Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

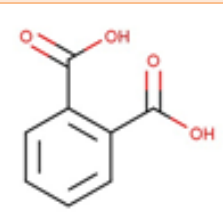
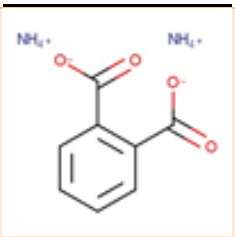
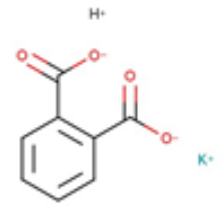
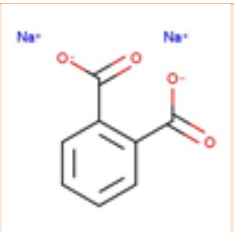
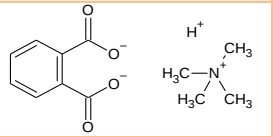
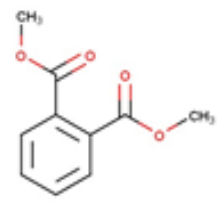
Date: June 2021

Group Name: *Ortho*-phthalates

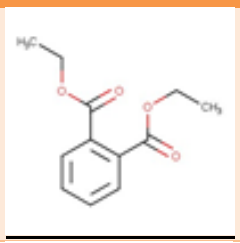
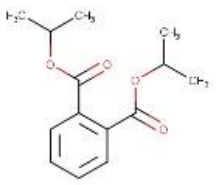
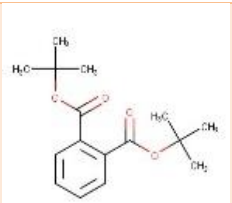
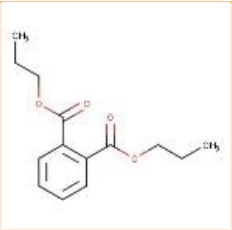
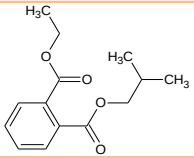
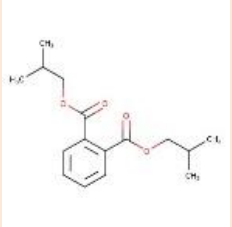
General structure: -

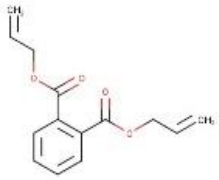
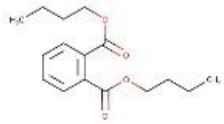
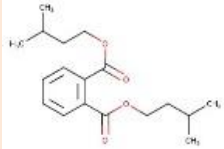
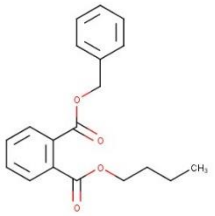
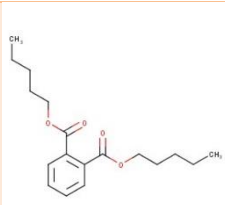
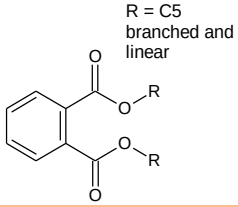
Revision history

Version	*Date*	*Description*
1.0	June 2021	

EC/List number	CAS number	Substance name [and/ or substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical Structures
Subgroup 1: Phthalic acid and salts				
201-873-2	88-99-3	Phthalic acid (PA)	Full, not (publicly) available	
208-341-9	523-24-0	Diammonium phthalate	Full, not (publicly) available	
212-889-4	877-24-7	Potassium hydrogen phthalate	Full, 1-10	
240-106-6	15968-01-1	Disodium phthalate	Full, 100-1000	
416-900-5	79723-02-7	Tetramethylammonium hydrogen phthalate	Full, 10-100	
Subgroup 2: Short-chain length (C1-C2 backbone) linear and branched *ortho*-phthalates				
205-011-6	131-11-3	Dimethyl phthalate (DMP)	Full, > 1000	

[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

EC/List number	CAS number	Substance name [and/ or substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical Structures
201-550-6	84-66-2	Diethyl phthalate (DEP)	Full, > 1000	
210-086-3	605-45-8	Diisopropyl phthalate (DiPrP)	-	
250-204-0	30448-43-2	Di-tert-butyl phthalate (DtBP)	-	
Subgroup 3: Short-chain length (C3 backbone) linear and branched *ortho*-phthalates (sat. and unsat.)				
205-015-8	131-16-8	Dipropyl phthalate (DPrP)	-	
701-355-0	94491-96-0	Ethyl isobutyl phthalate (EiBP)	-	
201-553-2	84-69-5	Diisobutyl phthalate (DIBP)	Full, not (publicly) available	

EC/List number	CAS number	Substance name [and/ or substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical Structures
205-016-3	131-17-9	Diallyl phthalate (DAP)	Full, not (publicly) available	
Subgroup 4: Medium-chain length (C4-C6 backbone) linear and branched *ortho*-phthalates incl. aromatics and cyclics				
201-557-4	84-74-2	Dibutyl phthalate (DBP)	Full, > 1000	
210-088-4	605-50-5	Diisopentyl phthalate (DiPP)	Full, not (publicly) available	
201-622-7	85-68-7	Benzyl butyl phthalate (BBP)	Full, not (publicly) available	
205-017-9	131-18-0	Dipentyl phthalate (DPP)	-	
284-032-2	84777-06-0	1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	-	

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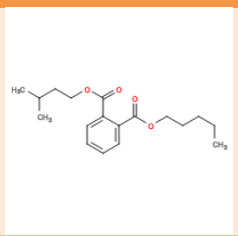
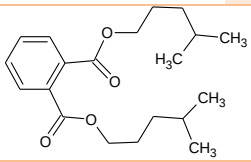
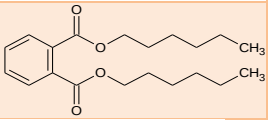
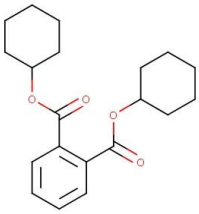
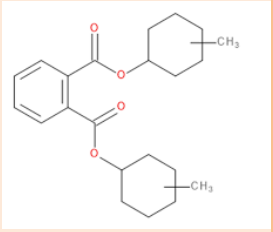
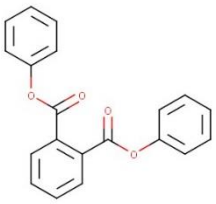
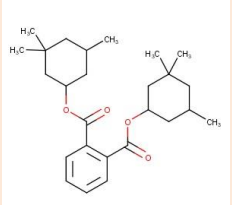
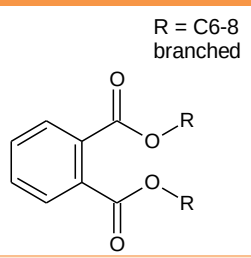
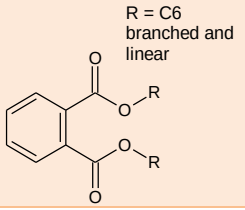
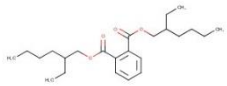
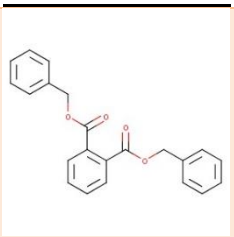
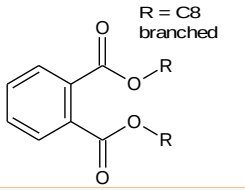
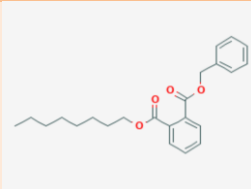
933-378-9	776297-69-9	n-pentyl-isopentylphthalate (PiPP)	-	
276-090-2	71850-09-4	Diisohexyl phthalate (DiHP)	-	
201-559-5	84-75-3	Dihexyl phthalate (DHP)	-	
201-545-9	84-61-7	Dicyclohexyl phthalate (DCHP)	Full, 100-1000	
248-765-1	27987-25-3	Bis(methylcyclohexyl) phthalate (MDCHP)	Full, not (publicly) available	
201-546-4	84-62-8	Diphenyl phthalate (DPhP)	-	
253-682-9	37832-65-8	Bis(3,3,5-trimethyl cyclohexyl) phthalate (D3MCHP)	-	

EC/List number	CAS number	Substance name [and/ or substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical Structures
276-158-1	71888-89-6	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (D68P, branched)	-	
271-093-5	68515-50-4	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	**-**	
204-211-0	117-81-7	Bis(2-ethylhexyl) phthalate (DEHP)	Full, > 1000	
208-344-5	523-31-9	Dibenzyl phthalate (DBzP)	-	
248-523-5	27554-26-3	Diisooctyl phthalate[2] (DiOP)	-	
215-000-8	1248-43-7	Benzyl octyl phthalate	-	

[2] From the DiOP RAC opinion (2018), it appears that the technical substance consists up to 75% of constituents with hydrocarbon chains corresponding to C5-C6. Therefore, this substance was included in subgroup 4.

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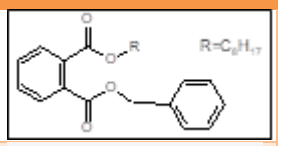
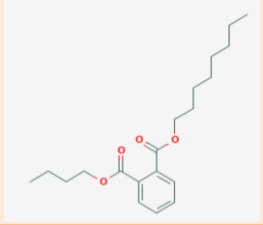
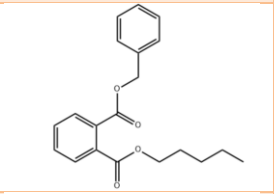
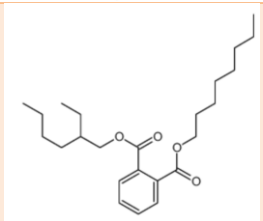
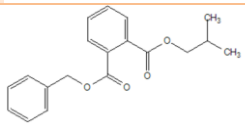
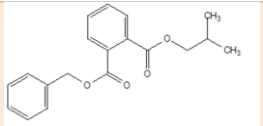
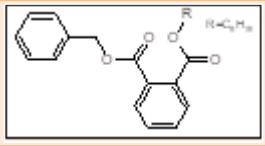
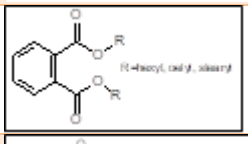
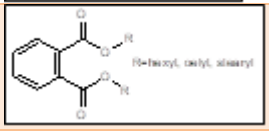
248-335-3	27215-22-1	Benzyl isooctyl phthalate	-	
201-562-1	84-78-6	n-butyl octyl phthalate	-	
	1240-18-2	n-pentyl benzyl phthalate	-	
	3461-26-5	2-ethylhexyl octyl phthalate	-	
	72170-45-7	iso-butyl benzyl phthalate	-	
	144648-76-0	iso-butyl benzyl phthalate	-	
	72170-46-8	*iso*-pentyl benzyl phthalate	-	
678-163-8	126198-74-1	1,2-Benzenedicarboxylic acid, 1-isononyl 2-(phenylmethyl) ester	-	
284-662-8	84961-72-8	1,2-Benzenedicarboxylic acid, mixed hexyl and oleyl and stearyl diesters	-	
667-836-1	75673-16-4	(+)-Mono-(1,2,2-Trimethylpropyl) phthalate	-	

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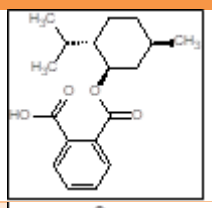
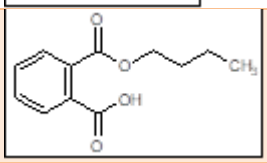
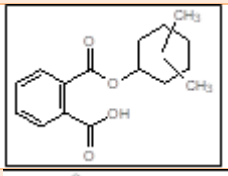
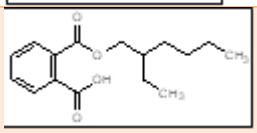
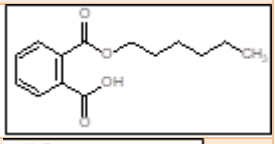
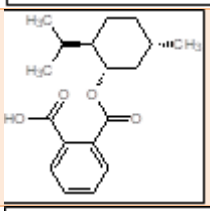
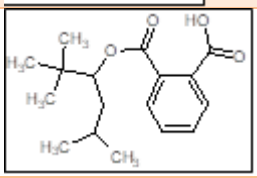
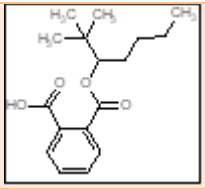
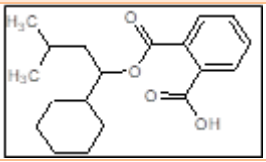
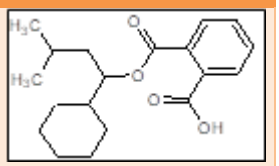
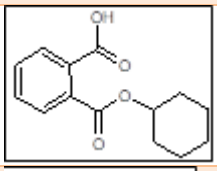
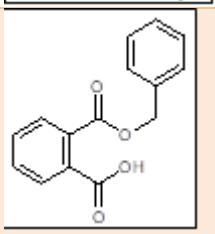
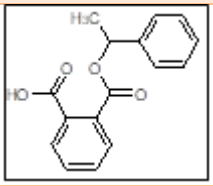
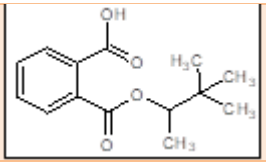
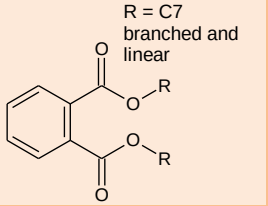
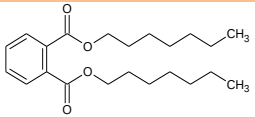
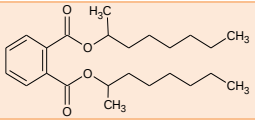
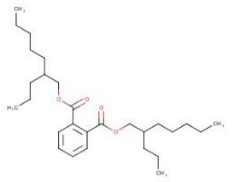
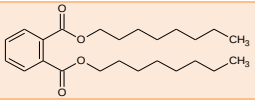
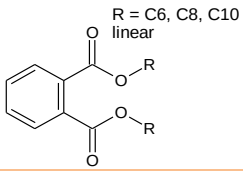
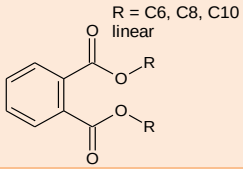
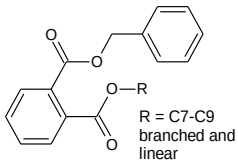
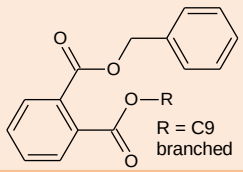
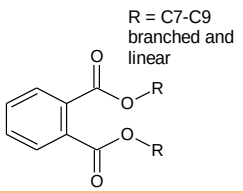
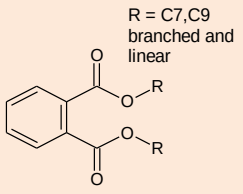
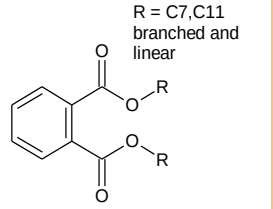
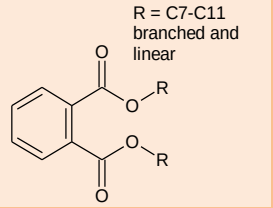
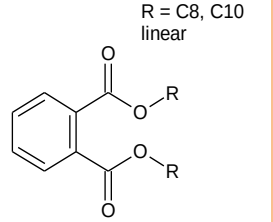
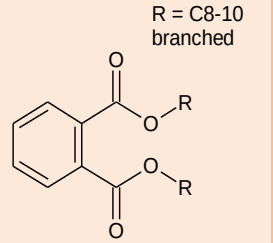
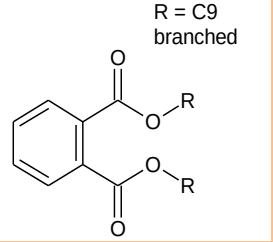
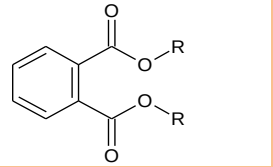
625-655-5	33744-74-0	1,2-Benzenedicarboxylic acid, 1-[(1*R*,2*S*,5*R*)-5-methyl-2-(1-methylethyl)cyclohexyl] ester	-	
205-036-2	131-70-4	Butyl hydrogen phthalate	-	
215-344-9	1322-94-7	(dimethylcyclohexyl) hydrogen phthalate	-	
224-477-1	1322-94-8	(2-ethylhexyl) hydrogen phthalate	-	
246-302-8	1322-94-9	hexyl hydrogen phthalate	-	
633-405-1	53623-42-0	1,2-Benzenedicarboxylic acid, 1-[(1*S*,2*R*,5*S*)-5-methyl-2-(1-methylethyl)cyclohexyl] ester	-	
635-204-4	109591-02-8	1,2-Benzenedicarboxylic acid, 1-[1-(1,1-dimethylethyl)-3-methylbutyl] ester	-	
661-335-1	109591-01-7	1,2-Benzenedicarboxylic acid, 1-[1-(1,1-dimethylethyl)pentyl] ester	-	
635-262-0	111501-63-4	1,2-Benzenedicarboxylic acid, 1-(1-cyclohexyl-3-methylbutyl) ester	-	

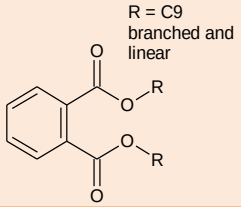
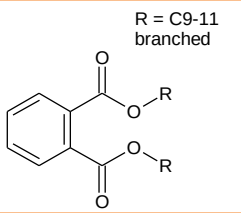
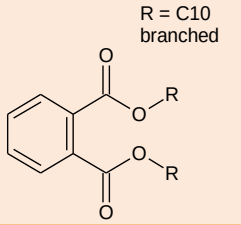
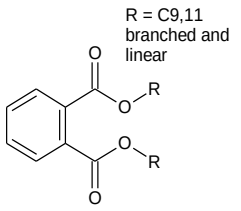
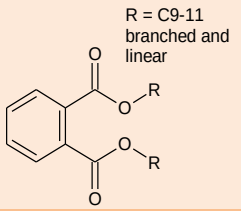
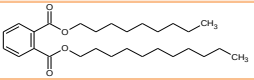
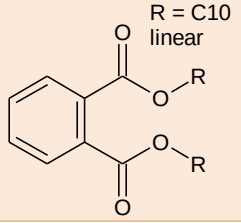
EC/List number	CAS number	Substance name [and/ or substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical Structures
635-262-0	111501-63-4	1,2-Benzenedicarboxylic acid, 1-(1-cyclohexyl-3-methylbutyl) ester		
809-729-6	7517-36-4	1,2-Benzenedicarboxylic acid, 1-cyclohexyl ester		
219-771-1	2528-16-7	Benzyl hydrogen phthalate		
664-374-2/664-327-6	33533-53-8/17470-31-4	1,2-Benzenedicarboxylic acid, 1-(1-phenylethyl) ester		
667-836-1	84489-36-1	1,2-Benzenedicarboxylic acid, 1-(1,2,2-trimethylpropyl) ester		
Subgroup 5: Medium-chain length (predominantly C7-C8 backbone) linear and branched *ortho*-phthalates				
271-086-7	68515-44-6	1,2-Benzenedicarboxylic acid, diheptyl ester, branched and linear	-	
222-885-4	3648-21-3	Diheptyl phthalate	-	
205-014-2	131-15-7	Bis(1-methylheptyl) phthalate	-	

EC/List number	CAS number	Substance name [and/ or substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical Structures
258-469-4	53306-54-0	Bis(2-propylheptyl) phthalate (DPHP)	Full, > 1000	
204-214-7	117-84-0	Dioctyl phthalate (DnOP)	-	
271-094-0	68515-51-5	1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters	Full, not (publicly) available	
272-013-1	68648-93-1	1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters	-	
271-082-5	68515-40-2	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	-	
701-339-3	No CAS	1,2-Benzenedicarboxylic acid, benzyl isononyl alkyl esters (D79P, branched and linear)	Full, not (publicly) available	
271-083-0	68515-41-3	1,2-Benzenedicarboxylic acid, di-C7-9-branched and linear alkyl esters	-	
601-082-6	111381-89-6	2-O-heptyl 1-O-nonyl benzene-1,2-dicarboxylate	-	 [3]

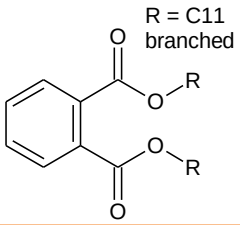
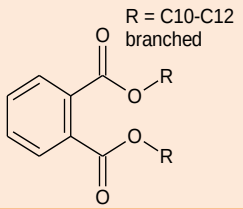
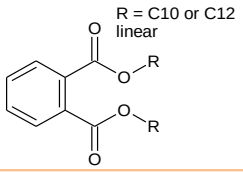
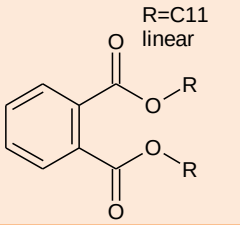
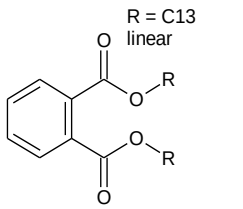
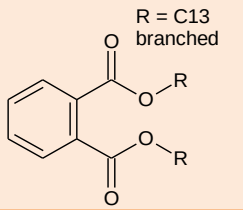
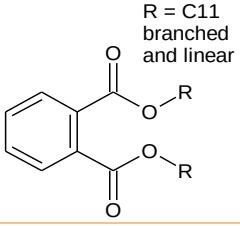
[3] The composition of this substance may in practice consist of C7-C9 isomers

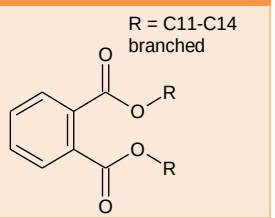
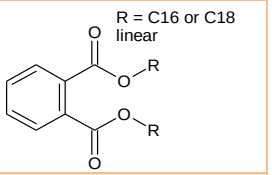
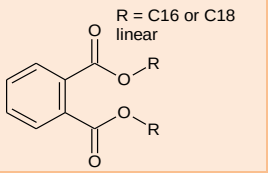
EC/List number	CAS number	Substance name [and/ or substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical Structures
601-083-1	111381-90-9	O2-(3-ethylpentyl) O1-(2-propyloctyl) benzene-1,2-dicarboxylate	-	 [4]
271-084-6	68515-42-4	O1-(3-ethyl-4-methylhexyl) O2-(2-propyloctyl) benzene-1,2-dicarboxylate (D711, branched and linear)	-	
275-809-7	71662-46-9	1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters (D810P)	Full, not (publicly) available	
271-090-9	68515-48-0	1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (DINP)	Full, > 1000	
249-079-5	28553-12-0	Di-''isononyl'' phthalate (DINP)	Full, > 1000	
Subgroup 6: Long-chain length (predominantly C9-C18 backbone) linear and branched *ortho*- phthalates				
201-560-0	84-76-4	Dinonyl phthalate (DNP)	-	

[4] The composition of this substance may in practice consist of C7-C11 mixed isomers

EC/List number	CAS number	Substance name [and/ or substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical Structures
271-087-2	68515-45-7	1,2-Benzenedicarboxylic acid, dinonyl ester, branched and linear (DNP, branched and linear)	-	
271-091-4	68515-49-1	1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (DIDP)	Full, > 1000	
247-977-1	26761-40-0	Di-''isodecyl'' phthalate (DIDP)	-	
601-084-7	111381-91-0	1,2-Benzenedicarboxylic acid, 1-nonyl 2-undecyl ester, branched and linear (NUP, branched and linear)	-	 [5]
271-085-1	68515-43-5	1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters (D911P, branched and linear)	Full, > 1000	
265-603-5	65185-89-9	Nonyl undecyl phthalate (NUP)	-	
201-561-6	84-77-5	Didecyl phthalate (DDP)	-	

[5] The composition of this substance may in practice consist of C9-C11 mixed isomers

EC/List number	CAS number	Substance name [and/ or substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical Structures
306-165-8	96507-86-7	Diisoundecyl phthalate (DiUP)	-	
700-989-5	-	1,2-benzenedicarboxylic acid, di-C10-12-branched alkyl esters (D1012P, branched)	Full, not (publicly) available	
931-251-2	-	bis(decyl and/or dodecyl) benzene-1,2-dicarboxylate	Full, not (publicly) available	
222-884-9	3648-20-2	Diundecyl phthalate (DUP)	Full, not (publicly) available	
204-294-3	119-06-2	Di(tridecyl) phthalate (DTDP)	-	
248-368-3	27253-26-5	Diisotridecyl phthalate (DiTP)	Full, not (publicly) available	
287-401-6	85507-79-5	Diundecyl phthalate, branched and linear (DUP, branched and linear)	Full, > 1000	

EC/List number	CAS number	Substance name [and/ or substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical Structures
271-089-3	68515-47-9	1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich (D1114P, branched)	Full, > 1000	
290-580-3	90193-76-3	1,2-Benzenedicarboxylic acid, di-C16-18-alkyl esters (D1618P)	Full, > 1000	
270-487-4	68442-70-6	1,2-Benzenedicarboxylic acid, mixed cetyl and stearyl esters	-	

In addition in subgroup 4 there are two registered substance(s) with non-publicly available identifier(s)

Contents

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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 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, 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[6]

[6] 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
FCM	Food Contact Material
NONS	Notified new substances
OEL	Occupational exposure limit
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

1 Overview of the group

ECHA has grouped structurally similar phthalate and phthalate-like esters, acids and salts in 4 groups, based on the number and position of the alkyl/aryl substituents: (i) ortho-phthalates, (ii) isophthalates, (iii) terephthalates and (iv) trimellitates. Assessment of regulatory needs for substances belonging to the *ortho*-phthalate group has been performed and documented in this report. Another report documents the assessment of regulatory needs for isophthalates, terephthalates and trimellitates.

The *ortho*-phthalate group consists of phthalate esters with a carbon chain range from C1 to C18 including linear and branched alkyl and aryl substituents in the R1/R2 positions. Additionally, there is a subgroup of phthalic acid and its salts which are precursors to the *ortho*-phthalate esters (subgroup 1).

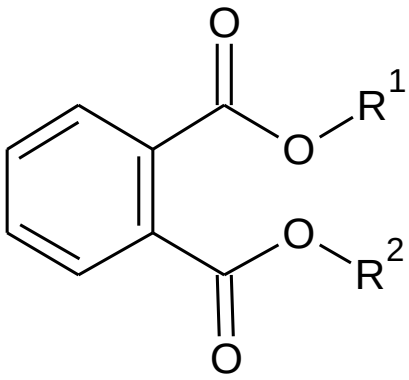

Figure 1: General *ortho*-phthalate ester structure

The subgroup naming and division is based on the longest hydrocarbyl chain on the alkyl substituent, here described as backbone range, and not the total carbon range of the alkyl substituent. This is exemplified below in Figure 2 for bis(2-ethylhexyl) phthalate (DEHP) which has two ethylhexyl (C8, blue) alkyl substituents with a C6 (red) backbone due to the branching in the ethylhexyl substituents.

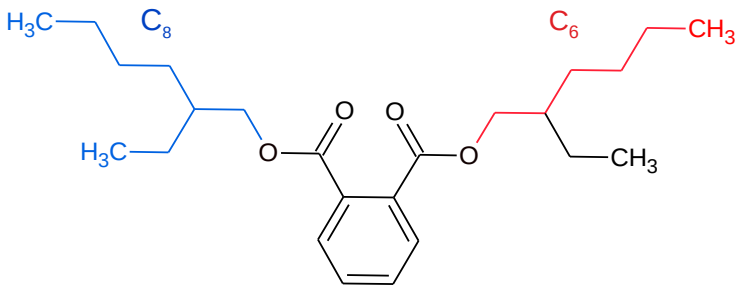

Figure 2: chemical structure of bis(2-ethylhexyl) phthalate

The group includes 91 substances, 32[7] of these are registered under REACH (17 well defined (WD), 15 UVCBs). The substances are well defined up to a carbon chain length of C7 where after the remainder are commonly UVCB substances with some variation in the carbon chain range. Phthalic acid and its salts are also well

[7] 32 registered of which: 28 are Art. 10 registrations, 1 transported isolated intermediate (TII), 2 NONS, 1 inactive.

defined. The UVCB substances are likely to contain common constituents and also contain the constituents showing lower carbon chains at lower concentration levels.

The substances were grouped in 6 subgroups (as indicated at the beginning of this document). This "grouping" is based on:

- the length of the backbone range at the R1/R2 positions as explained above and
- on the known/predicted (eco)toxicological profile based on the currently available information.

The main (potential) human health hazard for *ortho*-phthalates is related to reproductive toxicity, since a number of these substances already have a harmonised classification (CLH) for reproductive toxicity (all for development and in most cases also fertility) and they are structurally very similar (differing mainly in the length and branching of the alkyl chains). Some of them are also identified as endocrine disruptors (ED).

Based on the data screened in the REACH registration dossiers as well as other available information (e.g. literature, assessment reports of authorities, etc..), all substances in subgroup 4 for which data are available, show similar type of adverse effects on the development of the male reproductive organs, which are also sufficiently severe to trigger classification for development. The postulated anti-androgenic mode of action (MoA) is considered to be responsible for these effects. This group contains amongst others the phthalates DEHP, DBP and BBP which are substances of very high concern (SVHCs) included in the Candidate List. Subgroup 4 substances could potentially be present as constituents in substances of subgroups 5 and 6.

Substances in subgroup 1 do not show reproductive toxicity in the available studies, while the data available for substances in subgroup 2 show partly similar reproductive toxicity profile (in particular regarding developmental toxicity) to substances in subgroup 4. Based on the currently available data, substances with alkyl backbone length predominantly $\geq$ C7 (subgroup 5 and 6) do not appear to cause reproductive/developmental effects or appear to be much less potent than substances with C4-C6 alkyl backbone length (subgroup 4). However, the available data on some substances in subgroup 5 indicate adverse effects on thyroid and potential ED properties, which due to structural similarity and lack of reliable repeated dose toxicity data, cannot be excluded also for other substances in subgroup 5 and substances in subgroup 6.

A potential for endocrine disruption also applies to the environmental hazard assessment. While this hazard has not been subject to the same level of scrutiny, DEHP is a confirmed endocrine disruptor for the environment and recent data generated on DCHP indicates similar effects. Furthermore, data from the literature point towards a potential for environmental ED properties for substances ranging from DMP (C1) to DTDP (C13) thus covering subgroups 2 to 6. It should also be noted that a number of medium- to long-chain phthalates screen as potentially PBT/vPvB.

Ortho-phthalates, commonly referred to as "phthalates", are primarily used as plasticisers to add flexibility and resilience to plastic products. Beside the main technical function as plasticiser/softener, *ortho*-phthalates can have other functions, too, e.g. as solvent, binder, lubricating agent, dispersing agent, filler, intermediate, emollient, antioxidant, process regulator, dust suppressant, phlegmatiser.

There is a wide variety of products in which *ortho*-phthalates are used, e.g. in polymers, plastic articles, plastisol, dry-blends, thermoplastics, paint/coating/inks, adhesives, rubber, lubricants/waxes/polishes, metal working fluids, curing agents, hydraulic fluids, catalysts, solvents, sealants, construction materials or cosmetics. Some of the *ortho*-phthalates are used in food contact materials. Furthermore, some substances are registered for uses as co-formulants in plant protection and/or biocidal products.

Based on registration information, many of the registered substances are used widespread in high tonnages with potential for exposure to both human and the environment. The substances are registered for uses in industrial settings, by professional workers and consumers as well as for uses in articles. The potential release of phthalates from articles is of particular concern considering that for obtaining the desired properties large amounts of phthalates are typically added to polymers. Summarising the use information, the group has overall high potential for exposure to professional workers, consumers and the environment.

REACH registration data suggest that the medium-chain length *ortho*-phthalates (like DEHP) have been partly replaced by other types of substances, e.g., terephthalates and cyclohexanoates. This trend stems from the regulatory pressure on the medium-chain length *ortho*-phthalates (e.g. DEHP, BBP, DBP). All in all, the overall tonnage of ortho-phthalates used in the EU is still very high[8].

The group comprises quite a number of substances which have already been under regulatory scrutiny, e.g. identified as SVHC and included in the Authorisation List (see Annex 3). Some are restricted for use in certain articles. However, many structurally similar substances of the group are not yet regulated. The same applies to substances containing the regulated phthalates as constituent in significant concentrations.

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.

[8] Report on the operation of REACH and CLP 2021

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 combined with authorisation due to (potential) reprotoxic, endocrine disrupting properties for human health and/or environment, PBT properties and potential for release/ exposure of **all substances in subgroup 4 and registered substances of subgroups 5 and 6**, **DMP (EC 205-011-6) and DEP (EC 201-5506)** in **subgroup 2**, **DAP (EC 205-016-3) in subgroup 3.**

Many substances included in **subgroup 4** have a harmonised classification for reproductive toxicity: 9 as Repr. 1B (H360FD), 2 Repr. 1B (H360 Df) and 2 as Repr. 1B (H360D). 6 out of these 9 substances are also identified as SVHCs due to ED properties. The screening also identified 30 substances which do not have harmonised classification, one of these is self-classified by the registrants as Repr. 1B (H360D).

The information on reproductive toxicity of *ortho*-phthalates belonging to this subgroup has been reviewed during the CLH processes under CLP, SVHC and restriction processes under REACH (ECHA 2008a, ECHA 2008b, ECHA 2011, ECHA 2012, ECHA 2013a, ECHA 2013b, ECHA 2014b, ECHA 2016, ECHA 2017a, ECHA 2017, ANSES 2017, ECHA 2018) and by Environment Canada (ENV Canada 2015b). Based on ECHA's assessment of currently available information (including registration dossiers), it is expected that all substances in **subgroup 4** are reproductive toxicants at least for development, potentially also for fertility. All of them are also expected to have ED properties for human health, which are a consequence of the same MoA. Furthermore, it is assumed that any *ortho*-phthalate, that is structurally similar to these substances (i.e. C4-C6 backbone, linear and branched, incl. aromatics and cyclic substituents), would also have similar reproductive toxic and ED properties.

Regarding endocrine disrupting (ED) properties for the environment, DEHP (EC 204-211-0) is already identified as ED for the environment and an update of Annex XIV is ongoing. Furthermore, data recently generated on DCHP (EC 201-545-9) also indicate a potential for ED properties for the environment. Based on the available information and on the structural similarity among the members of this subgroup it is assumed that all members are potentially ED for the environment.

It should also be noted that some subgroup 4 members also fulfil the PBT/vPvB screening criteria[9]. These substances may be already concluded as T based on reproductive toxicity hazard and/or aquatic toxicity. Considering current uncertainties on ED properties for the environment for some of these substances, it is proposed to clarify the PBT/vPvB properties in parallel to those actions proposed to clarify ED for the environment.

Several substances of subgroup 4 are already classified for Repr. 1B, have been identified as SVHC and have been included in the Authorisation List. There are also restrictions in place for several of them.

The registered uses include many wide-dispersive use profiles with high release potential to both humans and the environment.

[9] As defined in REACH Annex XIII and R11 Guidance on PBT assessment (https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f)

The assumption for this group of substances aims at taking the necessary actions to regulate all *ortho*-phthalates having a medium-chain length (C4-C6 backbone) structure and/or cyclic and/or aromatic in a coherent and timely manner whilst taking full account of the regulatory measures already in place. This is foreseen to be best achieved by combining restriction and authorisation.

As many of the *ortho*-phthalates end up in articles, it is very likely that restrictions are needed to address risks from article use. Several of the *ortho*-phthalates are already restricted in childcare articles and some other plasticised materials like cables and coated fabrics used by consumers. A restriction on *ortho*-phthalates in articles could be triggered by Art. 69(2) if the substances were included in the Authorisation List and the sunset date has passed. However, initiating such restriction directly after or in parallel to the CLH process would allow taking the identified necessary regulatory measure (restriction) several years earlier compared to the route of subjecting the substances first to the authorisation requirement.

Therefore, following or in parallel harmonised classification and labelling, a restriction addressing the risks from use of these *ortho*-phthalates in articles is proposed.

In parallel, we propose to address the ED properties through identification as SVHC. Considering the number of *ortho*-phthalates already identified as SVHC and included in the Authorisation List, the need to include all of them in the Authorisation List has to be re-assessed after the scope of the proposed restrictions is clear. The main driver for that is to ensure coherence in regulatory actions, i.e. to make sure that the regulated *ortho*-phthalates of this subgroup are not easily replaced by structurally similar substances, thereby avoiding regrettable substitution.

Furthermore, it is proposed to explore, how to regulate ortho-phthalates as a group, rather than substance by substance, i.e how to achieve harmonised classification, restriction and/or SVHC identification, which would cover any ortho-phthalate which in its structure contains the backbone range of the alkyl substituent between C4-C6 carbon atoms and/or cyclic and/or aromatic alkyl substituents.

This would ensure not only that any ortho-phthalate currently identified, but also any "new" ortho-phthalate with similar structure would be covered and regulated. In addition, this could help regulating also UVCB or multi-constituent ortho-phthalate, which contain such constituents. Furthermore, it needs to be clarified, whether these substances could be identified as ED for the environment based on mammalian data.

There are several multi-constituent/UVCB substances of **subgroup 5 and 6** which are suspected to contain constituents with shorter carbon chains (i.e. those belonging to subgroup 4). The limited available studies with these multi constituent/UVCB substances in general do not show reproductive toxicity (except for EC 271-084-6, which is classified as Repr. Cat 1B and is suspected to contain at least some constituents belonging to subgroup 4). However, if these substances contain the above-mentioned constituents, they would in any case need to be regulated based on these constituents, if present at relevant concentrations.

Depending on the above, it is expected that regulating the medium-chain length phthalates (subgroup 4) may also be sufficient to regulate the substances of subgroups 5 and 6. In addition, there is indication from the available data that some substances in group 5 may have ED properties for thyroid. Due to structural similarity and limited reliable repeated dose toxicity data, this cannot be excluded also for (some) other substances in subgroup 5 and 6.

In case these (or certain) substances cannot be (sufficiently) regulated based on presence of constituents, further data generation will be needed for many of them, since the currently available data is not sufficient to conclude on their potential hazardous properties and/or extensive read-across is applied which would need to be verified via a compliance check (CCH). This is particularly true for environmental endpoints where there is a lack of reliable data to support the toxicity and PBT/vPvB assessment. For several substances data generation (SEv or CCH) is currently ongoing, for some of them the results of these processes need to be awaited and taken into account before progressing with the next steps.

The main concern with **DMP** (EC 205-011-6) and **DEP** (EC 201-550-6) of **subgroup 2** stems from recent literature data which indicates potential ED hazard for the environment (among others, inhibition of DHT-stimulated AR activity in vitro (Engel *et al.* 2017), increased E2 production and in E2/T ratio in an in vitro MVLN cell line assay and effects on gene regulation in vivo in a zebrafish embryo assay (Lee *et al.*, 2019), exposure to DEP induced an increased expression of androgen-related genes in an *in vivo* Western clawed frog assay (Bisseger *et al.* 2018)).

Regarding other potential environmental hazards, it is concluded that there is no PBT/vPvB hazard for DMP and DEP as these substances are unlikely to be persistent and their log Kow does not indicate high bioaccumulation potential. However, these substances do appear to show a high aquatic toxicity hazard profile. Since there are remaining uncertainties with the available data further data generation is required.

Both substances are used in high tonnages in the EU (>1,000 tpa), mainly as plasticiser, e.g. in thermoplastics and paints, but also in cosmetics, as solvent or curing agent. Also, the use in biocides (co-formulant) is registered. Releases to the environment are expected to be high. There are indications that DEP is used in food contact materials.

The available data for **DAP** (EC 205-016-3), which belongs to **subgroup 3**, indicate potential reproductive toxicity and ED properties. This potential hazard still needs to be verified by further data generation (CCH). The available data also indicates that the MoA for these potential properties likely differs from substances in subgroup 4 (medium-chain length (C4-C6 backbone) *ortho*-phthalates incl. aromatic and cyclic). The substance is registered for use in paints (e.g. for plastic articles) but there is also indication for potential use as food contact material.

Following the same reasoning as described above for substances in subgroups 4, 5 and 6, if the potential hazard properties of DEP, DMP and DAP are confirmed then the most appropriate regulatory tool to address the concern linked to the use of such substances would be restriction and authorisation as parallel actions. For DEP and DMP SVHC identification confirming the ED properties for the environment would be needed first.

Based on currently available information, there is no need for EU regulatory risk management for **all substances in subgroup 1 and remaining substances of subgroups 2 and 3** due to either low hazard potential and/or low potential for exposure.

Based on ECHA's assessment of information available in the registration dossiers, phthalic acid (EC 201-873-9) is expected to have low (potential) toxicological and environmental hazard. However, due to lack of reliable data on human health endpoints and extensive read-across used, compliance check needs to be initiated to confirm this assumption.

For three substances in subgroup 1 (EC 208-341-9, 212-889-4 and 240-106-6) no environmental or human health hazard could be identified based on the limited data available in the registration dossiers. Data generation on phthalic acid is expected to inform also on potential hazard properties of these salts.

If after data generation the low hazard potential is confirmed for those three substances of subgroup 1 and phthalic acid there will be no need for EU regulatory risk management.

Although one of the phthalic acid salts (EC 416-900-5) has indications of potential reproductive toxicity based on information available in the registration dossiers, the potential for exposure to HH and ENV is expected to be low based on the use profile (capacitor fluid and electrolytic solvent in batteries and accumulators) and therefore there is currently no need for EU regulatory risk management.

However, due to lack of reliable data, compliance check is proposed to be initiated for clarifying the aquatic toxicity of the substance.

DIBP has been identified as SVHC (Repr and ED HH) and included in Annex XIV (for Repr). Amendment of the Annex XIV entry to reflect also the ED HH is ongoing. With regard to human health, the substance is considered as sufficiently regulated.

There are significant indication from literature data that DIBP may show an ED hazard for the environment. The substance is currently registered only for intermediate uses (F, I) in the manufacture of chemicals and as catalyst precursor. There are no professional or consumer uses registered, nor any article service life.

No data generation is currently proposed for DIBP (EC 201-553-2) based on current use pattern. Since DIBP is already concluded as ED HH, it could be evaluated if the data used to reach this conclusion are population relevant and therefore sufficient to conclude ED for the environment as well, which may allow a relatively straight forward identification as ED ENV.

It should be noted that DIBP is restricted by entry 51 Annex XVII for use in articles used by consumers or indoors (more details in Annex 3). There are also indications that the substance may be used in food contact materials, although this is currently not reflected in the registrations[10]. If there are changes in use pattern/registrations, substance evaluation could be considered, followed by SVHC identification as ED ENV (if this is confirmed) and amendment of Annex XIV.

However, currently there is no need for further EU regulatory risk management measures because it is considered sufficiently regulated for HH and due to low potential for exposure of the environment.

Based on currently available information, there is no need for EU regulatory risk management for **all substances not being registered (or registration being inactive)**

While it cannot be excluded that substances of this group may have hazardous properties, none of the subgroup members are actively registered at the moment. Therefore, none of the substances in the group need EU regulatory risk

[10] Draft opinion on identification and prioritisation for risk assessment of phthalates, structurally similar substances potentially used as plasticisers in materials and articles intended to come into contact with food" under public consultation until 5 Nov-16 Dec 2021.

management actions at the moment, apart from the actions that stem from Article 69(2) from some of the substances (271-094-0 and 272-013-1). However, data generation and revisiting this conclusion should be considered if the registration status changes.

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
Subgroup 1	**Phthalic acid and salts**				
201-873-2 (PA)	No hazard or unlikely hazard	No hazard or unlikely hazard	Mainly used as pH regulating agent (leather industry) in industrial settings	**Currently no need for EU RRM** Justification: Overall, no or unlikely hazard that would lead to concern for the reported uses	CCH
208-341-9 **212-889-4** **240-106-6**	No hazard or unlikely hazard	No hazard or unlikely hazard	Mainly used as additive in inks, pH regulating agent, processing aid for leather and textile with potential for exposure/release	**Currently no need for EU RRM** Justification: Overall, no or unlikely hazard that would lead to concern for the reported uses	No action pending CCH on phthalic acid
416-900-5	Known or potential hazard for reproductive toxicity, systemic toxicity	Known or potential hazard for aquatic toxicity	Mainly used as capacitor fluid, electrolytic solvent in batteries and accumulators. Low potential for exposure/release	**Currently no need for EU RRM** Justification: Expected low potential for exposure to both	CCH

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			expected.	human health and environment	
Subgroup 2	**Short-chain length (C1-C2 backbone) linear and branched ortho-phthalates**				
205-011-6 (DMP) **201-550-6 (DEP)**	No hazard or unlikely hazard	Known or potential hazard for aquatic toxicity and ED	Used as plasticiser, solvent, binder, cosmetics in different life cycle stages including articles leading to potential exposure to both human health and the environment. (potentially) used in FCM	**Need for EU RRM: Restriction combined with authorisation** Justification: The substances may end up in articles where potential for exposure cannot be excluded It is suggested to address the potential exposure to these substances in a similar manner as for substances in subgroup 4.	**First step:** CCH SEV **Next steps (if hazard confirmed):** SVHC identification Restriction (use in articles) Authorisation
210-086-3 (DiPrP) **250-204-0 (DtBP)**	No hazard or unlikely hazard	Known or potential hazard for aquatic toxicity and ED	Substances not registered therefore no use information available from the registration dossiers.	**Currently no need for EU RRM** Justification: The substances are currently not registered Actions (including data generation) will be re-considered when the assessment will be revisited if the	**No action**

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				registration status changes.	
Subgroup 3	**Short-chain length (C3 backbone) linear and branched *ortho*-phthalates (sat. and unsat.)**				
205-016-3 (DAP)	Known or potential hazard for reproductive toxicity and ED	Known or potential hazard for aquatic toxicity and ED	Use in paint with potential for exposure to human health and releases to the environment (Potentially) used in FCM	**Need for EU RRM: Restriction combined with authorisation** <u>Justification</u>: The substances may end up in articles where potential for exposure cannot be excluded It is suggested to address the potential exposure to these substances in a similar manner as for substances in subgroup 4.	**First step:** CCH Consider SEv after CCH for ED ENV **Next steps (if hazard confirmed):** CLH Restriction (use in articles) SVHC identification Authorisation
201-553-2 (DIBP)	Known hazard for reproductive toxicity and ED	Known or potential hazard for aquatic toxicity and ED	Only intermediate uses	**Currently no need for EU RRM** <u>Justification</u>: The substance is only use as intermediate and already included on the Candidate list for ED HH. Actions (e.g. clarification of potential	**No action**

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				ED ENV) will be re-considered when the assessment will be revisited if the registration status/uses change.	
205-015-8 (DPrP) **CAS 94491-96-0 (EiBP)**	Known or Potential hazard for reproductive toxicity and ED based on structural similarity	Known or potential hazard for aquatic toxicity and ED	Not registered – no use information	**Currently no need for EU RRM** Justification: Substances currently not registered. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status changes	**No action**
Subgroup 4	**Medium-chain length (C4-C6 backbone) linear and branched *ortho*-phthalates incl. aromatic and cyclic**				
Not(publicly) available	Known or potential hazard for reproductive toxicity and ED based on structural similarity	Known or potential hazard for aquatic toxicity and ED	Not(publicly) available	**Need for EU RRM: Restriction combined with authorisation** Justification: The aim is to regulate all *ortho*-phthalates having a medium-chain length (C4-C6 backbone) structure	**Group actions C4-C6:** Group entry for CLH and SVHC on Repro and ED HH **Restriction** (use in articles) **ED expert group consultation** on ED

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				and/or cyclic and/or aromatic in a coherent and timely manner whilst taking full account of the regulatory measures already in place. This is foreseen to be best achieved by combining restriction and authorisation Many of the *ortho*-phthalates end up in articles, it is very likely that restrictions are needed to address risks from article use. Several of the *ortho*-phthalates are already restricted in childcare articles and some other plasticised materials like cables and coated fabrics used by consumers. In parallel, it is proposed to address the ED properties through identification as SVHC. Considering the number of *ortho*-phthalates already identified as SVHC and included in	ENV based on mammalian data. *If ED ENV cannot be concluded based on ED HH* ***and there are changes in use pattern*****:** 1. SEv for ENV ED 2. Group entry for SVHC covering Repro, ED HH and ED ENV if confirmed **Authorisation**
201-557-4 (DBP)	Known hazard for reproductive toxicity and ED	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	Use as plasticiser in various applications. Also some other uses registered (e.g. catalyst, solvent, ceramics, propellant) by industrial, professional, consumer and article service leading to potential exposure to both human health and the environment		**CCH** **Restriction** (use in articles) **ED expert group consultation** on ED ENV based on mammalian data. *If ED ENV cannot be concluded based on ED HH*: 1. SEv for ENV ED

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			Potentially used in FCM	the Authorisation List, the need to include all of them in the Authorisation List has to be re-assessed after the scope of the proposed restrictions is clear. Furthermore, it is proposed to explore, how to regulate ortho-phthalates as a group, rather than substance by substance to ensure not only that any ortho-phthalate currently identified, but also any "new" ortho-phthalate with similar structure would be covered and regulated. In addition, this could help regulating also UVCB or multi-constituent ortho-phthalate, which contain such constituents.	*If ED ENV and/or PBT is confirmed:* 2. SVHC identification (for ENV) 3. Amendment of Annex XIV entry
210-088-4 (DiPP)	Known hazard for reproductive toxicity and potential ED based on structural similarity	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	Use as propellant		**CCH** **Restriction** (use in articles) **Group actions C4-C6:** Group entry for SVHC HH (ED) 1. SVHC identification (for ED HH) **ED expert group consultation** on ED ENV based on mammalian data *If ED ENV cannot be concluded based on ED*

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
					HH ***and there are changes in use pattern****:* 2. SEv for ENV ED *If ED ENV and/or PBT is confirmed:* 3. SVHC identification (for ENV) 4. Amendment of Annex XIV entry
201-622-7 (BBP)	Known hazard for reproductive toxicity and ED	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	Uses reported in the registration dossier are not clear Potentially used in FCM		**CCH** **Restriction** (use in articles) **ED expert group consultation** on ED ENV based on mammalian data *If ED ENV cannot be concluded based on ED HH* ***and there are changes in use pattern****:* 1. SEv for ENV ED *If ED ENV is confirmed:*

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
					2. SVHC identification for ENV 3. Amendment of Annex XIV entry *If ED ENV is not confirmed* 4. To consider SEv to address remaining concern on PBT/vPvB
284-032-2	Known hazard for reproductive toxicity and ED	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	Not registered. No use information		**Group actions C4-C6:** Group entry for CLH and SVHC on Repro and ED HH for those that are not yet classified/identified as SVHC **Restriction** (use in articles)

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
205-017-9 (DPP) **933-378-9 (PiPP)** **276-090-2 (DiHP)** **201-559-5 (DHP)** **276-158-1 (D68P, branched)** **271-093-5** **248-523-5 (DiOP)**	Known hazard for reproductive toxicity and potential ED based on structural similarity	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED			**ED expert group consultation** on ED ENV based on mammalian data. *If ED ENV cannot be concluded based on ED HH* ***and there are changes in use pattern:***

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
201-546-4 (DPhP) **253-682-9 (D3MCHP)** **208-344-5 (DBzP)** **215-000-8** **248-335-3** **201-562-1** **CAS 1240-18-2** **CAS 3461-26-5** **CAS 72170-45-7** **CAS 144648-76-0** **Iso-pentyl benzyl phthalate** **678-163-8** **284-662-8** **690-312-9** **625-655-5** **205-036-2** **215-344-9** **224-477-1** **246-302-8** **633-405-1** **635-204-4** **661-335-1** **635-262-0** **809-729-6** **219-771-1** **664-374-2/664-327-6** **809-729-11**	Known or potential hazard for reproductive toxicity and ED based on structural similarity	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED			1. SEv for ENV ED 2. Data generation for PBT *If ED ENV and/or PBT is confirmed:* 3. SVHC identification for ENV (for substances already identified as SVHC for Repr and in Annex XIV), or Group entry for SVHC for the not yet identified substances (HH: Repro and ED; ENV: ED and/or PBT if confirmed); 4. Amendment of Annex XIV entries or Authorisation
201-545-9 (DCHP)	Known hazard for reproductive toxicity and ED	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	Use as plasticiser in various applications and as phlegmatizer in organic peroxides with		**CCH** **SEv ongoing** covering ENV ED.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			potential for exposure to humans and releases to the environment		Currently listed in 10th recommendation for inclusion in Annex XIV (Authorisation list) (Repr. and ED HH) **Restriction** (use in articles) **ED expert group consultation** on ED ENV based on mammalian data. *If ED ENV cannot be concluded based on ED HH:* 1. Check if ED ENV based on data generated under SEv. *If ED ENV and/or PBT is confirmed:* 2. SVHC identification 3. Annex XIV (if included by then) could be amended with ED ENV and/or PBT

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
248-765-1 (MDCHP)	Known or Potential hazard for reproductive toxicity and ED based on structural similarity	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	Use as plasticisers in polymers and paints with potential for exposure to humans and releases to the environment		**CCH** for PBT **Group actions C4-C6:** Group entry for CLH and SVHC HH (Repro/ED) **Restriction** (use in articles) **ED expert group consultation** on ED ENV based on mammalian data *If ED ENV cannot be concluded based on ED HH **and there are changes in use pattern:*** 1. SEv for ENV ED 2. Group entry for SVHC (HH: Repro and ED; ENV: ED and/or PBT if confirmed) 3. Authorisation
Not (publicly) available	Known or Potential hazard for reproductive toxicity and ED based on structural similarity	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	Not (publicly) available		**Group actions C4-C6:** Group entry for CLH and SVHC HH (Repro/ED) **Restriction** (use in

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
					articles) **ED expert group consultation** on ED ENV based on mammalian data *If ED ENV cannot be concluded based on ED HH* ***and there are changes in use pattern***: 1. SEv for ENV ED 2. Group entry for SVHC (HH: Repro and ED; ENV: ED and/or PBT if confirmed) 3. Authorisation
204-211-0 (DEHP)	Known hazard for reproductive toxicity and ED	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	Use as intermediate and plasticiser with potential for exposure to humans and releases to the environment		**No action**
Subgroup 5	**Medium-chain length (predominantly C7-C8 backbone) *ortho*-phthalates**				
258-469-4 (DPHP) **701-339-3 (D79P, branched and linear)**	Known or potential hazard for reproductive toxicity and ED	Known or potential hazard for PBT/vPvB and ED	Use as plasticiser with potential for exposure to humans and releases to the environment	**Need for EU RRM: Restriction combined with authorisation** Justification:	**Await outcome from pending SEv** **CCH**

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			EC 258-469-4 (potentially) used in FCM.	There are several multi-constituent/UVCB substances of subgroup 5 and 6 which are suspected to contain constituents with shorter carbon chains (i.e. those belonging to subgroup 4). If these substances contain the above-mentioned constituents, they would be regulated based on these constituents, if present at relevant concentrations. In addition, there is indication from the available data that some substances in group 5 may have ED properties for thyroid. Due to structural similarity and limited reliable repeated dose toxicity data, this cannot be excluded also for (some) other substances in subgroup 5 and 6.	These substances (potentially) include constituents with C4-C6 backbone, linear and branched, incl. aromatic and cyclic substituents; if confirmed, they could potentially be regulated based on these constituents. **Restriction** (use in articles) **ED expert group consultation** on ED ENV based on mammalian data. *If ED ENV cannot be concluded based on ED HH then:* 1. SEv for ED ENV (EC 701-339-3 only as 258-469-4 already under SEv) *Next steps if Repr, ED HH/ENV and/or PBT confirmed:* 2. SVHC identification

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				In case these (or certain) substances cannot be (sufficiently) regulated based on presence of constituents, further data generation will be needed for many of them. For those substances where the potential hazardous properties will be confirmed, similar actions as what proposed for subgroup 4 substances are anticipated.	3. Authorisation
271-090-9 (DINP) **249-079-5 (DINP)**	Known or potential hazard for reproductive toxicity and ED based on potential presence of C6 constituents (based on RAC opinion, studies with the substance does not warrant classification)	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	Use as plasticiser with potential for exposure to humans and releases to the environment P(Potentially used in FCM.		These substances (potentially) contain constituents with C4-C6 backbone, linear and branched, incl. aromatic and cyclic substituents; if confirmed, they could potentially be regulated based on these constituents. **Restriction** (use in articles) **CCH** **ED expert group consultation** on ED ENV based on mammalian data. *If ED ENV cannot be concluded based on ED HH then (from subgroup 4 constituents) then:* 1. SEv for ED ENV

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
					Next steps if Repr, ED HH/ENV and/or PBT confirmed: 2. SVHC identification 3. Authorisation
275-809-7 (D810P)	Known or potential hazard for reproductive toxicity and thyroid toxicity	Known or potential hazard for aquatic toxicity and ED	Use as plasticiser in paints and lubricants with potential exposure to human health and releases to the environment		**Await outcome from pending CCH** These substances (potentially) contain constituents with C4-C6 backbone, linear and branched, incl. aromatic and cyclic substituents; if confirmed, they could potentially be regulated based on these constituents. **Restriction** (use in articles) **ED expert group consultation** on ED ENV based on mammalian data. *Next steps if Repr, ED HH/ENV confirmed:*

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
					1. SVHC identification 2. Authorisation
271-086-7 **222-885-4** **205-014-2** **204-214-7 (DnOP)** **271-094-0** **272-013-1** **271-082-5** **271-083-0** **601-082-6** **601-083-1** **271-084-6 (D711, branched and linear)**	Known or potential hazard for reproductive toxicity and thyroid toxicity	Known or potential hazard for ED	Not registered. No use information EC 204-214-7 (potentially) used in FCM	**Currently no need for EU RRM** <u>Justification</u>: Substances currently not registered. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status changes	**No action**
Subgroup 6	**Long-chain length (predominantly C9-C18 backbone) linear and branched ortho-phthalates**				
271-091-4 (DIDP) **247-977-1 (DIDP)**	Known or potential hazard	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	Used as plasticiser in polymer, paints, adhesives, lubricants. Further uses in metal	**Need for EU RRM: Restriction combined with authorisation**	Potentially contains constituents with C4-C6 backbone, linear and branched, incl. aromatic

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
	for reproductive toxicity and ED based on constituents		working fluid and hydraulic fluids. Use in cosmetics Potential for exposure to humans and releases to the environment	<u>Justification:</u> There are several multi-constituent/UVCB substances of subgroup 5 and 6 which are suspected to contain constituents with shorter carbon chains (i.e. those belonging to subgroup 4). If these substances contain the above-mentioned constituents, they would be regulated based on these constituents, if present at relevant concentrations. In addition, there is indication from the available data that some substances in group 5 may have ED properties for thyroid. Due to structural similarity and limited reliable repeated dose toxicity data, this cannot be excluded also for (some) other substances in subgroup 5 and 6.	and cyclic substituents; if confirmed, they could potentially be regulated based on these constituents. **Restriction** (use in articles) **CCH** *Next steps if Repr, ED HH/ENV and/or PBT confirmed:* 1. SVHC identification 2. Authorisation *If not ED for ENV based on mammalian data (from subgroup 4 constituents) then:* 3. SEv for ED ENV *Next steps if hazard confirmed:* SVHC identification Authorisation
290-580-3 (D1618P) **271-089-3 (D1114P, branched)**	Known or potential hazard for reproductive toxicity and ED based on constituents	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	Use as plasticiser in polymer, paints, adhesives, lubricants, polishes. Further uses in metal working fluid, hydraulic fluids, cosmetics. Potential for exposure to humans and releases to the environment.		
271-085-1 (D911P, branched and linear) **222-884-9 (DUP)** **287-401-6 (DUP, branched and linear)**	Known or potential hazard for reproductive toxicity and ED based on constituents	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	Use as plasticiser with potential for exposure to humans and releases to the environment.		
700-989-5 (D1012P, branched) **931-251-2** **248-368-3 (DiTP)**	Known or potential hazard for reproductive toxicity and ED based on constituents	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	Use as plasticiser in polymers and adhesives, lubricant with potential for exposure to humans and releases to the environment.		

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				In case these (or certain) substances cannot be (sufficiently) regulated based on presence of constituents, further data generation will be needed for many of them. For those substances where the potential hazardous properties will be confirmed, similar actions as what proposed for subgroup 4 substances are anticipated.	
201-560-0 (DNP) **271-087-2 (DNP, branched and linear)** **601-084-7 (NUP, branched and linear)** **265-603-5 (NUP)** **201-561-6 (DDP)** **306-165-8 (DiUP)** **204-294-3 (DTDP)**	Known or potential hazard for reproductive toxicity and ED based on constituents	Known or potential hazard for PBT/vPvB, aquatic toxicity and ED	No use information as not registered	**Currently no need for (further) EU regulatory risk management** Justification: Substances currently not registered. Actions (including data generation) will be re-considered when the assessment will be revisited if the	**No action**

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
270-487-4				registration status changes	

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

Data extracted on July 2020

EC number (subgroup and CLP index number)	Substance name	Classification		
		Harmonised classification in CLP	Additional Self-classification in registration dossier	Additional classification in C&L notifications
Subgroup 2: Short-chain length backbone (C1-C2) linear and branched phthalates				
201-550-6	diethyl phthalate	Not classified	Not classified	Repr. 2 (H361d) Skin Sens. 1 Skin Irrit. 2 Eye Irrit. 2 Acute Tox. 3/4 STOT RE 2 STOT SE 3 Aq. Acute 1 Aq. Chronic 1
205-011-6	dimethyl phthalate	Not classified	Not classified	Eye Irrit. 2 Skin Irrit. 2 Acute Tox. 3 STOT SE 3 Aq. Chronic 3
210-086-3	diisopropyl phthalate	Not classified	Not registered	Skin Irrit. 2 Eye Irrit. 2 STOT SE 3 Carc. 2
250-204-0	di-tert-butyl phthalate	Not classified	Not registered	Not classified
Subgroup 3: Short-chain length backbone (C3) linear and branched, sat. and unsat. phthalates				
201-553-2 (Index No 607-623-00-2)	diisobutyl phthalate	Repr. 1B (H360Df)	Aq. Acute 1 Aq. Chronic 1	Acute Tox. 3/4
205-016-3 (Index No 607-086-00-4)	diallyl phthalate	Acute Tox. 4 Aq. Acute 1 Aq. Chronic 1	Skin Sens. 1B Acute Tox 4	Carc. 2
205-015-8	dipropyl phthalate	Not classified	Not registered	Carc. 2 Repr. 2 Aq. Chronic 2
(701-355-0)	Ethyl isobutyl phthalate	Not classified	Not registered	Not notified
Subgroup 4: Medium-chain length backbone (C4-C6) incl. aromatic and cyclic phthalates				
201-545-9 (Index No 607-719-00-4)	dicyclohexyl phthalate	Repr. 1B (H360D) Skin Sens. 1	Aq. Chronic 2	Repr. 2 (oral) Aq. Chronic 3 Skin Irrit. 2 Eye Irrit. 2

EC number (subgroup and CLP index number)	Substance name	Classification		
		Harmonised classification in CLP	Additional Self-classification in registration dossier	Additional classification in C&L notifications
				STOT SE 3 (lungs or organs)
201-546-4	Diphenyl phthalate	Not classified	Not registered	Skin Irrit. 2 Eye Irrit. 2 STOT SE 3 Resp. Sens. Aq. Acute 1
201-557-4 (Index No 607-318-00-4)	dibutyl phthalate	Repr. 1B (H360Df) Aq. Acute 1	Aq. Chronic 1	Carc. 1A Repr. 2
201-559-5 (Index No 607-702-00-1)	dihexyl phthalate	Repr. 1B (H360FD)	Not registered	Aq. Acute 1
201-622-7 (Index No 607-430-00-3)	benzyl butyl phthalate	Repr. 1B (H360Df) Aq. Acute 1 Aq. Chronic 1	Not available	Acute Tox. 3/4
204-211-0 (Index No 607-317-00-9)	bis(2-ethylhexyl) phthalate	Repr. 1B (H360FD)	Aq. Acute 1	Aq. Chronic 3/2 Eye Irrit. 2 Carc. 2 Repr. 1A
205-017-9 (Index No 607-426-00-1)	di-n-pentyl phthalate	Repr. 1B (H360FD) Aq. Acute 1	Not registered	Repr. 1A
208-344-5	Dibenzyl phthalate	Not classified	Not registered	Not classified
210-088-4 (Index No 607-426-00-1)	diisopentyl phthalate	Repr. 1B (H360FD) Aq. Acute 1	Skin Sens. 1	Skin Sens. 1
248-523-5 (Index No 607-740-00-9)	Diisooctyl phthalate	Repr. 1B (H360FD)	Not registered	Aq. Chronic 4
248-765-1	bis(methylcyclohexyl) phthalate	Not classified	Repr. 1B (H360D) Skin Irrit. 2 Skin Sens. 1B	Eye Irrit. 2 Acute Tox. 3 STOT SE 3 Aq. Chronic 3
253-682-9	Bis(3,3,5-trimethylcyclohexyl) phthalate	Not classified	Not registered	Skin Irrit. 2 Eye Irrit. 2 STOT SE 3
271-093-5 (Index No 607-710-00-5)	1,2-benzenedicarboxylic acid, dihexylester, branched and linear	Repr. 1B (H360FD)	Not registered	Repr. 2 (H361)
276-090-2 (Index No 607-737-00-2)	Diisohexyl phthalate	Repr. 1B (H360FD)	Not registered	Not notified

EC number (subgroup and CLP index number)	Substance name	Classification		
		Harmonised classification in CLP	Additional Self-classification in registration dossier	Additional classification in C&L notifications
276-158-1 (Index No 607-483-00-2)	1,2-benzenedicarboxylic acid di-c6-8-branched alkylesters, C7-rich	Repr. 1B (H360D)	Not registered	No additional hazards
284-032-2 (Index No 607-426-00-1)	benzenecarboxylic acid, dipentylester, branched and linear	Repr. 1B (H360FD) Aq. Acute 1	Not registered	No additional hazards
933-378-9 (Index No 607-426-00-1)	n-pentyl-isopetylphthalate	Repr. 1B (H360FD) Aq. Acute 1	Not registered	No additional hazards
Subgroup 5: Medium-chain length backbone (predominantly C7-C8) phthalates				
204-214-7	Dioctyl phthalate	Not classified	Not registered	Repr. 2 (H361) Skin Sens. 1 Resp. Sens. 1 Aq. Chronic 4
205-014-2	Bis(1-methylheptyl) phthalate	Not classified	Not registered	Not classified
222-885-4	diheptyl phthalate	Not classified	Not registered	Repr. 2 (H361) Skin Irrit. 2 Eye Irrit. 2 STOT SE 3
249-079-5	di-''isononyl'' phthalate	Not classified	Not classified	Repr. 2 (H361) Acute Tox. 4 Resp. Sens. 1A Aq. Acute 1
258-469-4	bis(2-propylheptyl) phthalate	Not classified	Not classified	Not classified
271-082-5	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	Not classified	Not registered	Aquatic Acute 1 Aquatic Chronic 2
271-083-0	1,2-Benzenedicarboxylic acid, di-C7-9-branched and linear alkyl esters	Not classified	Not registered	Not classified
271-084-6 (Index No 607-480-00-6)	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	Repr. 1B (H360Df)	Not registered	No additional hazards

EC number (subgroup and CLP index number)	Substance name	Classification		
		Harmonised classification in CLP	Additional Self-classification in registration dossier	Additional classification in C&L notifications
271-086-7	1,2-benzenedicarboxylic acid, diheptyl ester, branched and linear	Not classified	Not registered	Not classified
271-090-9	1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich; DINP	Not classified	Not classified	Aq. Acute 1 Repr. 2 Skin Irrit. 2 Eye Irrit. 2
271-094-0	1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters	Not classified	Not classified	Not classified
272-013-1	1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters	Not classified	Not registered	Not notified
275-809-7	1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters	Not classified	Not classified	Not classified
601-082-6	1,2-Benzenedicarboxylic acid, heptyl nonyl ester, branched and linear	Not classified	Not registered	Not classified
601-083-1	1,2-Benzenedicarboxylic acid, 1-heptyl 2-undecyl ester, branched and linear	Not classified	Not registered	Not classified
701-339-3	1,2-Benzenedicarboxylic acid, benzyl isononyl alkyl esters	Not classified	Not classified	Not classified
Subgroup 6: Long-chain length backbone (predominantly C9-C18) phthalates				
201-560-0	Dinonyl phthalate	Not classified	Not registered	Skin Irrit. 2 Eye Irrit 2 STOT SE 3
201-561-6	Didecyl phthalate	Not classified	Not registered	Not classified
204-294-3	Di(tridecyl) phthalate	Not classified	Not registered	Not classified

EC number (subgroup and CLP index number)	Substance name	Classification		
		Harmonised classification in CLP	Additional Self-classification in registration dossier	Additional classification in C&L notifications
222-884-9	diundecyl phthalate	Not classified	Not classified	Aq. Chronic 1/3
247-977-1	Di-''isodecyl'' phthalate	Not classified	Not registered	Skin Irrit. 2 Eye Irrit. 2 Aq. Acute 1 Aq. Chronic 1/2
248-368-3	diisotridecyl phthalate	Not classified	Not classified	Not classified
265-603-5	Nonyl undecyl phthalate	Not classified	Not registered	Not classified
270-487-4	1,2-Benzenedicarboxylic acid, mixed cetyl and stearyl esters	Not classified	Not registered	Not classified
271-085-1	1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters	Not classified	Not classified	Acute Tox. 2
271-087-2	1,2-Benzenedicarboxylic acid, dinonyl ester, branched and linear	Not classified	Not registered	Not classified
271-089-3	1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich	Not classified	Not classified	Aq. Chronic 1
271-091-4	1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich	Not classified	Not classified	Aq. Acute 1 Skin Irrit. 2 Eye Irrit. 2
287-401-6	diundecyl phthalate, branched and linear	Not classified	Not classified	Not classified
290-580-3	1,2-Benzenedicarboxylic acid, di-C16-18-alkyl esters	Not classified	Not classified	Not classified

EC number (subgroup and CLP index number)	Substance name	Classification		
		Harmonised classification in CLP	Additional Self-classification in registration dossier	Additional classification in C&L notifications
306-165-8	Diisoundecyl phthalate	Not classified	Not registered	Not classified
601-084-7	1,2-Benzenedicarboxylic acid, 1-nonyl 2-undecyl ester, branched and linear	Not classified	Not registered	Not classified
700-989-5	1,2-Benzenedicarboxylic acid, di-C10-12-branched alkyl esters	Not classified	Not classified	Not classified
931-251-2	Reaction mass of bis(decyl and dodecyl) benzene-1,2-dicarboxylate and bis-decyl benzene-1,2-dicarboxylate	Not classified	Not classified	Not classified
Subgroup 1: Acid and its salts				
201-873-2	phthalic acid	Not classified	Eye Dam. 1	Eye Irrit. 2 Skin Irrit. 2 Acute Tox. 4 STOT SE 3
208-341-9	diammonium phthalate	Not classified	Not classified	Not classified
212-889-4	potassium hydrogen phthalate	Not classified	Not classified	Muta. 2 Repr. 2 (H361fd) Eye Irrit. 2 Skin Irrit. 2 STOT SE 3
240-106-6	disodium phthalate	Not classified	Not classified	STOT SE 3
416-900-5 (Index No 607-478-00-5)	tetramethylammonium hydrogen phthalate	Acute Tox. 3 STOT RE 2 Aq. Acute 1	Eye Irrit. 2 Aq. Chronic 1 (M=1)	No additional hazards

Note: NC, not classified

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

Data extracted on March 2020

	201-545-9	201-550-6	201-553-2	201-557-4	201-622-7	204-211-0	205-011-6	205-016-3	210-088-4	222-884-9	248-368-3	248-765-1	249-079-5	258-469-4	271-085-1	271-089-3	271-090-9	271-091-4	275-809-7	287-401-6	290-580-3	700-989-5	701-339-3	931-251-2
Use in polymers, PVC, rubber, plastic articles, in plastisol and dry-blends	F, I, P, C, A			F, I, P, A	F	F, I, P, C, A		I		F, I	F, I, P, A	F, I, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, C, A	F, I, A	F, I, P, A	F, I, P, C, A	F, I, P, C, A	F, I, C, A	I, A		F, I, P, C, A
Use in thermoplastics		F, I, P, A					I, P																	
Paints, coatings, inks, toners							F, I, P, C, A	F, I, A				F, I, P, A	F, I, P, C, A			I		I, P	F, I, P, C, A	I, P, A	I, P, C		F, I, P, C, A	I, P
Adhesives							F, I				F, I, P, C		F, I, P, C			I, P	I	I, P	I, P, C, A	I, P, A				I, P, C, A
Lubricant, waxes, greases											F, I, P,		F, I, P, C			F, I, P		F, I, P, C	I, P, C, A		F, I, P, C			I, P, C, A

	201-545-9	201-550-6	201-553-2	201-557-4	201-622-7	204-211-0	205-011-6	205-016-3	210-088-4	222-884-9	248-368-3	248-765-1	249-079-5	258-469-4	271-085-1	271-089-3	271-090-9	271-091-4	275-809-7	287-401-6	290-580-3	700-989-5	701-339-3	931-251-2
											C, A													
Polishes and waxes																I					I, P, C			
Metal working fluids																I		I			I, P			
Curing agent							F, I, A																	
Use in organic peroxides as phlegmatiser and dispersing agent	F, I, P, C						I, P						F, I, P, C											
Hydraulic fluids																I		I			I, P, C			
Use in cosmetics, fragranced products, detergents		F, I, P, C, A					F, I, P, C									F, C		F, I, C			I, P, C			

	201-545-9	201-550-6	201-553-2	201-557-4	201-622-7	204-211-0	205-011-6	205-016-3	210-088-4	222-884-9	248-368-3	248-765-1	249-079-5	258-469-4	271-085-1	271-089-3	271-090-9	271-091-4	275-809-7	287-401-6	290-580-3	700-989-5	701-339-3	931-251-2
Use as catalyst/pre-catalyst		F, I	F, I	F, I																				
Intermediate		F, I	F, I			F, I	I							I							I			
Solvent				I			I, C, A														I, P, C			
Use in ceramics				I																				
Construction materials/ Sealants													F, I, P, C								I, P, C			
Fuel additive/ additised fuels																F, P		F, P			F, I, P			
Propellant				F, I					I, C, 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

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

Data extracted in March 2020

Regulatory history summary

Candidate List

There are 16 substances identified as SVHC:

- 4 for Repr. and ED HH (BBP, DBP, DIBP, DCHP)
- 1 for Repr. and ED HH and ED ENV (DEHP)
- 11 for Repr.

Companies have certain legal obligations resulting from the inclusion of substances in the Candidate List. Based on the received Substances in Articles (SiA) notifications, there are indications for presence in articles for five substances (DEHP, DBP, DIBP, BBP, DCHP [11]).

Authorisation List (Annex XIV)

14 substances are included in the Authorisation List (Annex XIV), currently all for being toxic to reproduction. The European Commission still needs to amend four entries (BBP, DBP, DIBP, DEHP) in the Authorisation List for those phthalates that were - after inclusion in Authorisation List - in addition identified as having also endocrine disrupting properties.

This amendment will mean that some uses which until now have been exempted may require authorisation, such as:

1. uses of the four phthalates in mixtures in concentrations equal or above 0.1 % w/w (so far the concentration limit has been 0.3 % w/w);
2. some uses of DEHP (e.g. in food contact materials) that will no longer fall under the 'generic exemptions from the authorisation requirement' due to the endocrine disrupting effects on the environment of DEHP

Certain uses are generically exempt from authorisation if the substance is only identified for human health hazards. Those uses are:

- Use in cosmetic products (Art. 56(5)(a) REACH)
- Use in food contact materials (Art. 56(5)(b) REACH)
- Use in medical devices (Art. 60(2) and 62(6) REACH)

Restrictions (Annex XVII)

Some of the *ortho*-phthalates are restricted under REACH. Below a brief overview of relevant entries:

Entry 30 - All phthalates listed under that entry in Annex XVII (harmonised classified as Repr. 1A or 1B)

[11] Number of notifications varies between 1 and 129 per substance (as of December 2019).

Placing on the market restricted for supply to general public at or above the specific or the generic concentration limit as
- Substances
- Constituent of other substances
- Mixtures

Entry 51 – DEHP, DBP, BBP, DIBP

- Restricted in toys and childcare articles ≥0.1% (originally for DEHP, DBP, BBP).
- Restriction was amended (covering in addition now DIBP) to restrict substances >0.1% by weight (individually or in combination) in plasticised materials in articles used by consumers or indoors (e.g. cables, coated fabrics, sports equipment). Certain exemptions. Most elements of the restriction took effect from July 2020.

Entry 52 - DINP, DIDP, DnOP

- Restricted in plasticised material, in toys and childcare articles which can be placed in the mouth by children ≥0.1%

Possibility for restrictions under Art. 69(2)

Furthermore, after the sunset date has passed for a substance included on the Authorisation List, ECHA is required to assess if the use of a substance in articles is adequately controlled and, if not, prepare a restriction dossier (Art. 69(2) REACH).

For the four phthalates (DEHP, BBP, DBP, DIBP) entry 51 of Annex XVII was updated as mentioned above as consequence of implementing Art. 69(2). For a further six *ortho*-phthalates the sunset date passed in July 2020, therefore the respective 69(2) assessment is required. For the *ortho*-phthalates covered by Annex XIV entries 44-46 the sunset date passes in February 2023.

An overview of the Article 69(2) status for the *ortho*-phthalates is given in Table .

Table 1 Overview of Article 69(2) status

Annex XIV Entry No	Substance	Intrinsic property referred to in Art. 57	Last application date	Sunset date	Status	Conclusion
04	Bis(2-ethylhexyl) phthalate (**DEHP**) EC 204-211-0	Toxic for reproduction (category 1B)[12]	21 August 2013	21 February 2015	Finalised. Regulation published in the in the Official Journal of the European Union 18.12.2018	Commission regulation (EU) 2018/2005 of 17 December 2018 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.322.01.0014.01.ENG&toc=OJ:L:2018:322:TOC
05	Benzyl butyl phthalate (**BBP**) EC 201-622-7					
06	Dibutyl phthalate (**DBP**) EC 201-557-4					
07	Diisobutyl Phthalate (**DIBP**) EC 201-553-2					
33	Diisopentyl phthalate EC 210-088-4 (**DIPP**)	Toxic for Reproduction (category 1B)	04 January 2019	04 July 2020	Sunset date passed. Assessment required.	
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich EC 276-158-1	Toxic for Reproduction (category 1B)	04 January 2019	04 July 2020	Sunset date passed. Assessment required.	
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (**DHNUP**) EC 271-084-6	Toxic for Reproduction (category 1B)	04 January 2019	04 July 2020	Sunset date passed. Assessment required.	
36	1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear EC 284-032-2	Toxic for Reproduction (category 1B)	04 January 2019	04 July 2020	Sunset date passed. Assessment required.	

[12] Entries should be amended as those substances have been further identified as EDs. Amendment recommendation by ECHA was sent to Commission in July 2019.

38	Dipentyl phthalate EC 205-017-9	Toxic for Reproduction (category 1B)	04 January 2019	04 July 2020	Sunset date passed. Assessment required.	
39	n-pentyl-isopentylphthalate EC 933-378-9	Toxic for Reproduction (category 1B)	04 January 2019	04 July 2020	Sunset date passed. Assessment required.	
44	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear EC: 271-093-5	Toxic for reproduction (Article 57c)	27 August 2021	27 February 2023		
45	Dihexyl phthalate EC: 201-559-5	Toxic for reproduction (Article 57c)	27 August 2021	27 February 2023		
46	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5) EC: 271-094-0, 272-013-1	Toxic for reproduction (Article 57c)	27 August 2021	27 February 2023		

Regulation (EU) 10/2011 'Food Contact Materials' (FCM)

Six of the substances are included in the Union list of authorised substances and may be used in the manufacture of plastic materials to be intended to come into contact with food (Annex I of EU 10/2011). Those have an FCM substance number and are the following: DAP, DBP, BBP, DEHP, DINP, DIDP.

Table 2 Overview of regulatory processes (registered substances).

EC/List number	RMOA	Authorisation		Restriction*	CLH	Other
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
201-545-9	YES	Repr. ED HH	Listed in 10th recommendation for inclusion in Annex XIV		Skin Sens 1 (H317) Repr 1B (H360D)	
201-553-2		Repr. ED HH	Entry 7 (for Repr). Amendment of Annex XIV entry recommended to add ED HH.	Entry 51	Repr 1B (H360Df)	
201-557-4		Repr. ED HH	Entry 6 (for Repr). Amendment of Annex XIV entry recommended to add ED HH.	Entry 51	Aquatic Acute 1 (H400) Repr 1B (H360Df)	
201-622-7		Repr. ED HH	Entry 5 (for Repr). Amendment of Annex XIV entry recommended to add ED HH.	Entry 51	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Repr 1B (H360 Df)	
204-211-0		Repr. ED HH ED ENV	Entry 4 (for Repr). Amendment of Annex XIV entry recommended to add ED HH and ED ENV.	Entry 51	Repr 1B (H360FD)	
205-016-3					Acute Tox. 4 (H302) Aq. Acute 1 (H400) Aq. Chronic 1 (H410)	
210-088-4	YES	Repr	Entry 33 (for Repr)		Aquatic Acute 1 (H400) Repr 1B (H360FD)	

EC/List number	RMOA	Authorisation Candidate list	 Annex XIV	Restriction* Annex XVII	CLH Annex VI (CLP)	Other
222-884-9						SID adaptation process. New EC number is 287-401-6
249-079-5				Entry 52		
701-339-3						SID adaptation process. Previous EC 271-082-5
271-090-9				Entry 52		
271-091-4				Entry 52		
271-094-0	YES	Repr	Entry 46 (Repr)		-	*Inactive registration!* CL entry covers also **EC 272-013-1** but only if the substances contain ≥0.3% of dihexyl phthalate (EC No. 201-559-5)
287-401-6						SID adaptation process. Previous EC number was 222-884-9
416-900-5					Acute Tox. 3 (H301) STOT RE 2 (H373 **) Aq. Acute 1 (H400)	
701-339-3						This List number used after CCH. Previous identifier was EC 271-082-5.

EC/List number	RMOA	Authorisation		Restriction*	CLH	Other
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
201-545-9	YES	Repr. ED HH	Listed in 10th recommendation for inclusion in Annex XIV (Authorisation List)		Skin Sens 1 (H317) Repr 1B (H360D)	
201-553-2		Repr. ED HH	Entry 7 (for Repr). Amendment of Annex XIV entry recommended to add ED HH.	Entry 51	Repr 1B (H360Df)	
201-557-4		Repr. ED HH	Entry 6 (for Repr). Amendment of Annex XIV entry recommended to add ED HH.	Entry 51	Aquatic Acute 1 (H400) Repr 1B (H360Df)	
201-622-7		Repr. ED HH	Entry 5 (for Repr). Amendment of Annex XIV entry recommended to add ED HH.	Entry 51	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Repr 1B (H360 Df)	
204-211-0		Repr. ED HH ED ENV	Entry 4 (for Repr). Amendment of Annex XIV entry recommended to add ED HH and ED ENV.	Entry 51	Repr 1B (H360FD)	
205-016-3					Acute Tox. 4 (H302) Aq. Acute 1 (H400) Aq. Chronic 1 (H410)	
210-088-4	YES	Repr	Entry 33 (for Repr)		Aquatic Acute 1 (H400) Repr 1B (H360FD)	
222-884-9						SID adaptation process. New EC number is 287-401-6
249-079-5				Entry 52		

EC/List number	RMOA	Authorisation		Restriction*	CLH	Other
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
701-339-3						SID adaptation process. Previous EC 271-082-5
271-090-9				Entry 52		
271-091-4				Entry 52		
271-094-0	YES	Repr	Entry 46 (Repr)		-	*Inactive registration* CL entry covers also **EC 272-013-1** but only if the substances contain ≥0.3% of dihexyl phthalate (EC No. 201-559-5)
287-401-6						SID adaptation process. Previous EC number was 222-884-9
416-900-5					Acute Tox. 3 (H301) STOT RE 2 (H373 **) Aq. Acute 1 (H400)	
701-339-3						This List number used after CCH. Previous identifier was EC 271-082-5.

*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).

Table 3 Overview of regulatory processes (non-registered substances).

EC/List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
201-559-5		Repr	Entry 45 (Repr)		Repr 1B (H360FD)	
204-214-7				Entry 52	-	
205-017-9		Repr	Entry 38 (Repr)		Aquatic Acute 1 (H400) Repr 1B (H360FD)	
247-977-1				Entry 52		
248-523-5					*Repr 1B (H360FD)*	*RAC opinion 2018*
271-084-6		Repr	Entry 35 (Repr)		Repr 1B (H360Df)	
271-093-5		Repr	Entry 44 (Repr))		Repr 1B (H360FD)	
272-013-1		Repr	Entry 46 (Repr)			CL entry covers also EC **271-094-0** but only if the substances contain ≥0.3% of dihexyl phthalate (EC No. 201-559-5)
276-090-2					*Repr 1B (H360FD)*	*RAC opinion 2017*
276-158-1		Repr	Entry 34 (Repr)		Repr 1B (H360D ***)	
284-032-2		Repr	Entry 36 (Repr)		Aquatic Acute 1 (H400) Repr 1B (H360FD)	
933-378-9		Repr	Entry 39 (Repr)		Aquatic Acute 1 (H400) Repr 1B (H360FD)	List No in CLP: 933-378-9 Index No: 607-426-00-1

*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).