

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 20 October 2021

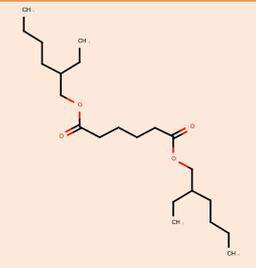
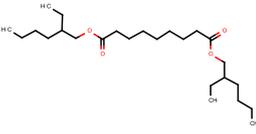
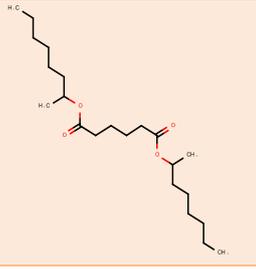
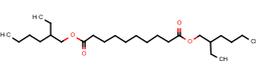
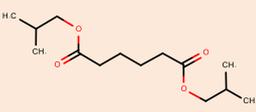
Group Name: Esters from linear saturated dicarboxylic acids and branched aliphatic alcohols

General structure: -

Revision history

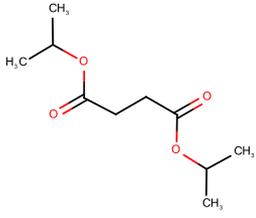
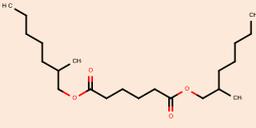
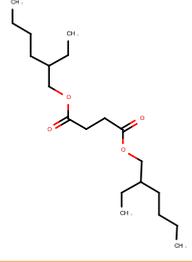
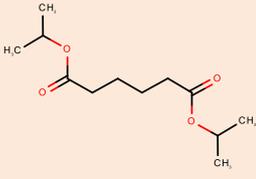
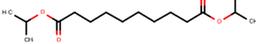
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ASSESSMENT OF REGULATORY NEEDS

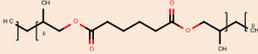
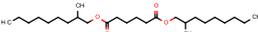
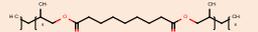
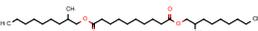
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203-090-1	103-23-1	bis(2-ethylhexyl) adipate		Full, >1000 T
203-091-7	103-24-2	bis(2-ethylhexyl) azelate		Full, 100-1000 T
203-601-8	108-63-4	bis(1- methylheptyl) adipate		Full, not (publicly) available
204-558-8	122-62-3	bis(2-ethylhexyl) sebacate		Full, 100-1000 T
205-450-3	141-04-8	diisobutyl adipate		Full, not (publicly) available

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

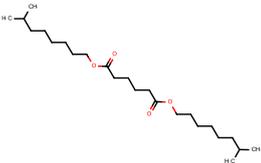
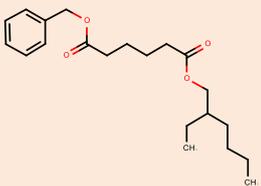
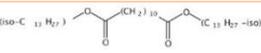
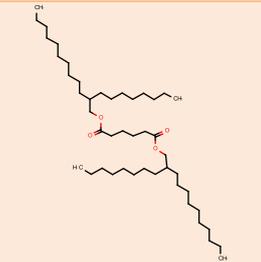
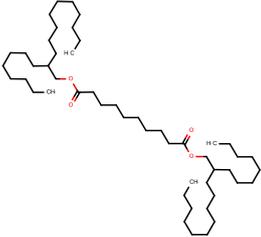
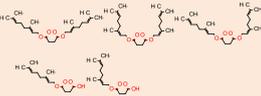
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EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
213-110-0	924-88-9	diisopropyl succinate		Full, not (publicly) available
215-553-5	1330-86-5	diisooctyl adipate		Full, 100-1000 T
220-836-1	2915-57-3	bis(2-ethylhexyl) succinate		Full, 1-10 T
230-072-0	6938-94-9	diisopropyl adipate		Full, 100-1000 T
231-306-4	7491-02-3	diisopropyl sebacate		Full, 100-1000 T

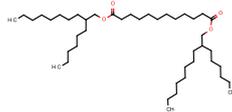
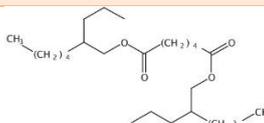
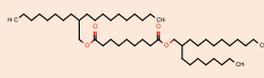
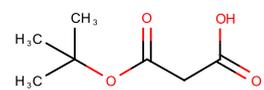
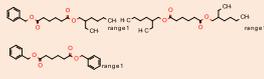
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247-660-8	26401-35-4	diisotridecyl adipate		Full, >1000 T
248-299-9	27178-16-1	diisodecyl adipate		Full, >1000 T
249-044-4	28472-97-1	diisodecyl azelate	 Rep structure (UVCB)	Full, >1000 T
249-047-0	28473-19-0	diisodecyl sebacate		Full, not (publicly) available
249-282-9	28880-24-2	diisooctyl succinate		Full, not (publicly) available

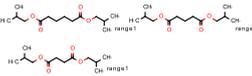
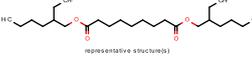
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EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
251-646-7	33703-08-1	diisononyl adipate		Full, >1000 T
261-234-9	58394-64-2	benzyl 2-ethylhexyl adipate		Not registered
283-822-4	84731-63-5	diisotridecyl dodecanedioate		Not registered
285-645-8	85117-94-8	bis(2-octyldodecyl) adipate		Not registered
401-590-6		KE 1951		NONS, not (publicly) available
415-190-4		A mixture of: ((Z)-3,7-dimethyl-2,6-octadienyl)oxycarbon ylpropanoic acid; di-((E)-3,7-dimethyl-2,6-octadienyl) butandioate; di-((Z)-3,7-dimethyl-2,6-octadienyl) butandioate; (Z)-3,7-dimethyl-2,6-octadienyl butandioate; ((E)-3,7-dimethyl-2,6-octadienyl)oxycarbon ylpropanoic acid		NONS, not (publicly) available

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439-900-7	2135940-09-7	bis(2-hexyldecyl)dodecane dioate	 <p>Representative structure (UVCB)</p>	NONS, not (publicly) available
451-450-3		<i>No public or meaningful name is available</i>		NONS, not (publicly) available
940-510-9	103043-58-9	Hexanedioic acid, 1,6-bis(2-propylheptyl) ester		Full, 100-1000 T
618-295-5	897626-46-9	Nonanedioic acid, 1,9-bis(2-octyldecyl) ester		Full, not (publicly) available
628-204-0	40052-13-9	3-(tert-butoxy)-3-oxopropanoic acid		TII or OSII, not (publicly) available
905-983-8		Reaction mass of benzyl 2-ethylhexyl adipate and bis(2-ethylhexyl) adipate and dibenzyl adipate		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
907-870-9		Reaction mass of bis(2-methylpropyl) pentanedioate and bis(2-methylpropyl)		Full, >1000 T
939-783-7	1474044-83-1	Decanedioic acid, reaction products with adipic acid and isotridecanol		Inactive, not (publicly) available
945-069-6		Diesters of alcohols, C7-9-iso-, C8-rich, 2-ethylhexyl and nonanedioic acid		Full, not (publicly) available

This table does not contain group members that are only notified under the CLP Regulation. 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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The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The 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
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
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
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials

1 Overview of the group

ECHA has grouped together 31 structurally similar substances defined as esters of linear saturated dicarboxylic acids and of branched alcohols.

The substances do not have any other functionality besides the dicarboxylates. Aromatic substances are not specifically covered by this group, but several substances of unknown or variable composition, complex reaction products or biological materials (UVCBs) of this group contain constituents with an aromatic moiety. The level of esterification varies between mono-esters and di-esters. The variable element of the substances in this group is the length of the carbon chains and positions and length of the branching. The dicarboxylate chain length ranges between C2 and C10, and the alcohol chain between C1 and C20.

This group is related to the group 'Esters from linear saturated dicarboxylic acids and of linear or cyclic aliphatic alcohols'. Some of the substances from both groups belong to the same registrant's category(ies) such as the 'Polyfunctional liphatic Ester (PFAE) linear' category and the 'Dibasic ester' category. Additionally, the group 'Linear dicarboxylic acids and their salts' and the group 'Branched primary alkyl alcohols', are also related to the current group based on their expected hydrolysis products.

21 of the substances have full registrations whereas 5 have on-site isolated intermediate or transported isolated intermediate registrations (TII or OSII). Based on information reported in the REACH registration dossiers, most substances in the group have uses in professional setting or consumer mixtures and/or articles, where exposure to human health and releases to the environment can be expected. The most common sectors or applications are lubricants, plastic/rubber, polymers, coatings, paints, cosmetics, washing and cleaning products, functional fluids. Other applications include water treatment, explosives, agrochemicals, fertilisers, fragrances, pharmaceuticals, polishes & waxes, adhesives, textiles/leather, biocide/pest control, fuels. The articles in which the substances can end up include plastic/rubber articles, textiles, explosives, coated articles, or soldered materials.

Most of the substances are used as plasticiser, binder and release agent, solvent, lubricant, functional fluid, intermediate and laboratory chemical.

Concerning plasticisers, three substances were identified as alternatives to phthalates, more specifically to bis(2-ethylhexyl) phthalate (DEHP, EC 204-211-0), and nine other substances are indicated to be plasticisers.

In relation to the potential for interchangeability, for substances that have the same application and similar structure, only the length of the carbon chains and branching pattern could have an impact. One could therefore expect that substances having both similar carbon chain length and/or similar branching pattern might be interchangeable in their uses.

One substance from this group, bis(2-ethylhexyl) adipate (EC 203-090-1) was assessed under substance evaluation (SEv) in 2020 for initial endocrine disruption, reproductive and developmental toxicity concerns based on its structural similarity with DEHP and use as plasticiser.

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

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for potential reproductive toxicity due to the potential for release/ exposure of the substances EC 203-090-1, EC 203-091-7, EC 203-601-8, EC 204-558-8, EC 215-553-5, EC 230-072-0, EC 231-306-4, EC 247-660-8, EC 248-299-9, EC 249-044-4, EC 249-047-0, EC 251-646-7, EC 283-822-4, EC 285-645-8, EC 618-295-5, EC 905-983-8, EC 907-870-9, EC 940-510-9, EC 945-069-6 in the group.

Overall, based on ECHA's assessment, from the human health side, all substances are potentially reproductive toxicants based on information from the existing studies available in the registration dossiers, the conclusions of the SEv report on EC 203-090-1, use of read-across adaptations and/or extrapolation due to structural similarity.

The fertility studies with EC 203-090-1 (OECD TG 415), EC 203-091-7 (OECD TG 422) and EC 905-983-8 (OECD TG 421) did not show any effect on the fertility index up to the limit dose of 1000 mg/kg bw/d. However, an increase in estrous cycle length in rats was observed in the high dose groups with EC 203-091-7 in the OECD TG 422 study and with EC 203-090-1 in an OECD TG 407 study. In addition, EC 203-090-1 caused an increase in ovarian follicle atresia in the latter study. Ovarian toxicity and disturbance of estrous cycle with EC 203-090-1 was also reported in rats treated for 2 or 4 weeks by gavage at doses of 1000 mg/kg bw/d and above in a non-guideline fertility study provided in the dossier. These results point at a possible effect of these substances on reproductive organs and functions in the female rats.

Regarding developmental toxicity, the available prenatal developmental toxicity studies in rats showed some poor or delayed ossification with EC 203-090-1 at

1800 ppm (equivalent to 170 mg/kg bw/d) and EC 905-983-8 at 500 mg/kg bw/d and above, in the absence of clear maternal toxicity. Some visceral defects in the pups (kinked and dilated ureter) were also noted with EC 203-090-1 but reported within the historical control range by the registrant. These effects were not confirmed in prenatal developmental toxicity studies in rabbits, although it should be noted that the highest dose tested for EC 203-090-1 was limited by maternal systemic toxicity to 145 mg/kg bw. In the OECD TG 414 studies with EC 249-047-0 and EC 940-510-9, a statistically significant decrease in fetal body weight was observed, together with a generalised reduction in ossification with EC 940-510-9, but associated with maternal toxicity for both substances.

There is no information on the possible mode of action for the effects observed and whether they can be attributed to the parent substance or to breakdown products. All group members are esters of dicarboxylic acid and there is a potential to hydrolyse by esterases in the body. On the basis of structural similarity and/or possible similarity on metabolic pathways the hazards identified are extrapolated to all group members.

From the environmental side, all substances in the group are potentially toxic to aquatic organisms except for EC 940-510-9 and EC 213-110-0. As there is an extensive use of read-across to EC 203-090-1 across the group, compliance check (CCH) is proposed to check read-across validity and clarify the potential hazards for the other substances in the group.

For the substances EC 283-322-4, EC 285-645-8 and EC 905-983-8, which are potentially reproductive and developmental toxicants and/or aquatic chronic, compliance check cannot be opened or would not bring further data on these endpoints (substances not being registered or low tonnage).

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Repr. 1 B.

CLH i) will require company level risk management measures (RMM) 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 28, 29, 30.

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 EC 203-090-1, EC 204-558-8, EC 215-553-5, EC 230-072-0, EC 248-299-9, EC 249-044-4 and EC 907-870-9 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.

Two substances are used in food contact materials (plastics) and would therefore require an authorisation for such use after their classification as Repr. 1. Three

substances are used in toys/child dedicated articles and would be banned after classification as Repr. 1, with a possibility for a derogation. At least EC 203-090-1 is used in medical devices, therefore, if classified as Repr.1, its use would be restricted with a possibility for a derogation.

CLH as aquatic chronic could be proposed after generation of new hazard data via CCH. EC 203-090-1 is linked via a read-across with EC 247-660-8 for which CLH as Aquatic Chronic 1 with M factor has been concluded in the course of SEv. It could be considered to add this endpoint to the proposal for classifying the substances as Repr. 1B in particular for those substances where an appropriate self-classification would not be available by registrants.

The (self or harmonised) classification as Aquatic Chronic 1 could trigger obligations under the Seveso Directive, depending on the potency and quantities stored. The substances for which such classification is likely (EC 203-090-1 and EC 415-190-4) are used in consumer products and have the potential for wide dispersive releases. The registration tonnage band for such substances is 100-1000 tpa. If classified as Aquatic Chronic 1, the substances would belong to Seveso category E1. Lower-tier requirements of the Seveso Directive would then have to apply. If the actual tonnage on a site is >200 tpa, then upper-tier requirements of the Seveso Directive would have to apply in addition.

Moreover, under the Waste Framework Directive, classification as hazardous waste depends on the contribution of other substances present in the waste. However, if the concentration of the substance classified as Aquatic Chronic 1 exceeds 0.25% in the waste, then the waste could be classified as hazardous (hazard property HP14 of the Waste Framework Directive).

Overall, as mentioned above, CLH would already have consequences on the consumer uses, however there are still concern with potential exposure of professional workers in many of the applications of the substances.

Many of the reported professional uses (e.g. washing and cleaning products, cosmetics and personal care products, lubricants and greases, coatings and paints) are expected to be widespread (at many sites and by many users). These professional uses are typically 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.

Consumers may be co-exposed to the substances used by professionals (e.g. cosmetics and personal care products).

Therefore, a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals** is suggested after CLH.

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 Sustainability³ which aims to extend to professional users under REACH the level of protection granted to consumers.

³ European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

Moreover, **restricting substances in articles** used by professionals or consumers (e.g. polymer preparations, coatings and paints, ink and toners, textile dyes, paper and board treatment products) should be considered in the context of the restriction of professional uses as potential exposure from articles needs further investigation first.

In relation to the industrial uses, many of them would be impacted by the "downstream" consequences, including the above-mentioned restrictions.

Moreover, industrial uses as plasticisers in polymer preparations and compounds will be further looked at as part of the restriction as regards to that safe use conditions can be established. Where needed, additional measure (e.g. occupational exposure limit) could be proposed.

Based on currently available information, there is no need for (further) EU regulatory risk management for remaining substances.

Due to not registered substance, NONS, and intermediate/inactive registration it is not possible to clarify the potential hazards of substances EC 220-836-1, EC 261-234-9, EC 401-590-6, EC 415-190-4, EC 439-900-7, EC 451-450-3, EC 628-204-0 and EC 939-783-7. Therefore, it is proposed that there is currently no need for EU RRM action on these substances. If the registration status changes, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

Looking at the chemical structures, neither one NONS, nor the C&L notified substance nor the substance with intermediate registration would be expected to be able to replace other substances in this group in terms of uses.

The substances with inactive registrations could be of concern because they are likely reproductive and developmental toxicants and likely pose a chronic aquatic toxicity hazard. Therefore, they would need to be moved to the regulatory group above in case their registration status changes in the future. One of these substances is a plasticiser.

The claimed NONS (EC 415-190-4) has a harmonised classification as Skin sens. 1. According to the limited information available, it seems to be a fragrance used in laundry softeners.

For industrial and professional uses, sufficient and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing the substance.

However, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern.

Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

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.

EC number,	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
203-090-1 203-091-7 203-601-8 204-558-8 215-553-5 230-072-0 231-306-4 247-660-8 248-299-9 249-044-4 249-047-0 251-646-7 283-822-4 285-645-8 618-295-5 905-983-8	Known or potential hazard for reproductive toxicity	Known or potential hazard for aquatic toxicity except for EC 940-510-9 and EC 213-110-0	<p>Widespread uses in professional setting or consumer mixtures and/or articles. Potential for exposure for workers and consumers and releases to the environment.</p> <p>Industrial use only as intermediate for EC 213-110-0.</p> <p>Article service life except for EC 231-306-4, EC 618-295-5, EC 907-870-9, EC 940-510-9, EC 945-069-6, EC 213-110-0 and EC 249-282-9</p>	<p>Need for EU RRM: Restriction</p> <p><u>Justification:</u> The harmonised classification as Repr. 1B would lead to generic restrictions of the substance(s) in consumer mixtures by means of the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. 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</p>	<p>First step: CCH Except for EC 283-822-4, EC 285-645-8, EC 905-983-8</p> <p>Next steps (if hazard confirmed): CLH Restriction</p>

ASSESSMENT OF REGULATORY NEEDS

EC number,	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
<p>907-870-9</p> <p>940-510-9</p> <p>945-069-6</p> <p>205-450-3</p> <p>213-110-0</p> <p>249-282-9</p>				<p>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.</p> <p>Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses.</p>	
<p>220-836-1</p> <p>261-234-9</p> <p>401-590-6</p> <p>415-190-4</p> <p>439-900-7</p>	<p>Known or potential hazard for reproductive toxicity and skin sensitisation for EC 415-190-4</p>	<p>Known or potential hazard for aquatic toxicity for EC 415-190-4</p>	<p>Widespread uses in professional setting or consumer mixtures and/or articles, Potential for exposure for workers and consumers and releases to the environment.</p>	<p>Currently no need for EU RRM</p> <p><u>Justification:</u> Due to NONS, not registered and inactive/intermediate registration no data generation is possible to</p>	<p>No action</p>

ASSESSMENT OF REGULATORY NEEDS

EC number,	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
<p>451-450-3 628-204-0 939-783-7</p>			<p>Industrial use only as intermediate for EC 628-204-0</p> <p>Article service except for EC 220-836-1, EC 628-204-0.</p>	<p>clarify the hazards currently. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change.</p> <p>Harmonised/self-classification followed by implementation of necessary RRM should be sufficient to ensure safe use at the workplace. The concern related to the presence of skin sensitizers in consumer mixtures is under investigation.</p>	

Annex 1: Overview of classifications

Data extracted on 22 April 2021.

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
203-090-1	bis(2-ethylhexyl) adipate	-	-	Aquatic Chronic 2 H411 [3 out of 126] Aquatic Chronic 1 H410 [2 out of 126] Acute Tox. 4 H302 [1 out of 126] Aquatic Chronic 4 H413 [1 out of 126] Eye Irrit. 2 H319 [9 out of 126] Repr. 2 H361 [1 out of 126] Aquatic Acute 1 H400 [15 out of 126] Skin Irrit. 2 H315 [9 out of 126] Carc. 2 H351 [1 out of 126] Acute Tox. 4 H332 [1 out of 126]
203-091-7	bis(2-ethylhexyl) azelate	-	-	-
203-601-8	bis(1-methylheptyl) adipate	-	-	-
204-558-8	bis(2-ethylhexyl) sebacate	-	-	Acute Tox. 4 H302 [2 out of 48]
205-450-3	diisobutyl adipate	-	-	Eye Irrit. 2 H319 [1 out of 35]
213-110-0	diisopropyl succinate	-	-	-
215-553-5	diisooctyl adipate	-	-	-
220-836-1	bis(2-ethylhexyl) succinate	-	-	-
230-072-0	diisopropyl adipate	-	-	Aquatic Acute 1 H400[1 out of 20] Skin Irrit. 2 H315[1 out of 20]
231-306-4	diisopropyl sebacate	-	-	-
247-660-8	diisotridecyl adipate	-	-	-
248-299-9	diisodecyl adipate	-	Repr. 1B H360, specific effect: May damage fertility.	Eye Irrit. 2 H319[3 out of 24] Skin Irrit. 2 H315[3 out of 24]
249-044-4	diisodecyl azelate	Aquatic Chronic 1 with M factor (*)	-	-
249-047-0	diisodecyl sebacate	-	-	-
249-282-9	diisooctyl succinate	-	-	-
251-646-7	diisononyl adipate	-	-	-
261-234-9	benzyl 2-ethylhexyl adipate	-	-	-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
283-822-4	diisotridecyl dodecanedioate	-	-	-
285-645-8	bis(2-octyldodecyl) adipate	-	-	-
401-590-6	401-590-6	-	-	-
415-190-4	A mixture of: ((Z)-3,7-dimethyl-2,6-octadienyl)oxycarbonylpropanoic acid; di-((E)-3,7-dimethyl-2,6-octadienyl)butanedioate; di-((Z)-3,7-dimethyl-2,6-octadienyl)butanedioate; (Z)-3,7-dimethyl-2,6-octadienylbutanedioate; ((E)-3,7-dimethyl-2,6-octadienyl)oxycarbonylpropanoic acid	Skin Sens. 1 H317	-	-
439-900-7	bis(2-hexyldecyl)dodecanedioate	-	-	-
451-450-3	451-450-3	-	-	-
940-510-9	Hexanedioic acid, 1,6-bis(2-propylheptyl) ester	-	-	-
618-295-5	Nonanedioic acid, 1,9-bis(2-octyldodecyl) ester	-	-	-
628-204-0	3-tert-butoxy-3-oxopropanoic acid	-	-	<i>Skin Corr. 1B H314 [intermediate (active)] Acute Tox. 2 H330 [intermediate (active)] Eye Irrit. 2 H319[2 out of 10] Acute Tox. 4 H302[2 out of 10] Acute Tox. 4 H312[1 out of 10] STOT Single Exp. 3 H335, affected organs: Respiratory system[1 out of 10] STOT Single Exp. 3 H335, affected organs: Respiratory tract[1 out of 10]</i>

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
				<i>Acute Tox. 4 H332[1 out of 10] Eye Damage 1 H318[1 out of 10] Skin Irrit. 2 H315[3 out of 10]</i>
905-983-8	Reaction mass of benzyl 2-ethylhexyl adipate and bis(2-ethylhexyl) adipate and dibenzyl adipate	-	-	-
-907-870-9	Reaction mass of bis(2-methylpropyl) pentanedioate and bis(2-methylpropyl)	-	-	-
939-783-7	Decanedioic acid, reaction products with adipic acid and isotridecanol	-	-	-
945-069-6	Diesters of alcohols, C7-9-iso-, C8-rich, 2-ethylhexyl and nonanedioic acid	-	-	-

(*) 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.

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

Data extracted on 22 April 2021.

Main types of applications structured by product or article types	203-090-1	203-091-7	203-601-8	204-558-8	205-450-3	213-110-0	215-553-5	220-836-1	230-072-0	231-306-4	247-660-8	248-299-9	249-044-4
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	F, I, P			F, I			F, I		F, I			F, I	F, I
PC 36: Water softeners	C			C			C		C	C		C	C
PC 37: Water treatment chemicals	F, I, P			F, I, P			F, I, P		F, I, P	I		F, I, P	F, I, P
PC 2: Adsorbents	F			F			F		F	F		F	F
PC 11: Explosives	I, P, A			P			P		P			P	P
PC 12: Fertilisers	C			F, I, P, C			C		C			F, I, P, C	C
PC 27: Plant protection products	P, C			P, C			P, C		F, P, C			P, C	P, C
PC 4: Anti-freeze and de-icing products	P, C			P, C			P, C		P, C			P, C	P, C
PC 35: Washing and cleaning products	F, I, P, C	I		F, I, P, C			F, I, P, C	I, P, C	F, I, P, C	F, I, P, C		F, I, P, C	F, I, P, C

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	203-090-1	203-091-7	203-601-8	204-558-8	205-450-3	213-110-0	215-553-5	220-836-1	230-072-0	231-306-4	247-660-8	248-299-9	249-044-4
PC 8: Biocidal products (e.g. disinfectants, pest control)	F, I, P, C			I, P, C			I, P, C		F, I, P, C	I, P, C		I, P, C	I, P, C
PC 28: Perfumes, fragrances	F, C			F, C			F, C		F, C	C		F, C	F, C
PC 3: Air care products	C			C			C		C	C		C	C
PC 39: Cosmetics, personal care products	F, I, P, C		F, P, C	F, P, C			F, P, C	F, C	F, P, C	F, P, C		F, P, C	F, P, C
PC 29: Pharmaceuticals	I, P			F, I, P			I, P		I, P, C	I, P		I, P	I, P
PC 31: Polishes and wax blends	P, C	C		F, P, C			P, C		P, C	P, C		P, C	P, C
PC 15: Non-metal-surface treatment products	I, C			C			C		C			C	C
PC 24: Lubricants, greases, release products	F, I, P, C, A	F, I, P, C		F, I, P, C			F, I, P, C	C,	F, I, P, C	F, I, P, C	F, I, P, C, A	F, I, P, C, A	F, I, P, C
PC 25: Metal working fluids	F, I, P, C			F, I, P, C			F, I, P, C		I, P, C	I	F, I	F, I, P, C	F, I, P, C
PC 16: Heat transfer fluids	F, I, P, C			C			C		C			C	I, P, C
PC 17: Hydraulic fluids	F, I, P, C			F, I, P, C			F, I, P, C		I, P, C		F, I, P, C	F, I, P, C	F, I, P, C

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	203-090-1	203-091-7	203-601-8	204-558-8	205-450-3	213-110-0	215-553-5	220-836-1	230-072-0	231-306-4	247-660-8	248-299-9	249-044-4
PC 13: Fuels	F, I, P, C			I, P, C,			I, P, C		I, P, C			F, I, P, C	I, P, C
PC 32: Polymer preparations and compounds	F, I, P, C, A	I, P, A	A?	F, I, P, C, A	F, I, P, A?		F, I, P, C		F, I, P, C	F, I, C,	F, I, C, A	F, I, P, C, A	F, I, P, C, A?
PC 1: Adhesives, sealants	F, I, P, C	C		F, I, P, C			F, I, P, C	C,	F, I, P, C			F, I, P, C	F, I, P, C
PC 9c: Finger paint	F, I, P, C			F, I, C			C		F, C			C	C
PC 9b: Fillers, putties, plasters, modelling clay	F, I, P, C			F, I, C			I, C		I, C	I		I, C	I, C
PC 9a: Coatings and paints, thinners, paint removes	F, I, P, C, A	I, A		F, I, P, C	F, I, P, C, A		F, I, P, C	C,	F, I, P, C	F, I, C		F, I, P, C	F, I, P, C
PC 18: Ink and toners	F, I, P, C, A			F, I, P, C			F, I, P	C	F, I, P	F, I		F, I, P, C	F, I, P
PC 26: Paper and board treatment products	F, I, A			I			I		I			I	I
PC 34: Textile dyes, and impregnating products	F, I, C, A			F, I, C, A			F, I, C, A		F, I, C, A			F, I, C, A	F, I, C, A

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	203-090-1	203-091-7	203-601-8	204-558-8	205-450-3	213-110-0	215-553-5	220-836-1	230-072-0	231-306-4	247-660-8	248-299-9	249-044-4
PC 23: Leather treatment products	F, I, P , C			F, I, P , C			F, I, P , C		F, I, P , C	P , C		F, I, P , C	F, I, P , C
PC 14: Metal surface treatment products	I			I			I		I	I		I	I
PC 38: Welding and soldering products, flux products	I, P , A												
PC 33: Semiconductors				F, I									
PC 21: Laboratory chemicals	F, I, P	F, I		F, I, P	F		F, I, P	I	F, I, P	F, I, P	F	F, I, P	F, I, P
PC 19: Intermediate	F, I			F, I		I	I		I	I		F, I	F, I
PC 30: Photo-chemicals													

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

	249-047-0	249-282-9	251-646-7	415-190-4	451-450-3	618-295-5	628-204-0	905-983-8	907-870-9	939-783-7	940-510-9
PC 4: Anti-freeze and de-icing products									P, C		
PC 35: Washing and cleaning products				I, C					I, P, C		
PC 8: Biocidal products (e.g. disinfectants, pest control)									C		
PC 28: Perfumes, fragrances	F								C		
PC 3: Air care products									C		
PC 39: Cosmetics, personal care products		F, P, C			I, P				C		
PC 29: Pharmaceuticals							I				
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, A		F, I, P, C		I, P	F, I, P, C			C	F, I, P	F, I, P

ASSESSMENT OF REGULATORY NEEDS

	249-047-0	249-282-9	251-646-7	415-190-4	451-450-3	618-295-5	628-204-0	905-983-8	907-870-9	939-783-7	940-510-9
PC 25: Metal working fluids	F					F, I, P, C					
PC 16: Heat transfer fluids									C		
PC 17: Hydraulic fluids	F, I, P, C								I, P, C	F	
PC 13: Fuels	F, I, P, C										
PC 32: Polymer preparations and compounds	F, I, P, A		F, I, A					F, I, A	F, I, P	F, I, C, A	
PC 1: Adhesives, sealants									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		I						I, P, C		
PC 18: Ink and toners									C		

ASSESSMENT OF REGULATORY NEEDS

	249-047-0	249-282-9	251-646-7	415-190-4	451-450-3	618-295-5	628-204-0	905-983-8	907-870-9	939-783-7	940-510-9
PC 26: Paper and board treatment products									F		
PC 34: Textile dyes, and impregnating products									C		
PC 23: Leather treatment products									C		
PC 21: Laboratory chemicals			F, I					P			F
PC 19: Intermediate	F						I		I		
PC 30: Photo-chemicals									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.

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

Data extracted on 6 May 2021.

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