-794-6 and 243-169-8	EC 230-794-6, 278-031-6, 413-670-8 and 437-360-7 (latter two being non-updated NONs) indicate only industrial uses. The other substances indicate industrial uses, and in addition professional uses (lubricants, heat transfer fluids, metal working fluids, hydraulic fluids, in polymer preps, coatings, fillers, adhesives and inks)	Need for EU RRM: Restriction Justification: The 18 th ATP to CLP now includes the harmonised classification of this group in CLP Annex VI as Repr. 1B ¹⁵ . This should trigger a restriction on the industrial, professional and consumer uses, and article service life.	First step: Restriction And also CLH for EC 413-670-8 ¹⁶

¹⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0692&from=EN>

¹⁶ EC 413-670-8 has a separate entry in Annex VI to CLP and would need to go through the standard CLH procedure to update the entry (with a dossier etc.).

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Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
413-670-8 437-360-7			and article service life for the majority, with a small number indicating consumer uses (ECs: 205-249-0, 219-536-3, 243-169-8 and 243-283-8).		
3,5,5-trimethylhexanoic acid and salts 221-975-0 220-169-6 258-901-1 264-731-9 283-563-7 299-890-3	Known or potential hazard for reproductive toxicity	Known or potential hazard for aquatic toxicity EC, 221-975-0, 258-901-1, 283-563-7,	All the substances indicate industrial and professional uses in their registrations, with EC 264-731-9 additional having consumer uses (as a coating) and EC 264-731-9 and 283-563-7 indicating article service life. The professional uses include washing and cleaning products as well as lubricants, heat transfer fluids, metal working fluids, and use in polymer preparations, coatings and inks, and there is	Justification: Compliance check is ongoing for EC 221-975-0 but EOGRTS results warrant a Reprotoxic 1B H360FD classification. Once completed, a group harmonised classification is proposed for the substance and its salts.	First step: Pending Action Next steps (if hazard confirmed): CLH

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Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			significant potential for exposure.		
<p><i>Other acids and salts with known or potential hazard for reproductive toxicity plus 12 UVCBs that read-across</i></p> <p>200-922-5 201-195-7 246-885-9 248-093-9 248-570-1 250-178-0 261-716-9 266-369-7 421-140-2 700-021-1 812-724-1 940-217-6</p> <p>(plus 12 UVCBs that read-across)</p> <p>247-978-7 248-370-4 248-374-6 248-375-1 257-446-6</p>	<p>Known or potential hazard for reproductive toxicity</p> <p>Known or potential hazard for STOT RE for 248-374-6</p>	<p>Known or potential hazard for aquatic toxicity all zinc substance (see below).</p>	<p>All indicate industrial uses in their registrations, with EC 200-922-5 only indicating intermediate uses but listed as Food Contact Material indicating likely oral exposure. Remaining substances indicate professional and consumer uses, and article service life.</p> <p>The UVCBs also indicate industrial, professional and consumer uses and article service life.</p> <p>The professional and consumer uses are quite varied and the substances are not structurally similar, they include process regulators, metal working fluids,</p>	<p>Justification: The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration.</p> <p>Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. The restriction should also cover industrial and consumer uses,</p>	<p>First step: Pending Action</p> <p>On-going CCH for EC 200-922-5, 248-093-9, 248-570-1</p> <p>Propose CCH for EC 246-885-9, 201-195-7, 266-369-7, 421-140-2</p> <p>Propose CCH for the 12 UVCBs, depending on FUP</p> <p>Next steps (if hazard confirmed): CLH</p>

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Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
260-742-8 270-064-4 270-296-6 271-378-4 282-780-4 285-549-6 295-362-1			hydraulic fluids for EC 248-093-9, 248-570-1 and 246-885-9, and washing and cleaning products, perfumes and air care products for EC 201-195-7. There is significant potential for exposure.	and article service if possible. Authorisation could be considered for the industrial uses, if the restriction is not able to take care of the concern.	
940-217-6 230-794-6 243-169-8	Known or potential hazard for reproductive toxicity	Known or potential hazard for PBT/vPvB	EC 940-217-6 has industrial and professional uses as washing/cleaning products, lubricants and metal working fluids. There is significant potential for exposure. EC 230-794-6 has only industrial uses, so potentially limited exposures. EC 243-169-8 has industrial and professional uses as lubricants and heat transfer fluids, and	Currently not possible to assess the regulatory needs Justification: It is not possible to assess the needs for regulatory risk management as information on hazard is not sufficient to conclude on PBT/PMT. The needs for regulatory risk management actions will be assessed once	First step: CCH for 940-217-6 and 230-794-6 Propose CCH for 243-169-8 only if 230-794-6 is confirmed PBT

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Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			industrial, professional, consumer and article uses in coatings and inks.	generation of data is completed (CCH).	
All zinc compounds: EC 205-251-1, 286-272-3, 283-563-7, 248-370-4, 271-378-4, 282-780-4, 295-363-7	Known or potential hazard for reproductive toxicity	Known or potential hazard for aquatic toxicity	Industrial, professional, consumer and article uses for: EC 248-374-6, 205-251-1, 286-272-3, 283-563-7, 248-370-4, 271-378-4, 282-780-4., 295-363-7. The professional uses include lubricants, heat transfer fluids, metal working fluids, hydraulic fluids, in polymer preps, coatings, fillers, adhesives and inks. There is significant potential for exposure.	Need for EU RRM: CLH Justification: Harmonised classification followed by implementation of necessary RRMs should be sufficient to ensure safe use for environment.	First step: CLH
273-114-3 285-549-6.	Known or potential hazard	No hazard or unlikely hazard for aquatic toxicity	Industrial intermediate uses only. Limited	Currently no need for EU RRM	First step: Pending Action

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Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
	for reproductive toxicity		potential for exposure.	Justification: Correct self-classification followed by implementation of necessary RRM should be sufficient to ensure safe use.	Wait for the ongoing CCHs on the other substances that these two substances read-across to. Next steps (if hazard confirmed): CCH
243-077-8 248-374-6 261-999-9 278-031-6	Known or potential hazard for reproductive toxicity	Known or potential hazard for aquatic toxicity EC 278-031-6 is claimed to not meet criteria in REACH Annex III, but ECHA approved Read-across indicates potential for aquatic hazards.	Industrial use only for: EC 243-077-8 (washing and cleaning product, extraction agent). Industrial, professional and consumer use as a lubricant: EC 261-999-9, 248-374-6 (potential for exposure).	Currently no need for EU RRM Justification: Correct self-classification followed by implementation of necessary RRM should be sufficient to ensure safe use for environment.	First step: CCHs - Including checking if criteria in REACH Annex III are met for 278-031-6. Pending Action On related substances For Repro Next steps (if hazard confirmed): No action
All remaining substances: 201-796-4 202-594-9 202-777-3	Known or potential hazard for reproductive toxicity	No hazard or unlikely hazard for aquatic toxicity	Wide variety of industrial, professional, consumer and article uses including in	Currently no need for EU RRM Justification:	First step: No action

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Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
204-145-2 207-975-3 209-865-0 211-464-0 213-961-8 243-402-3 269-214-1 273-295-9 298-190-5 941-570-9	For 243-402-3, 941-570-9, 201-796-4, 202-594-9, 202-777-3, 213-961-8, 209-865-0, 211-464-0, 204-145-2 and 207-975-3 No hazard or unlikely hazard For 269-214-1, 273-295-9, 298-190-5		washing and cleaning products, lubricants, heat transfer fluids, metal working fluids, and use in polymer preparations, coatings and inks. Significant potential for exposure.	Overall, no or unlikely hazard that would lead to concern for the reported uses.	

Annex 1: Overview of classifications

Data extracted on 11.05.2022

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers, therefore the number may differ from the C&L inventory which displays number of notifiers.

EC/ List No	CAS numb er	Substance name	Harmonised classification	Classification in registrations ¹⁷	Classification in C&L notifications ¹⁸
205- 249-0	136- 51-6	calcium bis(2- ethylhexanoate)	-	<i>Repr. 2 H361 Eye Damage 1 H318</i>	<i>STOT Single Exp. 3 H335, affected organs: respiratory tract[2 out of 41] Skin Sens. 1 H317[1 out of 41] Acute Tox. 4 H302[1 out of 41] Repr. 2 H361, specific effect: H361d Suspected of damaging the unborn child.[1 out of 41] STOT Single Exp. 3 H335, affected organs: lungs[1 out of 41] Repr. 2 H361, specific effect: d[4 out of 41] Aquatic Chronic 4 H413[1 out of 41] Repr. 2 H361, specific effect: Suspected of damaging fertility. Suspected of damaging the unborn child[5 out of 41] STOT Single Exp. 3 H335[1 out of 41] Repr. 2 H361, specific effect: Suspected of damaging the unborn child.[3 out of 41] Eye Irrit. 2 H319[5 out of 41]</i>

¹⁷ The column gives the classifications in registrations received under REACH. Additional classifications in intermediate and in inactive registrations (if any) are annotated and displayed last. For each classification the table includes information on the hazard category, the hazard statement and any available information on specific effects (relevant for reproductive toxicity), specific concentration limits, M-Factors and affected organs. Two classifications differing in any of these aspects are considered different and are repeated in the table. The columns "Classifications in registrations" and "Classifications in C&L notifications" are empty if there are no Registrations/C&L notifications (hazard is unknown). The value '-' is displayed on the same columns when there are (relevant) submissions but they do not contain self-classifications (substance is not hazardous).

¹⁸ The column gives the additional classifications not found in registrations but found in active or inactive C&L notifications (without distinguishing them). For each classification this column also provides the number of C&L notifications that contain the classification out of the total number of C&L notifications received for the substance. A single C&L notification file submitted by a group of notifiers is only counted once. Therefore, the numbers may differ from the dissemination site which counts number of notifiers.

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					<i>Skin Irrit. 2 H315[8 out of 41]</i>
205-251-1	136-53-8	zinc bis(2-ethylhexanoate)	-	<i>Repr. 2 H361 Eye Irrit. 2 H319 Aquatic Acute 1 H400 Aquatic Chronic 3 H412 (section 6 of the IUCLID dossier indicates Aquatic Chronic 1, M=1)</i>	<i>STOT Single Exp. 3 H335[1 out of 76] Repr. 2 H361, specific effect:d[1 out of 76] Acute Tox. 4 H302[1 out of 76] Skin Sens. 1 H317[1 out of 76] Repr. 2 H361d: Suspected of damaging the unborn child.[1 out of 76] STOT Single Exp. 3 H335, affected organs: respiratory irritation[1 out of 76] Aquatic Chronic 1 H410[2 out of 76] Repr. 2 H361, specific effect: Suspected of damaging fertility. Suspected of damaging the unborn child[6 out of 76] Repr. 2 H361, specific effect: Suspected of damaging the unborn child.[2 out of 76] Skin Irrit. 2 H315[22 out of 76] Aquatic Chronic 2 H411[18 out of 76] STOT Single Exp. 3 H335, specific concentration: >=10[2 out of 76]</i>
243-283-8	19766-89-3	sodium 2-ethylhexanoate	-	<i>Repr. 2 H361</i>	<i>Skin Irrit. 2 H315[16 out of 38] STOT Single Exp. 3 H335, affected organs: Mancanza di dati[1 out of 38] Eye Irrit. 2 H319[15 out of 38] STOT Single Exp. 3 H335[1 out of 38] STOT Single Exp. 3 H335, affected organs: respiratory system[4 out of 38]</i>
221-625-7	3164-85-0	potassium 2-ethylhexanoate	-	<i>Repr. 2 H361 Skin Irrit. 2 H315 Eye Damage 1 H318</i>	<i>Repr. 2 H361, specific effect:d[2 out of 50] Aquatic Chronic 3 H412[1 out of 50] Aquatic Chronic 4 H413[1 out of 50] Repr. 2 H361, specific effect: Developmental toxicity[2 out of 50] Eye Irrit. 2 H319[14 out of 50]</i>
286-272-3	85203-81-2	Hexanoic acid, 2-ethyl-, zinc salt, basic	-	<i>Repr. 2 H361 Eye Irrit. 2 H319</i>	<i>STOT Single Exp. 3 H336, affected organs: Central nervous system[2 out of 22]</i>

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				<i>Aquatic Chronic 3 H412</i>	<i>STOT Rep. Exp. 2 H373, affected organs: Blood, Kidney, Pancreas[2 out of 22] Aquatic Chronic 2 H411[8 out of 22] Skin Irrit. 2 H315[11 out of 22] Repr. 2 H361, specific effect:d[1 out of 22] Aquatic Acute 1 H400[2 out of 22]</i>
413-670-8	-	nitrilotriethylene ammoniopropyl 2-ethylhexanoate (published ELINCS name)	<i>Skin Sens. 1 H317 Eye Irrit. 2 H319</i>	-	<i>Skin Sens. 1 H317[1 out of 1] Eye Irrit. 2 H319[1 out of 1] Aquatic Chronic 3 H412[1 out of 1]</i>
219-536-3	2457-02-5	strontium bis(2-ethylhexanoate)	-	<i>Repr. 2 H361, specific effect:H361d: Suspected of damaging the unborn child Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Damage 1 H318</i>	<i>Aquatic Chronic 4 H413[1 out of 8] Skin Sens. 1 H317[1 out of 8]</i>
243-169-8	19583-54-1	2-ethylhexanoic acid, iron salt (published EINECS name)	-	<i>Repr. 2 H361, specific effect:H361d: Suspected of damaging the unborn child. Acute Tox. 4 H302</i>	<i>Aquatic Chronic 2 H411[1 out of 12] Aquatic Chronic 4 H413[1 out of 12] Eye Irrit. 2 H319[1 out of 12] Skin Irrit. 2 H315[3 out of 12] Repr. 2 H361, specific effect:H361d Suspected of damaging the unborn child.[1 out of 12]</i>
230-794-6	7321-53-1	iron tris(2-ethylhexanoate)	-	-	<i>Eye Irrit. 2 H319[1 out of 6] Skin Irrit. 2 H315[1 out of 6]</i>
224-699-9	4454-16-4	nickel bis(2-ethylhexanoate)	<i>Carc. 1A H350i Repr. 1B H360D STOT RE 1 H372 Aquatic Acute 1 H400 Muta. 2 H341 Skin Sens. 1 H317 Resp. Sens. 1 H334 Aquatic Chronic 1 H410</i>	<i>Carc. 1A H350 Muta. 2 H341 Repr. 1B H360, specific effect:H360D: May damage the unborn child. Acute Tox. 4 H302 Resp. Sens. 1 H334 Skin Sens. 1 H317, specific concentration: >=.01</i>	<i>Skin Irrit. 2 H315[1 out of 3] STOT Single Exp. 2 H371, affected organs: Damage to organs[1 out of 3] Eye Irrit. 2 H319[1 out of 3] Skin Sens. 1 H317[2 out of 3] STOT Rep. Exp. 1 H372, specific concentration: >=1[2 out of 3] STOT Rep. Exp. 1 H372, affected organs: Damage to organs[1 out of 3] Aquatic Chronic 1 H410[3 out of 3]</i>

ASSESSMENT OF REGULATORY NEEDS

				<i>STOT Rep. Exp. 1 H372, affected organs: respiratory tract, specific concentration: >=1 Aquatic Acute 1, M=1 H400 Aquatic Chronic H400</i>	<i>Acute Tox. 4 H332[1 out of 3] Acute Tox. 4 H312[1 out of 3] Repr. 1B H360, specific effect:D[2 out of 3] Repr. 1B H360, specific effect: May damage the unborn child.[1 out of 3]</i>
239-685-8	15602-15-0	magnesium 2-ethylhexanoate	-	<i>Repr. 2 H361, specific effect:H361d: Suspected of damaging the unborn child Eye Damage 1 H318</i>	<i>Eye Irrit. 2 H319[1 out of 11] Repr. 2 H361, specific effect:H361d Suspected of damaging the unborn child.[1 out of 11] Repr. 2 H361[2 out of 11] Skin Corr. 1B H314[1 out of 11] Flam. Solid 1 H228[1 out of 11]</i>
263-502-0	62314-22-1	(2-hydroxypropyl)trimethylammonium 2-ethylhexanoate	-	<i>Repr. 2 H361 Skin Corr. 1C H314 Eye Damage 1 H318</i>	<i>Acute Tox. 4 H302[2 out of 3] Eye Irrit. 2 H319[2 out of 3]</i>
278-031-6	74931-55-8	2-ethylhexanoic acid, compound with 2-aminoethanol (1:1) (published EINECS name)	-	<i>Repr. 2 H361, specific effect: Suspected of damaging the unborn child Skin Corr. 1B H314 Eye Damage 1 H318</i>	-
231-480-1	7580-31-6	2-ethylhexanoic acid, nickel salt (published EINECS name)	<i>Carc. 1A H350i Repr. 1B H360D STOT RE 1 H372 Aquatic Acute 1 H400 Muta. 2 H341 Skin Sens. 1 H317 Resp. Sens. 1 H334 Aquatic Chronic 1 H410</i>	-	<i>Skin Sens. 1 H317[1 out of 2] Skin Sens. 1 H317, specific concentration: >=.01[1 out of 2] Resp. Sens. 1 H334[2 out of 2] Repr. 1B H360, specific effect:D[1 out of 2] Muta. 2 H341[2 out of 2] Aquatic Acute 1 H400[2 out of 2] Carc. 1A H350[2 out of 2] STOT Rep. Exp. 1 H372, affected organs: Damage to Organs[1 out of 2] STOT Rep. Exp. 1 H372, specific concentration: >=1[1 out of 2] Aquatic Chronic 1 H410[2 out of 2] Repr. 1B H360, specific effect: May damage the unborn child.[1 out of 2]</i>
437-360-7	-	No published name in ELINCS	-	-	<i>Acute Tox. 4 H312[1 out of 1]</i>

ASSESSMENT OF REGULATORY NEEDS

					<i>Skin Irrit. 2 H315[1 out of 1] Eye Irrit. 2 H319[1 out of 1]</i>
220-169-6	2650-30-8	sodium 3,5,5-trimethylhexanoate	-	<i>Acute Tox. 4 H302 Skin Corr. 1 H314 Eye Damage 1 H318</i>	-
299-890-3	93918-10-6	potassium 3,5,5-trimethylhexanoate	-	<i>Acute Tox. 4 H302 Skin Corr. 1 H314 Eye Damage 1 H318</i>	<i>Skin Irrit. 2 H315[2 out of 4] Eye Irrit. 2 H319[2 out of 4]</i>
264-731-9	64216-15-5	calcium 3,5,5-trimethylhexanoate	-	<i>Acute Tox. 4 H302 Eye Irrit. 2 H319</i>	-
283-563-7	84682-03-1	zinc 3,5,5-trimethylhexanoate	-	<i>Aquatic Acute 1, M=1 H400 Aquatic Chronic 3 H412</i>	-
243-077-8	19455-20-0	potassium isobutyrate	-	-	-
213-961-8	1069-66-5	sodium valproate	-	-	<i>Eye Damage 1 H318[5 out of 15] Repr. 1B H360, specific effect: H360D: May damage the unborn child[2 out of 15] Skin Irrit. 2 H315[9 out of 15] STOT Single Exp. 3 H335, affected organs: Respiratory system[2 out of 15] Repr. 1A H360[4 out of 15] Acute Tox. 4 H302[14 out of 15] STOT Rep. Exp. 1 H372, affected organs: Affected organs[1 out of 15] STOT Single Exp. 3 H335, affected organs: lungs[2 out of 15] Eye Irrit. 2 H319[4 out of 15] Repr. 1B H360[2 out of 15] Repr. 1A H360, specific effect: H360Df: May damage the unborn child, suspected of damaging fertility[4 out of 15] STOT Single Exp. 2 H371, affected organs: liver[1 out of 15]</i>
421-140-2	-	No published name in ELINCS	-	<i>Repr. 2 H361</i>	-

ASSESSMENT OF REGULATORY NEEDS

				<i>Skin Sens. 1B H317 Aquatic Chronic 3 H412</i>	
700-021-1	79992 -76-0	magnesium bis(2-ethylbutanoate); Butanoic acid, 2-ethyl-, magnesium salt (2:1)	-	<i>Skin Sens. 1 H317 Aquatic Acute 3 H402</i>	-
258-901-1	53988 -05-9	calcium isononanoate	-	-	<i>Acute Tox. 4 H302[4 out of 13] Eye Irrit. 2 H319[5 out of 13] Aquatic Chronic 4 H413[1 out of 13] Skin Irrit. 2 H315[4 out of 13]</i>
261-999-9	59963 -30-3	calcium isoctadecanoate	-	-	-
266-369-7	66469 -15-6	potassium isoctadecanoate	-	-	-
812-724-1	10670 5-37-7	Strontium decanoate, branched; Strontium neodecanoate	-	<i>Acute Tox. 4 H302 Eye Damage 1 H318</i>	-
248-374-6	27253 -32-3	manganese neodecanoate	-	<i>STOT Rep. Exp. 2 H373, affected organs: brain</i>	<i>Aquatic Chronic 4 H413[1 out of 15] Acute Tox. 4 H302[4 out of 15] Eye Irrit. 2 H319[2 out of 15] Acute Tox. 4 H332[2 out of 15] Skin Irrit. 2 H315[8 out of 15]</i>
260-742-8	57453 -97-1	magnesium neodecanoate	-	<i>Skin Irrit. 2 H315 Eye Damage 1 H318</i>	-
248-370-4	27253 -29-8	zinc neodecanoate	-	<i>Aquatic Chronic 3 H412</i>	<i>Aquatic Acute 1 H400[2 out of 33] Aquatic Chronic 1 H410[2 out of 33] Eye Irrit. 2 H319[4 out of 33] Aquatic Chronic 2 H411[6 out of 33] Skin Irrit. 2 H315[8 out of 33] Acute Tox. 4 H302[2 out of 33] STOT Rep. Exp. 2 H373[1 out of 33] STOT Single Exp. 3 H335[1 out of 33]</i>

ASSESSMENT OF REGULATORY NEEDS

282-780-4	84418 -68-8	Neodecanoic acid, zinc salt, basic	-	<i>Aquatic Acute 1, M=1 H400 Aquatic Chronic 2 H411</i>	<i>Skin Irrit. 2 H315[3 out of 6] Aquatic Chronic 3 H412[1 out of 6]</i>
248-375-1	27253 -33-4	calcium neodecanoate	-	<i>Skin Irrit. 2 H315 Eye Damage 1 H318</i>	-
247-978-7	26761 -42-2	potassium neodecanoate	-	<i>Skin Irrit. 2 H315 Eye Damage 1 H318</i>	<i>Eye Irrit. 2 H319[3 out of 9]</i>
257-446-6	51818 -55-4	neodecanoic acid, iron salt	-	<i>Acute Tox. 4 H302 Skin Irrit. 2 H315</i>	<i>Aquatic Chronic 3 H412[1 out of 1]</i>
270-296-6	68424 -35-1	Fatty acids, C9-13-neo-, calcium salts	-	<i>Aquatic Chronic 3 H412 [Article 10 (inactive)] Eye Irrit. 2 H319 [Article 10 (inactive)]</i>	<i>Skin Irrit. 2 H315[2 out of 7]</i>
295-362-1	92044 -83-2	Fatty acids, C9-13-neo-, potassium salts	-	<i>Skin Irrit. 2 H315 Eye Damage 1 H318</i>	-
270-064-4	68409 -80-3	Fatty acids, C6-19-branched, calcium salts	-	-	<i>Skin Irrit. 2 H315[7 out of 10] Aquatic Chronic 4 H413[1 out of 10]</i>
940-217-6	-	Fatty acids, C10-20-neo, potassium salts	-	<i>Repr. 2 H361, specific effect: Developmental Eye Irrit. 2 H319 Aquatic Chronic 2 H411</i>	-
271-378-4	68551 -44-0	Fatty acids, C6-19-branched, zinc salts	-	<i>Aquatic Chronic 2 H411</i>	<i>Skin Irrit. 2 H315[12 out of 16] Eye Irrit. 2 H319[1 out of 16] Aquatic Acute 1 H400[2 out of 16]</i>
295-363-7	92044 -84-3	Fatty acids, C9-13-neo-, zinc salts	-	<i>Aquatic Chronic 3 H412</i>	-
200-922-5	75-98-9	pivalic acid		<i>Acute Tox. 4 H302 Eye Irrit. 2 H319 Skin Irrit. 2 H315</i>	<i>Acute Tox. 3 H331 Acute Tox. 4 H312 Acute Tox. 4 H332 Skin Corr. 1B H314 Eye Dam. 1 H318 Met. Corr. 1 H290 Not Classified</i>
201-195-7	79-31-2	isobutyric acid		<i>Acute Tox. 3 H311 Skin Corr. 1B H314 Eye Dam. 1</i>	<i>Acute Tox. 3 H301 Acute Tox. 4 H332 Skin Corr. 1C H314</i>

ASSESSMENT OF REGULATORY NEEDS

				<i>H318 Flam. Liq. 3 H226</i>	
201-796-4	88-09-5	2-ethylbutyric acid		<i>Acute Tox. 3 H311 Eye Irrit. 2 H319 Skin Irrit. 2 H315 STOT RE 2 H373 (Blood, liver, and kidneys, Oral)</i>	<i>Acute Tox. 4 H312 Eye Dam. 1 H318 STOT SE 3 H335 Repr. 2 H361 Aquatic Chronic 2 H411</i>
202-594-9	97-61-0	2-methylvaleric acid		<i>Acute Tox. 5 H303 Acute Tox. 5 H313 Skin Corr. 1C H314 Eye Dam. 1 H318</i>	<i>Acute Tox. 4 H312 Skin Corr. 1B H314 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Met. Corr. 1 H290</i>
202-777-3	99-66-1	2-propylvaleric acid		<i>Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Dam. 1 H318 Repr. 1A H360 Repr. 1B H360</i>	<i>Acute Tox. 4 H312 Acute Tox. 4 H332 Skin Corr. 1B H314 Eye Irrit. 2 H319 STOT SE 3 H335</i>
204-145-2		2-methylbutyric acid		<i>Acute Tox. 4 H302 Acute Tox. 4 H312 Eye Damage 1 H318 Skin Corr. 1B H314</i>	<i>Acute Tox. 3 H301 Acute Tox. 3 H311 Skin Corr. 1C H314 Skin Sens. 1 H317 Asp. Tox. 1 H304 Aquatic Chronic 2 H411 Flam. Liq. 3 H226 Flam. Liq. 4 H227 Met. Corr. 1 H290 Not Classified</i>
205-743-6	149-57-5	2-ethylhexanoic acid	<i>Repr. 2 H361d</i>	<i>Aquatic Chronic 3 H402</i>	<i>Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314 Eye Dam. 1 H318 Eye Irrit. 2 H319 Aquatic Chronic 3 H412</i>
207-975-3	503-74-2	isovaleric acid		<i>Skin Corr. 1B H314 Eye Dam. 1 H318</i>	<i>Acute Tox. 3 H311 Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1C H314 Met. Corr. 1 H290</i>

ASSESSMENT OF REGULATORY NEEDS

209-865-0	116-53-0	2,2-dimethylbutyric acid		<i>Acute Tox. 4 H302 Eye Damage 1 H318 Skin Irrit. 2 H315</i>	<i>Eye Irrit. 2 H319 Skin Corr. 1C H314 STOT SE 3 H335 Met. Corr. 1 H290</i>
211-464-0	646-07-1	4-methylvaleric acid		<i>Acute Tox. 4 H312 Eye Irrit. 2 H319 Skin Irrit. 2 H315</i>	<i>Acute Tox. 3 H311 Acute Tox. 4 H302 Skin Corr. 1B H314 Skin Corr. 1C H314 Eye Dam. 1 H318</i>
221-975-0	3302-10-1	3,5,5-trimethylhexanoic acid		<i>Acute Tox. 4 H302 Eye Dam. 1 H318 Skin Irrit. 2 H315</i>	<i>Eye Irrit. 2 H319 STOT SE 3 H335 Aquatic Chronic 3 H412</i>
243-402-3	19889-37-3	2-ethyl-2-methylbutyric acid		<i>Acute Tox. 4 H302 Eye Irrit. 2 H319 Skin Irrit. 2 H315 STOT SE 3 H335 (Inhalation)</i>	<i>Not Classified Eye Irrit. 2 H319 Skin Irrit. 2 H315 STOT SE 3 H335 Acute Tox. 4 H302</i>
246-885-9	25354-97-6	2-hexyldecanoic acid		<i>Skin Sens. 1 H317</i>	<i>Eye Irrit. 2 H319 Skin Irrit. 2 H315 STOT SE 3 H335 Aquatic Chronic 3 H412</i>
248-093-9	26896-20-8	neodecanoic acid		-	<i>Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Dam. 1 H318 Eye Irrit. 2 H319 STOT SE 3 H335 Aquatic Chronic 3 H412 Not classified</i>
248-570-1	27610-92-0	2-butyloctanoic acid		-	<i>Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335 Aquatic Chronic 3 H412 Not Classified</i>
250-178-0	30399-84-9	isooctadecanoic acid		-	<i>Skin Irrit. 2 H315 Not Classified</i>
261-716-9	59354-78-8	neononanoic acid		-	<i>Not Classified</i>

ASSESSMENT OF REGULATORY NEEDS

269-214-1	68201-37-6	Octadecanoic acid, branched and linear		-	-
273-114-3	68938-07-8	Fatty acids, C9-13-neo-		<i>Aquatic Chronic 3 H412</i>	<i>Acute Tox. 4 H302 Not Classified</i>
273-295-9	68955-98-6	Fatty acids, C16-18 and C18-unsatd., branched and linear		-	<i>Eye Irrit. 2 H319 Not Classified</i>
285-549-6	85116-96-7	Fatty acids, C10-20-neo-		<i>Skin Sens. 1 H317 Aquatic Chronic 2 H411</i>	<i>Acute Tox. 4 H302 Aquatic Chronic 3 H412 Not Classified</i>
298-190-5	93778-52-0	2-decyltetradecanoic acid		<i>Not Classified</i>	
941-570-9	-	Reaction mass of 2-butylheptanoic acid and 2-ethylnonanoic acid and 2-methyldecanoic acid and 2-propyloctanoic acid		<i>Eye Irrit. 2 H319 Skin Irrit. 2 H315</i>	-

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

Data extracted on 28/02/2022

Subgroups 1, 2 and 3

Subgroup	EC number	PC 20: Products such as pH-regulators, flocculants, precipitants, neutralisation agents	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 24: Lubricants, greases, release products	PC 25: Metal working fluids	PC 16: Heat transfer fluids	PC 17: Hydraulic fluids	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9a: Coatings and paints, thinners, paint removers	PC 18: Ink and toners	PC 14: Metal surface treatment products	PC 21: Laboratory chemicals	PC 19: Intermediate	PC 30: Photo-chemicals	
1	200-922-5							I												I	F, I	I	
1	201-195-7			I, P, C	C	F, I, C	C	F, I, C	F, I	P, C											I		
1	201-796-4																					I	
1	202-594-9																					I	
1	202-777-3								I													I	
1	204-145-2			I, P, C	C	F, C	C	P, C		P, C												I	
1	205-743-6		P		F						I, P	I, P		I, P			F, I			I, P	I		
1	207-975-3			I, P, C	C	F, C	C	P, C		P, C												I	
1	209-865-0																					I	
1	211-464-0																					I	
1	221-975-0										I, P	I, P		I, P			F, I, P			I, P	F, I, P		
1	243-402-3																					I	
1	246-885-9	I, P																			F, I, P	I	
1	248-570-1							F, C			I, P	I, P	I, P	I, P					I, P				
1	298-190-5	I		I																	I		
1	941-570-9	I		I																	I		
2	248-093-9	F, I									I, P		I, P	I, P	I	I	F, I	F, I				I	
2	261-716-9																					I	
3	273-114-3																					I	
3	285-549-6																					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

Subgroup 4

EC number	PC 20: Products such as pH-regulators, flocculants, precipitants, neutralisation agents	PC 36: Water softeners	PC 37: Water treatment chemicals	PC 2: Adsorbents	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 24: Lubricants, greases, release products	PC 25: Metal working 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 21: Laboratory chemicals
250-178-0	I, P	I, P, C	F, I, P, C	I	F, I, P, C	P, C	C	F, I, P, C	I, P, C	C	C	F, P, C	I, P	P, C	F, I, P, C	I, P	F, I, P, C	F, I, P, C, A	P, C	F, I, C	F, I, P, C	I, P, C	I	F, I	F, I, P, C, A	I	F, I, P	
269-214-1	I, P	I, P, C	F, I, P, C	I	F, I, P, C	P, C	C	F, I, P, C	I, P, C	C	C	F, P, C	I, P	P, C	F, I, P, C	I, P	F, I, P, C	F, I, P, C	F, I, P, C	P, C	F, I, C	F, I, P, C	I, P, C	I	F, I	F, I, P, C, A	I	F, I, P
273-295-9	I, P	I, P, C	F, I, P, C	I	F, I, P, C	P, C	C	F, I, P, C	I, P, C	C	C	F, P, C	I, P	P, C	F, I, P, C	I, P	F, I, P, C	F, I, P, A	F, I, P, C	P, C	F, I, C	F, I, P, C	F, I, P, C	I, A	F, I	F, I, P, C, A	I	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

Subgroup 5: 2-Ethylhexanoic acid (EHA) salts

EC number	PC 20: Products such as pH-regulators, flocculants, precipitants, neutralisation agents	PC 37: Water treatment chemicals	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 24: Lubricants, greases, release products	PC 25: Metal working fluids	PC 16: Heat transfer fluids	PC 17: Hydraulic fluids	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removers	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 14: Metal surface treatment products	PC 7: Base metals and alloys	PC 21: Laboratory chemicals	PC 19: Intermediate	PC 40: Extraction agents	PC 41: Oil and gas exploration or production products
205-249-0	F, I									P				F, I, A			F, I, P, C, A	F, I, P, C								
205-251-1	F, I									F, I, P				F, I, A	F, I											F, I
219-536-3										F, I, P	F	F, I, P		F, I, A			F, I, P, C, A	F, I, P, C, A	A			I				
221-625-7										F, P				F, I, P, A	I, P	I, P	I, P							I		
224-699-9														F, I										F, I		
230-794-6														F	F		F, I	F, I								
231-480-1																										
239-685-8														F, I, A												
243-169-8										F, I, P	F	F, I, P		F, I, A			F, I, P, C, A	F, I, P, C				I				
243-283-8												F, I, P, C	F, I, P, C	F, I, A									I			
263-502-0														F, I, P	F, I, P		F, I, P						F, I, P	I		
278-031-6														F												I
286-272-3	F, I									F, I, P	F		F, I, P	F, I, A	F		F, I, P, C, A							F		
413-670-8																										
437-360-7																										

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

Subgroup 6: Salts of well-defined carboxylic acids

EC number	PC 20: Products such as pH-regulators, flocculants, precipitants, neutralisation agents	PC 37: Water treatment chemicals	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 24: Lubricants, greases, release products	PC 25: Metal working fluids	PC 16: Heat transfer fluids	PC 17: Hydraulic fluids	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removers	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 14: Metal surface treatment products	PC 7: Base metals and alloys	PC 21: Laboratory chemicals	PC 19: Intermediate	PC 40: Extraction agents	PC 41: Oil and gas exploration or production products
213-961-8																										
220-169-6		I, P	I, P					I, P															I			
243-077-8			I																							
264-731-9																	F, I, P, C, A								F, I	
283-563-7														F, I, A												
299-890-3		I, P	I, P					I, P						F, I						F, I						
421-140-2														I, A												
700-021-1														I, A												

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

Subgroup 8: Salts of branched fatty acids

EC number	PC 20: Products such as pH-regulators, flocculants, precipitants, neutralisation agents	PC 37: Water treatment chemicals	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 24: Lubricants, greases, release products	PC 25: Metal working fluids	PC 16: Heat transfer fluids	PC 17: Hydraulic fluids	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removers	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 14: Metal surface treatment products	PC 7: Base metals and alloys	PC 21: Laboratory chemicals	PC 19: Intermediate	PC 40: Extraction agents	PC 41: Oil and gas exploration or production products
270-064-4																	F, I, P, C	F, I, P, C								
270-296-6																	F, I, P, C, A	F, I, P, C								
271-378-4	I									F, I, P	F		F, I, P	F			F, I, P, C, A	F, I, P, C					F			
295-362-1																	F, I, A									
295-363-7										F, P							F, I, A									
940-217-6			F, I, P							F, I, P	F, I, P		F, I										F, I			

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

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

Data extracted on 10/03/2022

EC/List number	RMOA	Authorisation		Restriction		CLH	Actions not under REACH/ CLP*
		Candidate List	Annex XIV	Annex XVII	Annex VI (CLP)		
205-249-0						Ongoing	
205-251-1						Ongoing	
219-536-3						Ongoing	
221-625-7						Ongoing	
224-699-9						Ongoing	
230-794-6						Ongoing	
231-480-1						Ongoing	
239-685-8						Ongoing	
243-169-8						Ongoing	
243-283-8						Ongoing	
263-502-0						Ongoing	
278-031-6						Ongoing	
286-272-3						Ongoing	
413-670-8						Ongoing	
437-360-7						Ongoing	

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g., when the scope of the restriction is defined by its classification or the substance identification is broad (e.g., entries 3, 28-30 and 40).

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