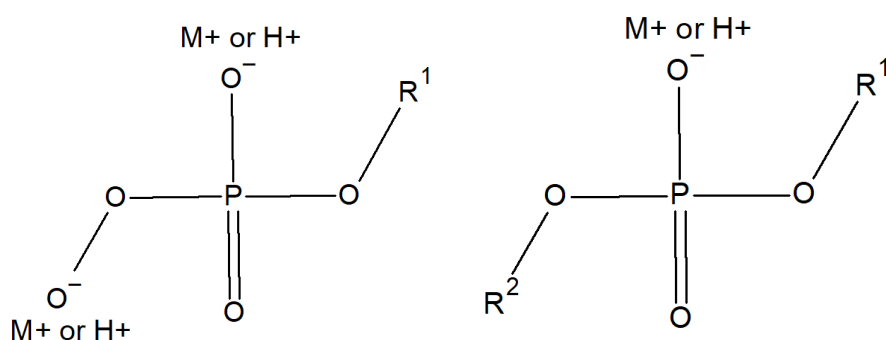


## Assessment of regulatory needs

**Authority: European Chemicals Agency (ECHA)**

**Group Name: Mono-, dialkyl phosphate esters and salts**

**General structure:**



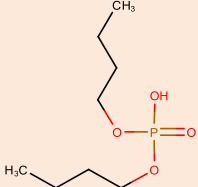
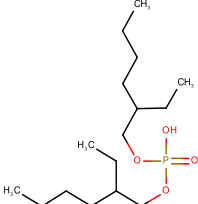
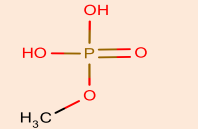
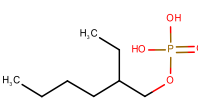
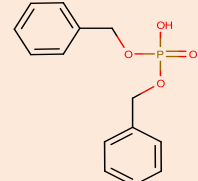
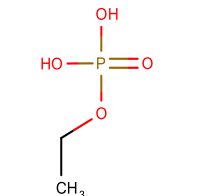
R<sup>1</sup> and R<sup>2</sup> are linear/branched alkyl chains ranging from C1 to C20 or benzyl moiety and M<sup>+</sup> is Na<sup>+</sup>, K<sup>+</sup> or NH<sub>4</sub><sup>+</sup>.

### Revision history

<i>Version</i>	<i>Date</i>	<i>Description</i>
<b>1.0</b>	29 March 2023	

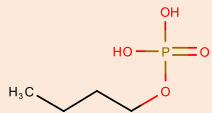
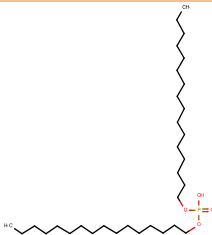
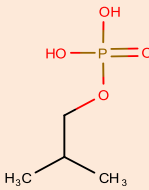
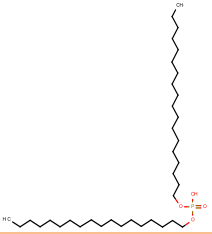
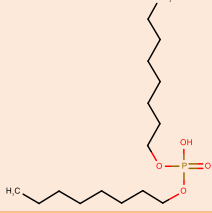
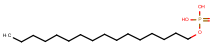
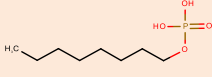
## ASSESSMENT OF REGULATORY NEEDS

## Substances within this group:

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) *
203-509-8	107-66-4	dibutyl hydrogen phosphate		Full, not (publicly) available
206-056-4	298-07-7	bis(2-ethylhexyl) hydrogen phosphate		Full, 100-1000
212-379-1	812-00-0	methyl dihydrogen phosphate		Full, not (publicly) available
213-967-0	1070-03-7	2-ethylhexyl dihydrogen phosphate		Full, not (publicly) available
216-602-3	1623-08-1	dibenzyl hydrogen phosphate		Cease manufacture
216-603-9	1623-14-9	ethyl dihydrogen phosphate		C&L notification

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

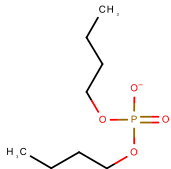
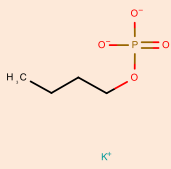
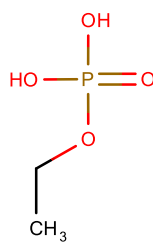
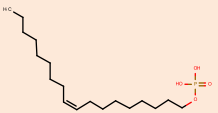
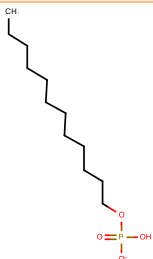
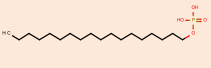
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) *
216-604-4	1623-15-0	butyl dihydrogen phosphate		C&L notification
218-594-7	2197-63-9	dihexadecyl hydrogen phosphate		C&L notification
219-576-1	2466-73-1	isobutyl dihydrogen phosphate		C&L notification
221-237-8	3037-89-6	dioctadecyl hydrogen phosphate		C&L notification
221-485-7	3115-39-7	dioctyl hydrogen phosphate		C&L notification
222-581-1	3539-43-3	hexadecyl dihydrogen phosphate		Full, not (publicly) available
223-638-3	3991-73-9	octyl dihydrogen phosphate		C&L notification

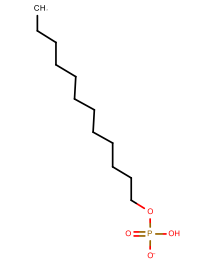
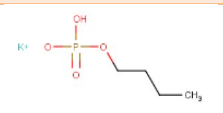
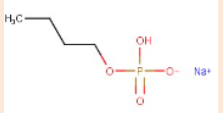
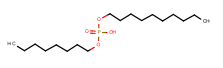
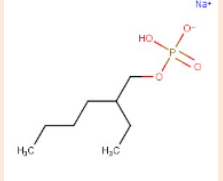
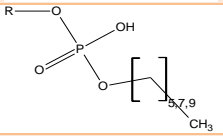
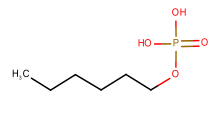
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) *
225-615-3	4971-47-5	ammonium bis(2-ethylhexyl) phosphate		C&L notification
228-602-0	6303-30-6	diisobutyl hydrogen phosphate		Full, not (publicly) available
235-741-0	12645-31-7	Phosphoric acid, 2-ethylhexyl ester		Full, 100-1000
235-799-7	12751-23-4	Phosphoric acid, dodecyl ester		OSII or TII
235-826-2	12788-93-1	Phosphoric acid, butyl ester		Full, 100-1000
242-768-1	19035-79-1	potassium hexadecyl hydrogen phosphate		Full, 100-1000

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) *
246-749-9	25238-98-6	potassium dibutyl phosphate		C&L notification
247-585-0	26290-70-0	dipotassium butyl phosphate		C&L notification
253-391-7	37203-76-2	Phosphoric acid, ethyl ester		Full, not (publicly) available
253-455-4	37310-83-1	9-Octadecen-1-ol, (Z)-, phosphate		Full, 100-1000
254-414-3	39322-78-6	Phosphoric acid, dodecyl ester, potassium salt		Full, 100-1000
254-466-7	39471-52-8	Phosphoric acid, octadecyl ester		C&L notification

## ASSESSMENT OF REGULATORY NEEDS

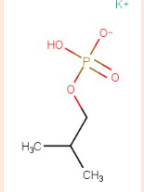
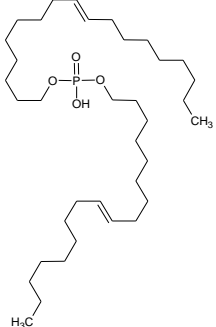
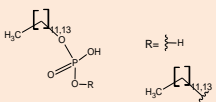
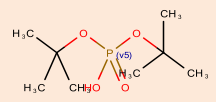
EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) *
256-865-1	50957-96-5	Phosphoric acid, dodecyl ester, sodium salt		C&L notification
258-261-3	52933-07-0	Phosphoric acid, isotridecyl ester	Not available	C&L notification
258-379-5	53126-06-0	Phosphoric acid, butyl ester, potassium salt		C&L notification
258-380-0	53126-67-3	Phosphoric acid, butyl ester, sodium salt		Full, not (publicly) available
269-041-1	68186-45-8	Phosphoric acid, decyl octyl ester		Full, 10-100
269-044-8	68186-64-1	Phosphoric acid, 2-ethylhexyl ester, sodium salt		Full, not (publicly) available
269-616-7	68307-94-8	Phosphoric acid, mono- and di-C6-10-alkyl esters		Cease manufacture
270-390-7	68427-32-7	decyl dihydrogen phosphate, potassium salt	Not available	Full, not (publicly) available
270-935-9	68511-03-5	Phosphoric acid, hexyl ester		OSII or TII

## ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) *
273-489-3	68987-29-1	1-Octadecanol, phosphate, potassium salt	Not available	Full, 100-1000
282-784-6	84418-71-3	Phosphoric acid, mono- and bis(branched and linear pentyl) esters		Full, 100-1000
284-851-5	84988-61-4	Phosphoric acid, isononyl ester		Full, not (publicly) available
289-108-9	86014-62-2	Phosphoric acid, 2-ethylhexyl ester, ammonium salt		Full, not (publicly) available
291-905-1	90506-43-7	Phosphoric acid, C12-18-alkyl esters, potassium salts	Not available	Full, not (publicly) available
291-907-2	90506-45-9	Phosphoric acid, C16-18-alkyl esters, potassium salts		Full, >1000
291-938-1*	90506-73-3	Phosphoric acid, mono- and di-C16-18-alkyl esters		C&L notification
291-941-8	90506-76-6	Phosphoric acid, mono- and di-iso-Bu esters	Not available	C&L notification

\* When a dossier is submitted without EC number, REACH-IT automatically assigns a List number to the dossier. Sometimes, due to IT technical limitations, duplicate List numbers are created. In this Group the following are considered duplicate entries: EC 291-938-1 and List Nr 939-526-9; likely also EC 308-806-7 and List nr 947-478-5. In general EC numbers take precedence over List numbers.

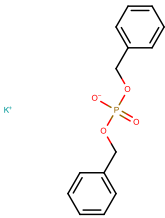
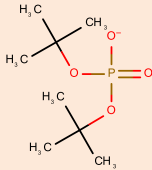
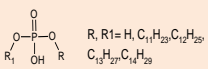
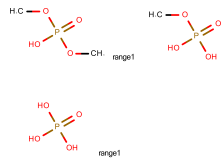
## ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) *
292-411-9	90605-13-3	Phosphoric acid, 2-methylpropyl ester, potassium salt		C&L notification
306-296-0	96792-60-8	Phosphoric acid, C12-15-branched and linear alkyl esters, sodium salts	Not available	C&L notification
307-075-1	97489-33-3	Phosphoric acid, C16-18-branched and linear alkyl esters, potassium salts	Not available	Full, not (publicly) available
307-095-0	97489-51-5	Phosphoric acid, mono- and bis(C16 and C18-unsatd. alkyl) esters		OSII or TII
308-020-4	97808-97-4	Phosphoric acid, mono- and di-C12-14-alkyl esters		Full, not (publicly) available
308-806-7*	98653-76-0	Phosphoric acid, C8-10-alkyl esters	Not available	Full, 1-10
608-874-0	33494-81-4	Phosphoric acid, bis(1,1-dimethylethyl) ester		Cease manufacture

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## ASSESSMENT OF REGULATORY NEEDS

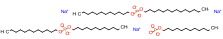
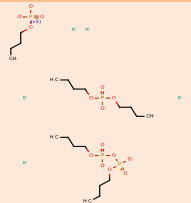
EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) *
616-628-9	78543-37-0	Phosphoric acid, bis(phenylmethyl) ester, potassium salt (1:1)		OSII or TII
619-702-9	33494-80-3	Phosphoric acid, bis(1,1-dimethylethyl) ester, potassium salt (1:1)		OSII or TII
701-370-2	-	Phosphoric acid, mono- and di-C12-18-(even numbered)-alkyl esters	Not available	OSII or TII
800-484-0	154518-38-4	Phosphoric acid, mono- and di-C11-14 (linear and branched) alkyl esters	 R <sub>1</sub> , R <sub>1</sub> = H, C <sub>11</sub> , H <sub>23</sub> , C <sub>12</sub> , H <sub>25</sub> , C <sub>13</sub> , H <sub>27</sub> , C <sub>14</sub> , H <sub>29</sub>	Full, 100-1000
807-789-8	111062-42-1	1-Octanol, reaction products with phosphorus oxide (P2O5), potassium salts	Not available	Full, not (publicly) available
812-497-9	1893414-79-3	Phosphoric acid, C14-15-branched and linear alkyl esters, potassium salts	Not available	Full, not (publicly) available
908-996-7	-	Reaction mass of methyl dihydrogen phosphate and orthophosphoric acid and dimethyl hydrogen phosphate		Full, not (publicly) available

## ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) *
911-302-5	-	Reaction mass of hexadecyl dihydrogen phosphate and dihexadecyl hydrogen phosphate		Full, not (publicly) available
911-351-2	-	Reaction mass of diisobutyl hydrogen phosphate and isobutyl dihydrogen phosphate		Full, 100-1000
911-501-7	-	Reaction mass of dioctyl hydrogen phosphate and octyl dihydrogen phosphate		Full, not (publicly) available
922-551-4	1187440-66-9	Alcohols, C20-22, reaction products with phosphorus oxide (P2O5)		Full, not (publicly) available
939-526-9*	90506-73-3	Phosphoric acid, mono- and di-C16-18-alkyl esters		Full, 100-1000
946-099-2	-	Phosphoric acid, mono C16-20 (branched, even numbered) alkyl esters	Not available	Cease manufacture
946-101-1	-	Phosphoric acid, mono- and di-C16-20-(even	Not available	Full, not (publicly) available

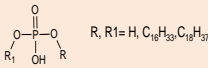
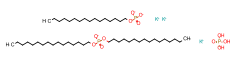
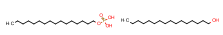
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## ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) *
		numbered, branched and linear)-alkyl esters		
946-154-0	-	Phosphoric acid, mono- and di-isotridecyl esters, potassium salts	Not available	Full, not (publicly) available
947-359-8	-	Phosphoric acid, mono- and di-C6-12-(even numbered)-alkyl esters, potassium salts	Not available	Full, not (publicly) available
947-360-3	-	Phosphoric acid, mono- and di-C12-18-(even numbered)-alkyl esters, sodium salts		Full, not (publicly) available
947-478-5*	-	Phosphoric acid, mono- and di-C8-10-(even numbered)-alkyl esters	Not available	Full, not (publicly) available
947-671-4	-	Phosphoric acid, isotridecyl esters	947-671-4	OSII or TII
947-719-4	-	Phosphoric acid, mono and bis-linear butyl esters, potassium salts		Full, 10-100
947-751-9	-	Phosphoric acid, hexadecyl esters, potassium salts with cetyl alcohol and isostearyl isostearate	Not available	Full, not (publicly) available

\* When a dossier is submitted without EC number, REACH-IT automatically assigns a List number to the dossier. Sometimes, due to IT technical limitations, duplicate List numbers are created. In this Group the following are considered duplicate entries: EC 308-806-7 and List nr 947-478-5. In general EC numbers take precedence over List numbers.

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) *
947-796-4	-	Phosphoric acid, hexadecyl phosphate esters, potassium salts with cetostearyl alcohol		Full, not (publicly) available
947-798-5	-	Reaction mass of orthophosphoric acid and potassium dihexadecyl phosphate and dipotassium hexadecyl phosphate		Full, not (publicly) available
947-877-4	-	Phosphoric acid, C4 and C12-14(even numbered) alkyl esters	Not available	OSII or TII
947-905-5	-	Reaction mass of hexadecyl dihydrogen phosphate and cetyl alcohol		Full, not (publicly) available
947-924-9	-	Phosphoric acid C12-alkyl and C18-alkyl esters, potassium salts	Not available	Full, not (publicly) available
947-954-2	-	Phosphoric Acid, C8-12(even-numbered) linear Alkyl Esters	Not available	Full, not (publicly) available
947-957-9	-	Phosphoric Acid, linear and branched Octyl Esters	Not available	Full, not (publicly) available
947-969-4	-	Phosphoric Acid, Esters with Alcohols, C11-14 iso, C13-rich	Not available	Full, not (publicly) available

## ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) *
947-971-5	-	Phosphoric Acid, C4 and C12-14(even-numbered) Alkyl Esters, Ammonium Salts	Not available	Full, not (publicly) available
949-965-8	-	Reaction products of hexadecyl dihydrogen phosphate, dihexadecyl hydrogen phosphate, hexadecan-1-ol, stearic acid, esters of C18 (branched and linear) fatty acids with C18 (branched and linear) alcohols, and potassium hydroxide	Not available	Full, not (publicly) available

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

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## **DISCLAIMER**

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

## Foreword

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

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

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

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

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

For more information on Assessment of regulatory needs please consult ECHA website\*.

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\* <https://echa.europa.eu/understanding-assessment-regulatory-needs>

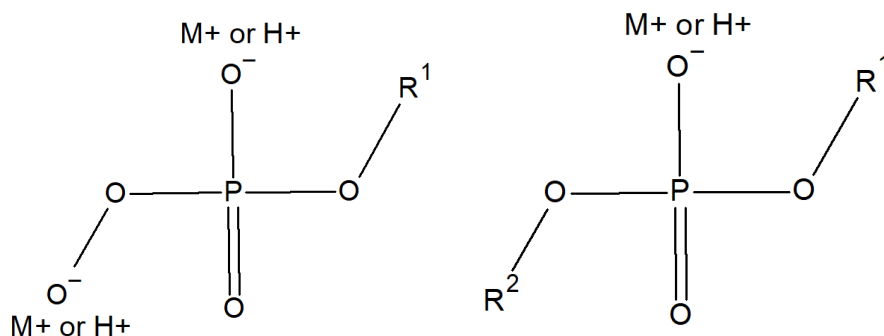


## Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

## 1 Overview of the group

ECHA has grouped together 80 structurally similar substances based on the presence of the phosphate ester and salt moiety shown in the figures below:



Where R<sup>1</sup> and R<sup>2</sup> are linear/branched alkyl chains ranging from C1 to C20 or benzyl moiety and M<sup>+</sup> is Na<sup>+</sup>, K<sup>+</sup> or NH<sub>4</sub><sup>+</sup>.

The group consists of mono-, multi-constituents and UVCB (mostly) substances. These substances mainly consist of mono and diphosphate esters.

The registration status of the substances is the following: 50 (including a duplication) with full (Article 10) registrations, 8 intermediate registrations (active), and 4 inactive registrations (2 intermediate and 2 Article 10).

Based on information reported in the REACH registration dossiers, the substances in the group (excluding intermediates and C&L notification only) are mainly used in the following ways:

- Three substances (ECs: 222-581-1, 235-741-0, 235-826-2) are used as: lubricants, hydraulic fluid, antiadhesive, adhesion promotor, antistatic agent, softener, surface active agent/surfactant, emulsifier, precursor, moisture scavenger, pH regulating agent, pigment, stabiliser, process regulator, corrosion inhibitor, catalyst, biocide, deodoriser (almost all the Process Categories (PCs) are indicated in their registrations).
- The remaining substances except those indicated below have (some of) the uses indicated above, and are additionally used as sealant, impregnation agent, processing aid, viscosity modifier, plasticiser, chelating agent, gelling modifier, finishing agent, internal mould release, dust suppressant, thickener, hair and skin conditioning agent. One to nine PCs (out of 33) are indicated in their respective registrations.
- One substance (EC 253-391-7) is used as flame retardant and anti-crystallising agent.
- For three substances (ECs: 270-390-7, 212-379-1 and 946-099-2) the REACH registration dossiers do not have information on the PCs but the following uses are indicated: use at industrial site (all the three substances), use in formulations (EC 212-379-1 and 946-099-2) and use in laboratory activities and in mixtures by professionals (EC 212-379-1).

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

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

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

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

## 2 Justification for the no need for regulatory risk management action at EU level

**Known or potential hazard for carcinogenicity (Carc 2)** has been identified for the two group members EC 203-509-8 (dibutyl hydrogen phosphate, DBP) and EC 235-826-2 (phosphoric acid, butyl ester). The first is self-classified as Carc 2 (H351). Both contain tributyl phosphate (TnBP, EC 204-800-2) as constituent/impurity up to 3% or 5%, respectively. TnBP has a CLH as Carc. 2 (urinary bladder cancer, based on not-threshold mode of action), therefore classification for Carc 2 would be warranted for both substances based on the presence of TnBP as constituent.

For the following group members, a hazard for skin sensitisation has been identified: EC 228-602-0, 308-020-4, 946-099-2 and 946-101-1. The registrants have self-classified the substances as Skin Sens. 1 or 1B H317.

Based on ECHA's assessment of currently available hazard information (valid guideline and GLP studies), no or unlikely hazards were identified for mutagenicity (based on studies for 26 group members), systemic (target-organ) toxicity (28-day and sub-chronic studies for 12 group members) and reproductive/developmental toxicity and ED potential (pre-natal developmental toxicity and/or reproduction screening studies for 16 group members).

However, the conclusions for the group overall are based on limited data and will need to be confirmed, when possible, through further data generation under compliance check (CCH). Therefore, CCH is proposed for the following group members: **EC 203-509-8, 206-056-4, 212-379-1, 235-741-0, 235-826-2, 242-768-1, 253-455-4, 254-414-3, 258-380-0, 269-044-8, 273-489-3, 282-784-6, 291-907-2, 800-484-0, 908-996-7, 911-351-2, 911-501-7, 922-551-4, 946-154-0, and 947-719-4.**

### Potential CMR hazard based on the presence of short chain trialkylphosphates as impurities

Potential CMR hazard with high uncertainty, (to be confirmed via data generation) for the following short chain trialkylphosphates has been identified under the related group Trialkyl phosphates:

- Tris(2-ethylhexyl) phosphate (**TEHP**, EC 201-116-6) - potential hazard of carcinogenicity (liver carcinoma observed) and for ED (thyroid effects);
- triethyl phosphate (**TEP**, EC 201-114-5) - potential hazard for carcinogenicity, mutagenicity, reproductive toxicity was extrapolated from **TMP**, EC 208-144-8 (CLH proposal for Repr. 1B/F, Muta 1B, Carc 1B, STOT RE 2 (neurotoxicity); and TEP has also potential for ED (thyroid effects). (Note: TMP itself is not identified as an impurity or constituent in any of the members of the current group); and
- trihexyl phosphate (**THP**; EC 219-774-8) – potential hazard for ED (thyroid effects).

The following group members contain the afore-mentioned short-chained trialkylphosphates in concentrations above the threshold of classification:

- EC 206-056-4, containing TEHP as impurity;
- EC 253-391-7, containing TEP as impurity;
- EC 270-935-9, containing THP as constituent and as impurity.

Since none of the identified potential CMR or ED hazards are confirmed yet for the above mentioned trialkylphosphates, it is proposed to wait for the findings from the studies requested on the impurities and once the data are available and hazards confirmed, to re-evaluate the group members.

For 41 group members no conclusion could be reached on **PBT/vPvB**. 21 substances fulfil the screening criteria\* for P/vP as they are not readily biodegradable. The other substances lack reliable data on this property and this conclusion is extrapolated based on structural similarities. None of the substances meet the T criteria set in Annex XIII (i.e. NOEC or EC10 < 0.01 mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2). However, given the lack of e.g. long-term aquatic toxicity for most this conclusion will need to be clarified by further data generation proposed below. Moreover, no conclusion on B/vB properties can be made as the log Kow is not a reliable predictor for these substances being ionisable and/or surface active and experimental data on this property, e.g. bioaccumulation or toxicokinetic studies are lacking. Consequently, ECHA recommends CCH to clarify PBT/vPvB properties for the following subset of substances: **EC 242-768-1, 253-455-4, 254-414-3, 273-489-3, 282-784-6, 291-907-2, 800-484-0, 911-351-2, 911-501-7, 922-551-4, 939-526-9, 946-101-1, 946-154-0, and 947-719-4**. The representative substances were chosen based on their potential for release from industrial, professional, consumer and/or article uses.

Based on ECHA's assessment of currently available hazard information, the substances EC 203-509-8, 206-056-4, 222-581-1, 235-741-0, 235-826-1, 258-380-0, 269-616-7, 289-108-9, 908-996-7 and 947-751-9 are unlikely to fulfil the PBT/vPvB (screening) criteria, because they are (likely) readily biodegradable or inherently biodegradable. These conclusions are based on ready biodegradability test results.

For the following group members there is a **known hazard for aquatic toxicity**: EC 282-784-6, 308-806-7, 800-484-0, 812-497-9, 946-101-1, 946-154-0, 947-

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\* 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](https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f))

751-9, 947-798-5, 947-905-5, 947-969-4, and 949-965-8. Registrants have self-classified the substances for Acute and/or Chronic aquatic toxicity (category 4, 3 or 2).

Also based on ECHA's assessment of currently available aquatic toxicity hazard information for the substances EC 206-056-4, 222-581-1, 235-741-0, 242-768-1, 258-380-0, 308-020-4, 908-996-7 no or unlikely hazard is anticipated. These substances are currently not self-classified for aquatic toxicity. However, this conclusion is based on limited data and will need to be confirmed, when possible, through further data generation under compliance check (CCH). This applies for the following substances: EC 206-056-4, 222-581-1, 235-741-0, 258-380-0, 308-020-4, 908-996-7.

**Based on currently available information, there is no need for (further) EU regulatory risk management for:**

- **Carcinogenicity** hazard of the substance **phosphoric acid, butyl ester** (EC 235-826-2).

Classification criteria for Carc. 2 (H351) are met for the substance, however, there is no self-classification reported in the registration dossier(s). Industry should update the registration dossiers with adequate classification and labelling information of the substance with Carc. 2 (H351) and inform accordingly the users of these substances (via a Safety Data Sheet update).

Adequate classification will require company level risk management measures (RMM) under the OSH legislation for workers to be in place. In addition, the classification as CMR Cat 2 – H351 will:

- require that the necessary safety measures are in place for specific sensitive workers, i.e. pregnant women in accordance with Directive 92/85/EEC and young people in accordance with Directive 94/33/EC.

In the registration dossier for the substance industrial and professional uses have been indicated, as well as consumer uses and article service life (as coatings, paints, thinners, and paint removers). Exposure is likely to be significant based on the aggregated tonnages, many sites/uses, and the types of use (activities where opportunity to exposure arises, such as roller and brushing application, surface cleaning products, etc.).

For industrial uses, it is expected that following the update of the registration dossiers with adequate classification and labelling information, registrants will implement necessary RMMs to ensure safe use at the workplace.

Potential exposure of professional users, consumers and exposure from articles need further investigation.

The reported professional uses in e.g. washing and cleaning, lubricants, metal working fluids, hydraulic fluids, coatings and paints, and metal surface treatment products are expected to be widespread (at many sites and by many users). Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation.

Consumers may be co-exposed to the substances used by professionals e.g. house painters. Furthermore, the substance is reported to be used in formulation of products of PC 39 (cosmetics and personal care products) not being possible to conclude on whether this results in exposure of consumers.

Moreover, potential exposure from articles needs further investigation, namely it should be clarified in which articles the substance is used. Based on the currently

available information it is not possible to conclude whether the substance is used in toys, in components of toys or in micro-structurally distinct parts of toys.

- **Carcinogenicity** hazard of the substance dibutyl hydrogen phosphate (DBP, EC 203-509-8). The substance is self-classified as Carc 2 (urinary bladder). Registrants indicate industrial uses, professional uses (use in laboratory and in products such as pH-regulators, flocculants, precipitants and neutralisation agents) and article service life (plastic articles, articles in vehicles). For industrial and professional uses, it is expected that based on the self-classification registrants have recommended necessary RMMs to ensure safe use at the workplace. Low exposure is expected from eventual releases from articles. Although the concern that the plastic article is used in toys cannot be excluded, since the registration does not advise against its use in toys, harmonised classification is currently not proposed.

Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

- **Skin sensitiser** hazards of the substances EC 228-602-0, 308-020-4, 946-099-2 (inactive registration) and 946-101-1. The substances are self-classified as Skin sens 1 or 1B. Registrants indicate industrial, professional, consumer uses and article service life.

For industrial and professional uses, sufficient and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation. For the substance EC 308-020-4 the registrant indicates article service life, being the (plastic) article used by workers.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing substance EC 946-101-1, indicated by the registrant to be used by consumers in products such as finger paints, fillers, putties, plasters, modelling clay, coatings and paints, thinners and paint removers.

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

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

Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

- **Aquatic toxicity** hazards of the substances EC 282-784-6, 308-806-7, 800-484-0, 812-497-9, 946-101-1, 946-154-0, 947-751-9, 947-798-5, 947-905-5, 947-969-4, 949-965-8. These substances are self-classified for Acute and/or Chronic aquatic toxicity (category 4, 3 or 2).

It is expected that based on the self-classification registrants have implemented necessary RMMs to ensure safe use. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

#### - **Intermediates**

The following substances are registered as intermediates: EC 216-602-3, 235-799-7, 270-935-9, 307-095-0, 608-874-0, 616-628-9, 619-702-9, 701-370-2, 947-671-4 and 947-877-4.

Unlikely HH hazards for CMR, ED, STOT RE and skin sens were assumed by extrapolation based on structural similarity for all these substances except for 216-602-3 and 616-628-9, for which is not possible to conclude on the hazard.

Regarding PBT/vPvB and aquatic toxicity no hazard conclusion can be made for the above substances based on lacking data, except for EC 619-702-9 and EC 608-874-0 which have a known aquatic toxicity hazard due to classification as Aquatic Chronic 3 and Aquatic Acute and Chronic 1, respectively. The latter is based on the classification of the stabiliser used in the composition, i.e. n-heptane.

Therefore, no EU regulatory risk management action is currently proposed for any of the aforementioned substances due to low exposure potential. It is worth noting however that the strategy may need to be revisited and need for further regulatory action reconsidered if there is a change in the registration status or reported uses for any of these substances.

#### **- C&L notifications only**

Unlikely HH hazards for CMR, ED, STOT RE and skin sens were assumed by extrapolation based on structural similarity for the following not registered substances: EC 216-603-9, 216-604-4, 218-594-7, 219-576-1, 221-237-8, 221-485-7, 223-638-3, 225-615-3, 246-749-9, 247-585-0, 254-466-7, 256-865-1, 258-261-3, 258-379-5, 291-938-1, 291-941-8, 292-411-9, and 306-296-0.

Regarding PBT/vPvB as well as aquatic toxicity no hazard conclusion can be made based on lacking data, except for two substances (EC 216-604-4 and EC 258-261-3) which have a known aquatic toxicity hazard due to classification notified (Aquatic Chronic 4 and Aquatic Chronic 2 respectively). However, there is remaining uncertainty because it is not clear based on which data these notifications were made. Due to not being registered substances it is not possible to clarify the potential hazards of substances.

Therefore, it is proposed that there is currently no need for EU RRM action on these substances. If the registration status changes, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

**Based on currently available information, it is not possible to assess the need for regulatory risk management** as information on hazard is not sufficient to conclude on PBT/vPvB hazards of the following substances: 212-379-1, 213-967-0, 228-602-0, 253-391-7, 253-455-4, 254-414-3, 269-041-1, 269-044-8, 270-390-7, 273-489-3, 282-784-6, 284-851-5, 291-905-1, 291-907-2, 307-075-1, 308-020-4, 308-806-7 (duplicate 947-478-5), 800-484-0, 807-789-8, 812-497-9, 911-302-5, 911-351-2, 911-501-7, 922-551-4, 939-526-9, 946-099-2, 946-101-1, 946-154-0, 947-359-8, 947-360-3, 947-478-5 (duplicate 308-806-7), 947-719-4, 947-796-4, 947-798-5, 947-905-5, 947-924-9, 947-954-2, 947-957-9, 947-969-4, 947-971-5 and 949-965-8.

The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).

### 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

**Table 1**

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Substances ECs: 203-509-8, 235-826-2	Known or potential hazard for carcinogenicity	No hazard or unlikely hazard	For both substances: Industrial and professional uses, in products such as pH-regulators, polymer preparation, laboratory chemicals and intermediates. For EC 235-826-2 additional industrial and professional uses in: water treatment, washing and cleaning, biocides, cosmetics and personal care products, non-metal and metal surface	<b>Currently no need for EU RRM</b>  <u>Justification:</u> Self-classification followed by implementation of necessary RRM should be sufficient to ensure safe use by workers at industrial settings <u>In addition, regarding EC 235-826-2:</u> Potential exposure of professional users, consumers and exposure from articles need further investigation.	<b>First step:</b> CCH for EC 235-826-2 and 203-509-8, to confirm no hazard or unlikely hazard for mutagenicity, systemic (target-organ) toxicity, reproductive toxicity and ED potential  <b>Next step:</b> No action



ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			<p>treatment products, lubricants, metal working fluids, hydraulic fluids, ink and toners, and textile dyes. For the use coatings and paints, industrial, professional, consumer uses, and article service life are indicated. For EC 235-826-2 exposure is 'likely to be significant' based on aggregated tonnage, many sites/uses, and the types of use. For EC 203-509-8 article service life (plastic articles, articles in vehicles) is also indicated for which low releases are expected.</p>		
<p>Substances ECs: 212-379-1, 213-967-0, 228-602-0, 242-768-1, 253-</p>	<p>Known or potential hazard for skin sensitisation</p>	<p>Inconclusive hazard for PBT/vPvB</p>	<p>Substances in this subgroup have a very wide variety of industrial,</p>	<p><b>Currently no need for EU RRM or not possible to assess the regulatory needs</b></p>	<p><b>First step:</b> CCH</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
<p>391-7, 253-455-4, 254-414-3, 269-041-1, 269-044-8, 270-390-7, 273-489-3, 282-784-6, 284-851-5, 291-905-1, 291-907-2, 307-075-1, 308-020-4, 308-806-7 (duplicate 947-478-5), 800-484-0, 807-789-8, 812-497-9, 911-302-5, 911-351-2, 911-501-7, 922-551-4, 939-526-9, 946-099-2, 946-101-1, 946-154-0, 947-359-8, 947-360-3, 947-478-5 (duplicate 308-806-7), 947-719-4, 947-751-9, 947-796-4, 947-798-5, 947-905-5, 947-924-9, 947-954-2, 947-957-9, 947-969-4, 947-971-5, 949-965-8</p>	<p>For ECs: 228-602-0, 308-020-4, 946-099-2, 946-101-1 (all self-classified Skin sens. 1 or 1B) No hazard or unlikely hazard for remaining substances of the sub-group.</p>	<p>Known or potential hazard for aquatic toxicity For ECs: 282-784-6, 308-806-7, 800-484-0, 812-497-9, 946-154-0, 947-751-9, 947-798-5, 947-905-5, 947-969-4, 949-965-8</p>	<p>professional, consumer uses, and article service life, in products such as (among others) washing and cleaning, lubricants, metal working fluids, heat transfer fluids, hydraulic fluids, textile dye, leather treatment and laboratory chemicals. There is significant potential for exposure.</p>	<p><u>Justification:</u> The need for EU RRM will be further investigated once the hazard properties will be clarified after data generation. A subset of the potential PBT/vPvB substances is proposed for data generation (indicated in the next column)</p> <p>Concerning the known hazards:</p> <p>For skin sensitisation: Self-classification followed by implementation of necessary RRM should be sufficient to ensure safe use at the workplace. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation.</p> <p>For aquatic toxicity: Self classification followed by</p>	<p>CCH for EC 212-379-1, 242-768-1, 253-455-4, 254-414-3, 269-044-8, 273-489-3, 282-784-6, 291-907-2, 308-020-4, 800-484-0, 911-351-2, 911-501-7, 922-551-4, 939-526-9, 946-101-1, 946-154-0, and 947-719-4</p> <p><b>Next step:</b> No action</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				implementation of necessary RRM should be sufficient to ensure safe use for environment	
Substances ECs: 206-056-4, 222-581-1, 235-741-0, 258-380-0, 269-616-7, 289-108-9, 908-996-7	No hazard or unlikely hazard	No hazard or unlikely hazard	Substances in this subgroup have a very wide variety of industrial, professional, consumer uses, and article service life, in products such as (among others) pH-regulators, water softeners, anti-freeze and de-icing, washing and cleaning, biocides, cosmetics and personal care, lubricants, polymer preparation, coatings, ink and toners, textile dyes, metal surface treatment products and laboratory chemicals.	<p><b>Currently no need for EU RRM</b></p> <p><u>Justification:</u> Overall, no or unlikely hazard that would lead to concern for the reported uses.</p>	<p><b>First step:</b> CCH</p> <p>CCH for EC 206-056-4, 222-581-1, 235-741-0, 258-380-0, and 908-996-7</p> <p><b>Next step:</b> No action</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			There is significant potential for exposure.		
Intermediates ECs: 216-602-3, 235-799-7, 270-935-9, 307-095-0, 608-874-0, 616-628-9, 619-702-9, 701-370-2, 947-671-4, 947-877-4	No hazard or unlikely hazard	Inconclusive hazard for PBT/vPvB  Inconclusive hazard for aquatic toxicity	Industrial intermediate uses only. Limited potential for exposure.	<b>Currently no need for EU RRM</b>  <u>Justification:</u> According to the reported uses, low potential for exposure to both human health and environment is expected. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change.	No action
C&L notifications (not registered) ECs: 216-603-9, 216-604-4, 218-594-7, 219-576-1, 221-237-8, 221-485-7, 223-638-3, 225-615-3, 246-749-9, 247-585-0, 254-466-7, 256-865-1, 258-261-3, 258-379-5, 291-	No hazard or unlikely hazard	Inconclusive hazard for PBT/vPvB  Inconclusive hazard for aquatic toxicity	Not known	<b>Currently no need for EU RRM</b>  <u>Justification:</u> As the substances are not registered no data generation is possible to clarify the hazards currently. Actions (including data generation) will be re-considered when the assessment will be	No action

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
938-1, 291-941-8, 292-411-9, 306- 296-0				revisited if the registration status and/or uses change.	

## Annex 1: Overview of classifications

Data extracted on 07.09.2022

**Table 2: Harmonised classification and reported self-classification**

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations <sup>6</sup>
203-509-8	107-66-4	Dibutyl hydrogen phosphate	-	Carc. 2 H351 Skin Corr. 1B H314 Eye Damage 1 H318
206-056-4	298-07-7	Bis(2-ethylhexyl) hydrogen phosphate	-	Acute Tox. 4 H302 Skin Corr. 1C H314 Eye Damage 1 H318
212-379-1	812-00-0	Methyl dihydrogen phosphate	-	Skin Corr. 1 H314
213-967-0	1070-03-7	2-ethylhexyl dihydrogen phosphate	-	-
222-581-1	3539-43-3	Hexadecyl dihydrogen phosphate	-	Eye Damage 1 H318
228-602-0	6303-30-6	Diisobutyl hydrogen phosphate	-	Skin Corr. 1 H314 Eye Damage 1 H318 Skin Sens. 1 H317
235-741-0	12645-31-7	Phosphoric acid, 2-ethylhexyl ester	-	Skin Corr. 1 H314 [intermediate (active)] Skin Corr. 1B H314 Eye Damage 1 H318
235-826-2	12788-93-1	Phosphoric acid, butyl ester	-	Carc. 2 H351 Skin Corr. 1B H314 Skin Corr. 1 H314 Eye Damage 1 H318
242-768-1	19035-79-1	potassium hexadecyl hydrogen phosphate	-	Eye Damage 1 H318
253-391-7	37203-76-2	Phosphoric acid, ethyl ester	-	Skin Corr. 1 H314 Eye Damage 1 H318
253-455-4	37310-83-1	9-Octadecen-1-ol, (Z)-, phosphate	-	Eye Damage 1 H318
254-414-3	39322-78-6	Phosphoric acid, dodecyl ester, potassium salt	-	Skin Irrit. 2 H315 Eye Damage 1 H318
258-380-0	53126-67-3	Phosphoric acid, butyl ester, sodium salt	-	Skin Irrit. 2 H315 Eye Damage 1 H318
269-041-1	68186-45-8	Phosphoric acid, decyl octyl ester	-	Skin Corr. 1A H314 Eye Damage 1 H318
269-044-8	68186-64-1	Phosphoric acid, 2-ethylhexyl ester, sodium salt	-	Skin Corr. 1B H314 Eye Damage 1 H318
269-616-7	68307-94-8	Phosphoric acid, mono- and di-C6-10-alkyl esters	-	Eye Irrit. 2 H319 [Article 10 (inactive)] Skin Irrit. 2 H315 [Article 10 (inactive)]
270-390-7	68427-32-7	Decyl dihydrogen phosphate, potassium salt	-	Acute Tox. 5 H303 Skin Irrit. 2 H315 Eye Damage 1 H318
273-489-3	68987-29-1	1-Octadecanol, phosphate, potassium salt	-	Eye Irrit. 2 H319

<sup>6</sup> The column gives the classifications in registrations received under REACH. Additional classifications in intermediate and in inactive registrations (if any) are annotated and displayed last. For each classification the table includes information on the hazard category, the hazard statement and any available information on specific effects (relevant for reproductive toxicity), specific concentration limits, M-Factors and affected organs. Two classifications differing in any of these aspects are considered different and are repeated in the table. The columns "Classifications in registrations" and "Classifications in C&L notifications" are empty if there are no Registrations/C&L notifications (hazard is unknown). The value '-' is displayed on the same columns when there are (relevant) submissions but they do not contain self-classifications (substance is not hazardous).

## ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations <sup>6</sup>
282-784-6	84418-71-3	Phosphoric acid, mono- and bis(branched and linear pentyl) esters	-	Skin Corr. 1B H314 Eye Damage 1 H318 Aquatic Chronic 3 H412
284-851-5	84988-61-4	Phosphoric acid, isononyl ester	-	Skin Corr. 1B H314 Eye Damage 1 H318
289-108-9	86014-62-2	Phosphoric acid, 2-ethylhexyl ester, ammonium salt	-	Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319
291-905-1	90506-43-7	Phosphoric acid, C12-18-alkyl esters, potassium salts	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319
291-907-2	90506-45-9	Phosphoric acid, C16-18-alkyl esters, potassium salts	-	Eye Irrit. 2 H319
307-075-1	97489-33-3	Phosphoric acid, C16-18-branched and linear alkyl esters, potassium salts	-	-
308-020-4	97808-97-4	Phosphoric acid, mono- and di-C12-14-alkyl esters	-	Eye Damage 1 H318 Skin Sens. 1 H317
308-806-7	98653-76-0	Phosphoric acid, C8-10-alkyl esters	-	Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Chronic 2 H411
800-484-0	154518-38-4	Phosphoric acid, mono- and di-C11-14 (linear and branched) alkyl esters	-	Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Chronic 2 H411
807-789-8	111062-42-1	1-Octanol, reaction products with phosphorus oxide (P2O5), potassium salt	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319
812-497-9	1893414-79-3	Phosphoric acid, C14-15-branched and linear alkyl esters, potassium salts	-	Aquatic Chronic 3 H412
908-996-7	-	Reaction mass of methyl dihydrogen phosphate and orthophosphoric acid and dimethyl hydrogen phosphate	-	Skin Corr. 1B H314 Eye Damage 1 H318
911-302-5	-	Reaction mass of hexadecyl dihydrogen phosphate and dihexadecyl hydrogen phosphate	-	Eye Damage 1 H318 [Article 10 (inactive)] Skin Irrit. 2 H315 [Article 10 (inactive)]
911-351-2	-	Reaction mass of diisobutyl hydrogen phosphate and isobutyl dihydrogen phosphate	-	Skin Corr. 1B H314
911-501-7	-	Reaction mass of dioctyl hydrogen phosphate and octyl dihydrogen phosphate	-	Skin Corr. 1 H314 Eye Damage 1 H318
922-551-4	-	Alcohols, C20-22, reaction products with phosphorus oxide (P2O5)	-	Eye Irrit. 2 H319
939-526-9	-	Phosphoric acid, mono- and di-C16-18-alkyl esters	-	Eye Irrit. 2 H319
946-099-2	-	Phosphoric acid, mono C16-20 (branched, even numbered) alkyl esters	-	Skin Sens. 1B H317 [Article 10 (inactive)] Eye Irrit. 2A H319 [Article 10 (inactive)]
946-101-1	-	Phosphoric acid, mono- and di-C16-20- (even numbered, branched and linear)-alkyl esters	-	Skin Sens. 1B H317 Aquatic Chronic 4 H413
946-154-0	-	Phosphoric acid, mono- and di-isotridecyl esters, potassium salts	-	Eye Damage 1 H318 Aquatic Chronic 3 H412
947-359-8	-	Phosphoric acid, mono- and di-C6-12-(even numbered)-alkyl esters, potassium salts	-	Skin Irrit. 2 H315 Eye Damage 1 H318
947-360-3	-	Phosphoric acid, mono- and di-C12-18-(even numbered)-alkyl esters, sodium salts	-	Skin Irrit. 2 H315 Eye Damage 1 H318
947-478-5	-	Phosphoric acid, mono- and di-C8-10-(even numbered)-alkyl esters	-	Skin Corr. 1 H314 Eye Damage 1 H318
947-719-4	-	Phosphoric acid, mono and bis-linear butyl esters, potassium salts	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319
947-751-9	-	Phosphoric acid, hexadecyl esters, potassium salts with cetyl alcohol and isostearyl isostearate	-	Aquatic Acute 1 H400
947-796-4	-	Phosphoric acid, hexadecyl phosphate esters, potassium salts with cetostearyl alcohol	-	-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations <sup>6</sup>
947-798-5	-	Reaction mass of orthophosphoric acid and potassium dihexadecyl phosphate and dipotassium hexadecyl phosphate	-	Eye Damage 1 H318 Aquatic Chronic 4 H413
947-905-5	-	Reaction mass of hexadecyl dihydrogen phosphate and cetyl alcohol	-	Eye Damage 1 H318 Aquatic Chronic 4 H413
947-924-9	-	Phosphoric acid C12-alkyl and C18-alkyl esters, potassium salts	-	Skin Irrit. 2 H315 Eye Damage 1 H318
947-954-2	-	Phosphoric Acid, C8-12(even-numbered) linear Alkyl Esters	-	Skin Corr. 1B H314 Eye Damage 1 H318
947-957-9	-	Phosphoric Acid, linear and branched Octyl Esters	-	Skin Corr. 1B H314 Eye Damage 1 H318
947-969-4	-	Phosphoric Acid, Esters with Alcohols, C11-14 iso, C13-rich	-	Skin Corr. 1B H314 Eye Damage 1 H318 Aquatic Acute 1 H400 Aquatic Chronic 2 H411
947-971-5	-	Phosphoric Acid, C4 and C12-14(even-numbered) Alkyl Esters, Ammonium Salts	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319
949-965-8	-	Not available	-	Aquatic Chronic 4 H413



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

Data extracted on 07.09.2022

**Table 3: Overview of main uses**

EC number	PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	PC 36: Water softeners	PC 37: Water treatment chemicals	PC 12: Fertilisers	PC 27: Plant protection products	PC 4: Anti-freeze and de-icing products	PC 35: Washing and cleaning products	PC 8: Biocidal products (e.g. disinfectants, pest control)	PC 28: Perfumes, fragrances	PC 3: Air care products	PC 39: Cosmetics, personal care products	PC 29: Pharmaceuticals	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 25: Metal working fluids	PC 16: Heat transfer fluids	PC 17: Hydraulic fluids	PC 13: Fuels	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removes	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 14: Metal surface treatment products	PC 21: Laboratory chemicals	PC 19: Intermediate	PC 40: Extraction agents	PC 30: Photo-chemicals					
203-509-8	I, P																		I																			
206-056-4	I, P																	I		I																		
212-379-1																																						
213-967-0	F																																					
222-581-1		F, I, P				F, I, P		F, I, P, C		F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C		F, I, P	F, I, P								F, I, P, C	F, I, P, C				F, I, P, C	F, I, P								
228-602-0	I																			I																		
235-741-0	F, I	F	F	F, C	F	F, I	F, I, P, C	F	F, C	F, C	F, C		F	F	F, I, P, C	F, I, P	F, I, P	F, I, P		I, A	F, I, P		F, I	F, I, P, C	F, I, P, C	A	F	F, I, A	F, I, A	F, I, A	F, I, P, C	I	F	F	F			
235-826-2	F, I, P		P			F, I, P	P				F, P			F, I	I, P	F, I, P		I, P						F, I, P, C	F, I, P		F, I, P		F, I, P	I, P	I							
242-768-1											F, I, P, C																F, I											
253-391-7																											F, P											
253-455-4											F, C			F, I	P												F, I											
254-414-3														I	F, I											F	F, I, A	F, I, A										
258-380-0																										F, I, A												
269-041-1															F, I, P, C	F, I, P	F										F, I	I										



## ASSESSMENT OF REGULATORY NEEDS

EC number	PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	PC 36: Water softeners	PC 37: Water treatment chemicals	PC 12: Fertilisers	PC 27: Plant protection products	PC 4: Anti-freeze and de-icing products	PC 35: Washing and cleaning products	PC 8: Biocidal products (e.g. disinfectants, pest control)	PC 28: Perfumes, fragrances	PC 3: Air care products	PC 39: Cosmetics, personal care products	PC 29: Pharmaceuticals	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 25: Metal working fluids	PC 16: Heat transfer fluids	PC 17: Hydraulic fluids	PC 13: Fuels	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removers	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 14: Metal surface treatment products	PC 21: Laboratory chemicals	PC 19: Intermediate	PC 40: Extraction agents	PC 30: Photo-chemicals				
947-360-3																																				F, P, A	
947-478-5 (duplicate 308-806-7)																																				I, A	
947-719-4	F													F, I, P	I																					F, I	
947-751-9											F, P, C																										F
947-796-4											F, P, C																										
947-798-5											F, P, C																										
947-905-5											F, P, C																										
947-924-9																																					F, I, A
947-954-2														F, I																							
947-957-9														F, I	I																						
947-969-4	F, I																																				F, I, A
947-971-5																																					
949-965-8											F, P, C																										

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life

**Intermediates** (industrial use only): 216-602-3, 235-799-7, 270-935-9, 307-095-0, 608-874-0, 616-628-9, 619-702-9, 701-370-2, 947-671-4, 947-877-4

**C&L notifications (not registered)**: 216-603-9, 216-604-4, 218-594-7, 219-576-1, 221-237-8, 221-485-7, 223-638-3, 225-615-3, 246-749-9, 247-585-0, 254-466-7, 256-865-1, 258-261-3, 258-379-5, 291-938-1, 291-941-8, 292-411-9, 306-296-0

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

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