Assessment of regulatory needs

Authority: ECHA

Date: 25 January 2021

Group Name: Esters from branched or non-aromatic cyclic dicarboxylic acids and aliphatic alcohols

General structure: -

Revision history

Version	*Date*	*Description*
1		

Substances within this group:

EC/List number	CAS number	Substance name and Substance name acronyms	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
200-981-7	76-72-2	diethyl ethyl(1-methylbutyl)malonate	OSII or TII, not (publicly) available
205-093-3	133-13-1	diethyl ethylmalonate	OSII or TII, not (publicly) available
201-016-2	77-25-8	diethyl diethylmalonate	OSII or TII, not (publicly) available
202-347-5	94-60-0	dimethyl cyclohexane-1,4-dicarboxylate	Full, not (publicly) available
205-089-1	133-08-4	diethyl butylmalonate	OSII or TII, not (publicly) available
210-175-7	609-08-5	diethyl methylmalonate	OSII or TII, not (publicly) available
210-519-6	617-52-7	dimethyl itaconate	Full, not (publicly) available
216-321-6	1559-02-0	diethyl cyclopropane-1,1-dicarboxylate	OSII or TII, not (publicly) available
218-451-9	2155-60-4	dibutyl itaconate	Full, not (publicly) available
221-696-4	3195-24-2	diethyl diallylmalonate	OSII or TII, not (publicly) available
223-239-4	3779-29-1	diethyl 1,1-cyclobutanedicarboxylate	OSII or TII, not (publicly) available
225-494-7	4883-79-8	methyl hydrogen (endo-endo)-bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylate	OSII or TII, not (publicly) available
227-998-2	6065-63-0	diethyl dipropylmalonate	OSII or TII, not (publicly) available
237-580-1	13846-31-6	diallyl hexahydrophthalate	Full, not (publicly) available
257-839-2	52313-87-8	dimethyl 3-methylpent-2-enedioate	OSII or TII, not (publicly) available
275-069-5	70969-58-3	diisobutyl hexahydrophthalate	Full, not (publicly) available
283-829-2	84731-70-4	bis(2-ethylhexyl) cyclohexane-1,4-dicarboxylate	Full, not (publicly) available
291-751-5	90474-13-8	diethyl 1,2-cyclopentanedicarboxylate	OSII or TII, not (publicly) available
414-240-2	6914-71-2	dimethylcyclopropane-1,1-dicarboxylate	OSII or TII, not (publicly) available
417-310-0	72903-27-6	diethyl 1,4-cyclohexanedicarboxylate	Full, not (publicly) available
428-870-0	-	di-(C9-C11-alkyl)-cyclohexane-1,4-dicarboxylate	NONS, not (publicly) available
431-890-2	166412-78-8	1,2-Cyclohexanedicarboxylic acid, 1,2-diisononyl ester [DINCH]	Full, >1000 t/y
438-840-9	N/A	DONOR S1	NONS, 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

473-290-3	N/A	[No public or meaningful name is available]	NONS, not (publicly) available
480-380-6	N/A	[No public or meaningful name is available]	NONS, not (publicly) available
486-070-7	N/A	RHODIASOLV IRIS	Full, not (publicly) available
607-155-9	22769-97-7	1,4-diethyl 2,3-bis(propan-2-ylidene)butanedioate	OSII or TII, not (publicly) available
607-321-0	2409-52-1	diethyl 2-methylidenebutanedioate	C&L notification
700-087-1	201872-72-2	Reaction mass of dimethyl 2,2,4-trimethylhexanedioate and dimethyl 2,4,4-trimethylhexanedioate	OSII or TII, not (publicly) available
701-012-5	-	1,4-Cyclohexanedicarboxylic acid, 1,4-diisononyl ester	Full, not (publicly) available
701-279-8	1931129-39-3	benzyl butyl cis-cyclohexane-1,2-dicarboxylate	Full, not (publicly) available
805-172-8	65646-25-5	dipropyl cyclohexane-1,2-dicarboxylate	Full, not (publicly) available
807-715-4	1354569-12-2	di(2-ethylhexyl) (2Z)-2-methyl-2-butenedioate	OSII or TII, not (publicly) available
810-685-5	1200806-67-2	1,2-cyclohexanedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester	C&L notification
813-684-8	691-83-8	diethyl (2Z)-2-methylbut-2-enedioate	OSII or TII, not (publicly) available
943-279-2	-	Reaction mass of bis(2-methylpropyl) (1R,2R,3R,6S)-3,6-dimethylcyclohexane-1,2-dicarboxylate and bis(2-methylpropyl) (1S,2S,3R,6S)-3,6-dimethylcyclohexane-1,2-dicarboxylate	Full, not (publicly) available
944-953-9	73326-59-7	reaction mass of diethyl (E)-2-methylbut-2-enedioate and diethyl (Z)-2-methylbut-2-enedioate	Full, not (publicly) available
947-827-1	-	C10-13-alkyl(branched, unsaturated)-succinic acid-4-(3-methyl-butyl)-ester	Full, not (publicly) available

This table contains also group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA will 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 a on 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 website[2].

[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
MS	EU Member State
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
PMT	Persistent, mobile in water and toxic
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together 38 structurally similar substances that are esters of branched or non-aromatic cyclic dicarboxylic acids with aliphatic alcohols. The substances include mono-constituent, multi-constituent, and UVCB substances. The substances are mostly diesters of di-carboxylic acids, including also two mono-esters of dicarboxylic acids. The dicarboxylate moieties are saturated or unsaturated, containing linear, branched, or cyclic structures. The alcohol moieties are saturated or unsaturated, containing only linear or branched structures except for one substance that contains an aromatic alcohol moiety.

From the 38 substances in the group, 34 have active registrations, of which 17 substances are only registered as intermediates (OSII or TII). Based on information reported in the REACH registration dossiers, most of the substances (30) in the group are reported to be used as intermediates (17 of which under strictly controlled conditions) and have non-widespread uses. The remaining eight substances have a range of applications ranging from narrow to very broad in terms of scope, having widespread professional and/or consumer use, with three having article service life in addition. The main applications are:

- Softener in the preparation of polymers and adhesives and sealants;
- Plasticiser in adhesives, sealants, coatings;
- Odour agent and/or fragrance in products such as washing cleaning products, perfumes and fragrances, air care products, cosmetics and personal care products, polishes and wax blends;
- Reprographic agents (toners) in products such as pigment in cosmetics, personal care products, coatings, inks, toners;
- Lubricating agent in lubricants, greases and release products;
- Solvent in very many products such as water softeners, water treatment chemicals, explosives, fertilisers, plant protection products, anti-freeze and de-icing products, washing and cleaning products, biocidal products (e.g. disinfectants, pest control), perfumes, fragrances, air care products, cosmetics, personal care products, etc.;
- Corrosion inhibitor in lubricants, greases, release product, metal working fluid, heat transfer fluid, hydraulic fluids.

From the above information, it is expected that there is potential for exposure to workers (industrial and professional), consumers (from mixtures and articles) and potential for release to the environment.

In 2016, France performed an RMOA on substance EC 431-890-2 due to potential ED concern and concluded that no further action was needed.

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 action

Based on currently available information, there is a need for (further) EU regulatory risk management – namely restriction of seven substances (EC/List 237-580-1, 275-069-5, 205-093-3, 807-715-4, 438-840-9, 428-870-0 and 480-380-6) based on potential PBT/vPvB hazards.

Seven substances meet the screening criteria for P/vP and B/vB and are therefore potentially PBT/vPvB.

Two of the substances have full registrations (EC 237-580-1 and 275-069-5), for which the potential PBT hazard findings need to be confirmed by data generation. The remaining 5 substances (EC/List 205-093-3, 807-715-4, 438-840-9, 428-870-0 and 480-380-6), which also meet the PBT screening criteria, have either transported intermediate registrations or are NONs substances (without registration dossiers under REACH). Therefore, data generation via dossier evaluation is not possible. Substance evaluation could be proposed for data generation in the case of the claimed NONS substance (EC 438-840-9) however due to the tonnage and use only as intermediate, this is not proposed.

If the PBT/vPvB hazard is confirmed for the two substances, as next step, the substances should be identified as SVHC to officially confirm the PBT/vPvB hazard followed by a restriction. It is proposed to consider whether to include the additional 5 substances that screen for PBT/vPvB in a restriction proposal and whether to propose SVHC as a step towards restriction for these 5 substances. It can also be considered whether to combine restriction with authorisation.

Four of the substances are used as intermediates in industrial settings for which the potential for release is assumed to be limited; two of the substances are according to registrants exclusively used under strictly controlled conditions.

Based on information from registration dossiers of EC 275-069-5 and the unclaimed NONS dossier for EC 480-380-6 these two substances seem to be used as softeners or plasticisers in the production of polymer articles. EC 275-069-5 (active registrations) and EC 428-870-0 (unclaimed NONS) are also used in coatings. These substances have a high potential for exposure from widespread uses in articles.

Restriction could cover the article service life from especially EC 275-069-5 (428-870-0 and 480-380-6 are unclaimed NONS). Including the other four substances with potential PBT/vPvB properties in such a restriction may avoid they would serve as substitutes (in particular to EC 275-069-5). At the same time, restriction of targeted industrial and formulation uses could be considered to address release to the environment (alternatively, authorisation may be considered to complement as well). The exact scope of the restriction would have to be further investigated in later assessment phases.

Authorisation cannot cover intermediate uses of four of the substances (including EC 275-069-5), but it can cover other industrial uses including the incorporation of the substances into articles. SVHC identification would also lead to an obligation for industry to consider the substance as a PBT/vPvB and ensure minimisation. Authorisation could ensure that emissions from such (potentially) PBT/vPvB substances would be minimised as much as practically possible in industrial installations. Authorisation drives substitution and for uses that cannot be substituted quickly, it contributes to limiting releases at industrial sites. Once the substances are on the Authorisation List, ECHA would investigate their use in articles if they cause risk and proposes a restriction if not adequately controlled (article 69(2)).

Preferably, the substances are addressed as a group. Restriction could cover the uses of the substances in one regulatory action, rather than initiating another parallel action (authorisation).

The proposed restriction could also address concerns related to skin sensitisation of EC 275-069-5 and aquatic toxicity hazards of the seven substances, which do not seem to be correctly classified.

In conclusion, there is a slight preference for restriction.

Based on currently available information, there is no need for further EU regulatory risk management for 31 substances.

This conclusion is reached for these substances because the available data suggests low potential toxicity or low potential for exposure. The following additional considerations are made:

a) 15 substances have only intermediate uses; 1 substance (List # 813-684-8) has a self-classification based on an impurity for Germ cell mutagenicity 1B and Carcinogenicity 1B. Therefore, no EU regulatory risk management action is currently proposed for any of the aforementioned substances due to low exposure potential. It is worth noting however that the strategy may need to be revisited and need for further regulatory action reconsidered if there is a change in the registration status or reported uses for any of these substances.

b) seven substances have a classification for aquatic toxicity (see Annex 1), which seems to be adequate and there is no other hazard identified. Substances EC 414-240-2 and 417-310-0 have a harmonised classification for aquatic toxicity. Substances EC/List 202-347-5, 607-155-9, 805-172-8, 943-279-2 and 947-827-1 are self-classified for aquatic toxicity and the classification appears to be adequate based on the data available. For two substances (EC 210-519-6 and 218-451-9) information on aquatic toxicity is inconclusive. For substances showing aquatic toxicity it is expected that correct self-classification and implement necessary RMMs to ensure safe use. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management[3].

c) two substances (EC/List 944-953-9 and 210-519-6) are self-classified as Skin sensitising 1 or 1B. 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 substances. There is a concern related to skin sensitisers (potentially) present in consumer mixtures (e.g. washing and cleaning products) 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 been already 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. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

d) For 9 substances generation of further data is needed or there are pending actions. However, further EU RRM action is not proposed at this point because low toxicity is likely.

[3] This includes EC 701-279-8 which is used as a plasticiser in coatings of electrical batteries and accumulators, plastic articles, rubber articles and fabrics, textiles and apparel. This substance is listed on the 'plasticiser' list from the mapping exercise done under the Plastic Additives Initiative (https://echa.europa.eu/mapping-exercise-plastic-additives-initiative#table). However, the typical concentration is not indicated in that mapping exercise, nor in the registration dossier. At this early stage, the preliminary thinking is that there could be a relatively high release potential of these plasticisers from the rubber, plastic and fabric/textile articles containing this substance.

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/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
205-093-3 (intermediate) **237-580-1** **275-069-5** 428-870-0 (unclaimed NONS) 438-840-9 (NONS) 480-380-6 (unclaimed NONS) 807-715-4 (intermediate)	No hazard or unlikely hazard Only for 275-069-5: Known or potential hazard for skin sensitisation	Known or potential hazard for PBT/vPvB for aquatic toxicity	Mainly industrial uses as intermediate with limited exposure potential; 275-069-5, 428-870-0 and 480-380-6 seem to be used as softeners or plasticisers in the production of polymer articles, in coatings or as solvents with high potential for exposure from widespread uses in articles.	Need for EU RRM: Restriction Justification: SVHC identification to officially confirm PBT/ vPvB hazard, restriction to address concerns from industrial uses (incl. intermediates) and releases from articles.	**First step:** CCH to confirm PBT/vPvB potential for 237-580-1 and 275-069-5 **Next steps (if hazard confirmed):** SVHC identification Restriction
200-981-7 201-016-2 202-347-5 205-089-1 210-175-7	No hazard or unlikely hazard Only for 210-519-6 and 944-953-9:	No hazard or unlikely hazard Only for 202-347-5, 414-240-2, 417-310-	Mainly industrial uses as intermediates. Only 283-829-2, 417-310-0, 431-890-2,	Currently no need for EU RRM Justification:	CCH for 202-347-5 210-519-6 218-451-9 417-310-0

210-519-6 216-321-6 218-451-9 221-696-4 223-239-4 225-494-7 227-998-2 257-839-2 283-829-2 291-751-5 414-240-2 417-310-0 431-890-2 473-290-3 486-070-7 607-155-9 607-321-0 700-087-1 701-012-5 701-279-8 805-172-8 810-685-5 813-684-8 943-279-2 944-953-9 947-827-1	Known or potential hazard for skin sensitisation Known or potential hazard for EC 813-684-8 for carcinogenicity and mutagenicity	0, 607-155-9, 805-172-8, 943-279-2 and 947-827-1: Known or potential hazard for aquatic toxicity Only for 210-519-6 and 218-451-9: Inconclusive hazard for aquatic toxicity	486-070-7, 701-012-5, 701-279-8, 944-953-9 and 947-827-1 have widespread uses by professionals or consumers in various applications or in articles with potential for exposure	No or unlikely hazards or low potential or exposure. For substances showing skin sensitisation or aquatic toxicity correct self-classification should trigger sufficient measures under workplace or environmental legislation. Skin sensitisers in consumer mixture are addressed by ongoing work of MS and ECHA.	431-890-2 486-070-7, 701-012-5 701-279-8 947-827-1 Pending action for 283-829-2

Annex 1: Harmonised classifications and self-classifications reported by registrants

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
200-981-7	diethyl ethyl(1-methylbutyl)malonate	-	-	Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319
201-016-2	diethyl diethylmalonate	-	-	-
202-347-5	dimethyl cyclohexane-1,4-dicarboxylate	-	Eye Irrit. 2, H319; Aquatic Chronic 3, H412	Skin Irrit. 2, H315; STOT SE 3, H335;
205-089-1	diethyl butylmalonate	-	Eye Irrit. 2, H319	-
205-093-3	diethyl ethylmalonate	-	Flam. Liq. 4, H227	-
210-175-7	diethyl methylmalonate	-	-	-
210-519-6	dimethyl itaconate		Skin Irrit. 2, H315 ; Skin Sens. 1B, H317	Acute Tox. 4, H302 ; Skin Corr. 1C, H314 ; Skin Sens. 1, H317 ; Eye Irrit. 2, H319; STOT SE 3, H335; (Inhalation), H335
216-321-6	diethyl cyclopropane-1,1-dicarboxylate	-	-	Flam. Sol. 2, H228 ; Acute Tox. 1, H300 ; Acute Tox. 1, H310; Acute Tox. 2, H330;
218-451-9	dibutyl itaconate	-	-	Eye Irrit. 2, H319; Aquatic Chronic 4, H413
221-696-4	diethyl diallylmalonate		Eye Irrit. 2, H319; Skin Irrit. 2, H315; STOT SE. 3, H335	STOT SE 3, H335 (Inhalation)
223-239-4	diethyl 1,1-cyclobutanedicarboxylate	-	-	Skin Irrit. 2, H315 ; Eye Irrit. 2, H319; STOT SE 3, H335, (Lungs), (Inhalation)
225-494-7	methyl hydrogen (endo-endo)-bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylate	-	Skin Irrit. 2, H315 ; Eye Irrit. 2, H319;	STOT SE 3, H335 (other: unknown)

			STOT SE 3, H335 (Inhalation)	
227-998-2	diethyl dipropylmalonate	-	-	Acute Tox. 4, H302 ; Skin Irrit. 2, H315; STOT SE 3, H335;
237-580-1	diallyl hexahydrophthalate	-	Aquatic Chronic 3, H412	-
257-839-2	dimethyl 3-methylpent-2-enedioate	-	-	-
275-069-5	diisobutyl hexahydrophthalate	-	Skin Sens. 1, H317	-
283-829-2	bis(2-ethylhexyl) cyclohexane-1,4-dicarboxylate	-	-	-
291-751-5	diethyl 1,2-cyclopentanedicarboxylate	-	-	-
414-240-2	dimethylcyclopropane-1,1-dicarboxylate	Aquatic Chronic 3, H412	-	-
417-310-0	417-310-0 – [diethyl cyclohexane-1,4-dicarboxylate]	Aquatic Chronic 2, H411	-	-
428-870-0	428-870-0 [di-(C9-C11-alkyl)-cyclohexane-1,4-dicarboxylate]	Aquatic Chronic 4, H413		
431-890-2	431-890-2 [1,2-Benzenedicarboxylic acid, 1,2-diisononyl ester]	-	-	-
438-840-9	DONOR S1	-	-	-
473-290-3	[No public or meaningful name is available]	-	-	-
480-380-6	[No public or meaningful name is available]	-	-	-
486-070-7	RHODIASOLV IRIS	-	-	-
607-155-9	607-155-9 [1,4-diethyl 2,3-bis(propan-2-	-	-	Aquatic Chronic 2, H411

	ylidene)butanedioate]			
607-321-0	diethyl 2-methylidenebutanedioate	-	-	Eye Irrit. 2, H319
700-087-1	Reaction mass of dimethyl 2,2,4-trimethylhexanedioate and dimethyl 2,4,4-trimethylhexanedioate	-	-	-
701-012-5	1,4-Cyclohexanedicarboxylic acid, dinonyl ester, branched and linear	-	-	-
701-279-8	benzyl butyl cis-cyclohexane-1,2-dicarboxylate	-	Aquatic Chronic 3, H412	-
805-172-8	dipropyl cyclohexane-1,2-dicarboxylate	-	Aquatic Chronic 3, H412	-
807-715-4	807-715-4 [di(2-ethylhexyl) (2Z)-2-methyl-2-butenedioate]	-	Asp. Tox. 1, H304; Aquatic Chronic 4, H413	STOT RE 2, H373, (kidneys) (Oral); Aquatic Acute 1, H400; Aquatic Chronic 1, H410
810-685-5	1,2-cyclohexanedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester	-	-	Aquatic Chronic 2, H411
813-684-8	diethyl (2Z)-2-methylbut-2-enedioate	-	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Muta. 1B, H340; Carc. 1B, H350;	-
943-279-2	Reaction mass of diisobutyl (1R,2R,3R,6S)-3,6-dimethylcyclohexane-1,2-dicarboxylate and diisobutyl (1S,2S,3R,6S)-3,6-dimethylcyclohexane-1,2-dicarboxylate	-	-	Aquatic Chronic 2, H411

944-953-9	Reaction mass of diethyl (2E)-2-methylbut-2-enedioate and diethyl (2Z)-2-methylbut-2-enedioate	-	Skin Sens. 1B, H317	-
947-827-1	C10-13-alkyl(branched, unsaturated)-succinic acid-4-(3-methyl-butyl)-ester	-	-	Skin Irrit. 2, H315; Eye Dam. 1, H318; Aquatic Chronic 2, H411

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

Substances proposed for restriction

Main types of applications structured by product or article types	EC/ List 205-093-3	EC/ List 237-580-1	EC/ List 275-069-5	EC/ List 428-870-0	EC/ List 438-840-9	EC/ List 480-380-6	EC/ List 807-715-4
PC 32: Polymer preparations and compounds		F, I	F, I, A			I, A	
PC 1: Adhesives, sealants							
PC 9a: Coatings and paints, thinners, paint removes			F, I, A	I, A			
PC 19: Intermediate	I		F, I		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

Substance with no need for EU RRM having widespread uses

Main types of applications structured by product or article types	EC/List 283-829-2	EC/List 417-310-0	EC/List 431-890-2	EC/List 486-070-7	EC/List 701-012-5	EC/List 944-953-9	EC/List 947-827-1	EC/ List 701-279-8
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents				C				
PC 36: Water softeners				C				
PC 37: Water treatment chemicals				F, I, P, C				
PC 11: Explosives				P				
PC 12: Fertilisers				C				
PC 27: Plant protection products			F	C				
PC 4: Anti-freeze and de-icing products				P, C				
PC 35: Washing and cleaning products		I, P, C		I, P, C		I, P, C		
PC 8: Biocidal products (e.g. disinfectants, pest control)		C		C		C		

PC 28: Perfumes, fragrances		F, C		C		C		
PC 3: Air care products		C		C		C		
PC 29: Pharmaceuticals								
PC 39: Cosmetics, personal care products		C	F	C		C		
PC 31: Polishes and wax blends		P, C		C		P, C		
PC 15: Non-metal-surface treatment products				C				
PC 24: Lubricants, greases, release products			F	I, P, C			F, I, P, C	
PC 25: Metal working fluid				I, P			F, I, P	
PC 16: Heat transfer fluid				C			F, I, P	
PC 17: Hydraulic fluids				I, P, C			F, I, P	
PC 13: Fuels				I, P, C				
PC 32: Polymer preparations and compounds	F, I, P, C, A		F, I, A	F, I, P	F, I, A			
PC 1: Adhesives, sealants			F, I, P, C	C				C
PC9c: Finger paint			F, P					
PC 9b: Fillers, putties, plasters, modelling clay			F, P					
PC 9a: Coatings and paints, thinners, paint removes			F, I, P					F, I, P, C, A
PC 18: Inks and toners			F, I, P					
PC 26: Paper and board treatment products			F					
PC 34: Textile dyes, and impregnating products			F					
PC 19: Intermediate				I				

Substances with no need for EU RRM having no widespread use and/or only intermediate use

Main types of applications structured by product or article types	PC 32: polymer preparations and compounds	PC 9b: Fillers, putties, plasters, modelling clay	PC 19: intermediate
EC/List 200-981-7			I
EC/List 201-016-2			I
EC/List 202-347-5	F, I		F, I
EC/List 205-093-3			I
EC/List 210-175-7			F, I
EC/List 210-519-6	F	I	I
EC/List 216-321-6			I
EC/List 218-451-9	I		
EC/List 221-696-4			I
EC/List 223-239-4			I
EC/List 225-494-7			I

EC/List 227-998-2			I
EC/List 257-839-2			I
EC/List 291-751-5			I
EC/List 414-240-2			I
EC/List 473-290-3			I
EC/List 607-155-9			I
EC/List 607-321-0			I
EC/List 700-087-1			I
EC/List 805-172-8			I
EC/List 810-685-5			
EC/List 813-684-8			I
EC/List 943-279-2			I

Annex 3: Overview of completed or ongoing regulatory risk management activities (23.10.2020)

EC/List number	RMOA	Authorisation		Restriction	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
431-890-2	Yes					