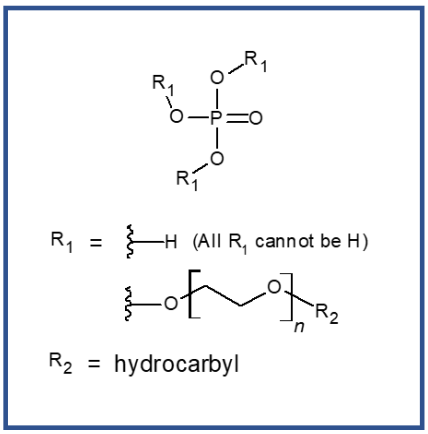
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Ethoxylated alcohol phosphates and phosphinic acid derivatives

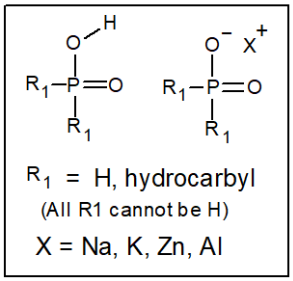
General structure:

Ethoxylated alcohol phosphates (subgroup 1)

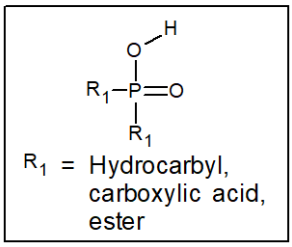


Phosphinic acid derivatives

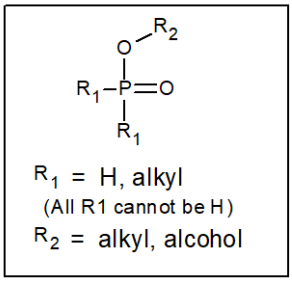
Subgroup 2: Hydrocarbylphosphinic acids and salts



Subgroup 3: Hydrocarbylphosphinic acids substituted with carboxylic acids and esters



Subgroup 4: Phosphinic acid esters

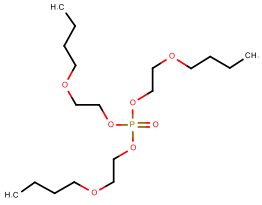
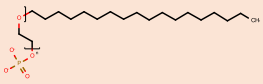
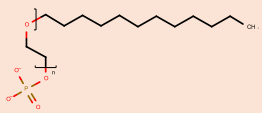
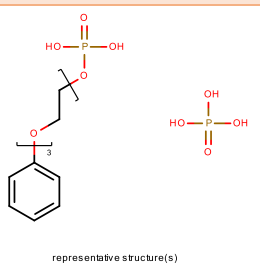


Revision history

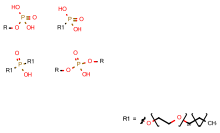
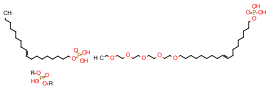
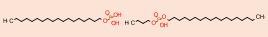
Version	*Date*	*Description*
1.0	3 August 2023	

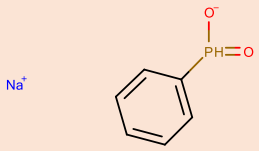
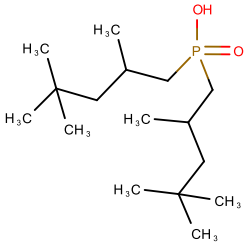
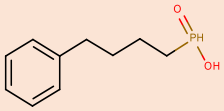
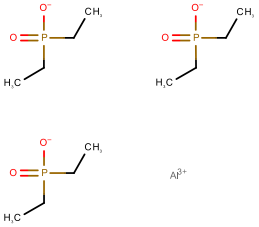
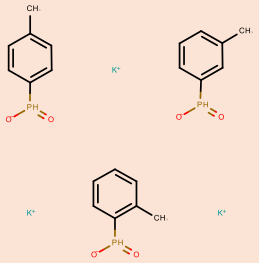
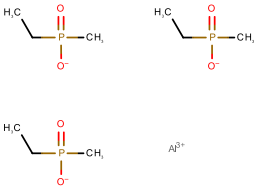
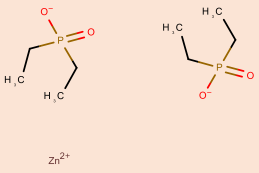
Substances within this group:

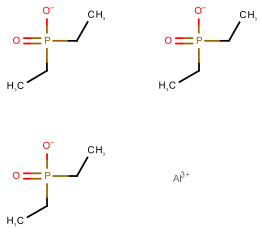
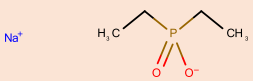
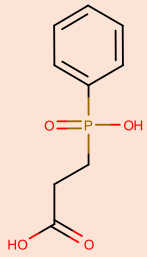
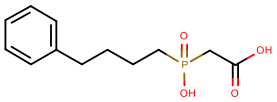
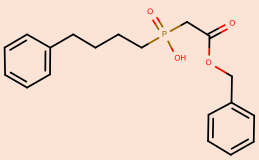
Note: Several substances in this group have confidential EC or List numbers and therefore were labelled as X1-X6. These labels might not appear in sequence in the report.

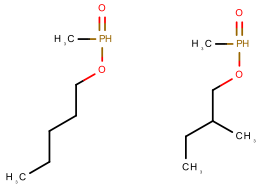
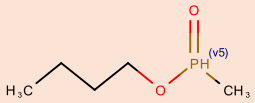
EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
Sub-group 1: Ethoxylated alcohol phosphates				
201-122-9	78-51-3	Tris(2-butoxyethyl) phosphate		Full, 100-1000
500-155-9	62362-49-6	Octadecan-1-ol, ethoxylated, phosphates		Full, not (publicly) available
500-295-0	106233-09-4	Alcohols, C16-18, ethoxylated, phosphates		Full, 10-100
609-689-8	39464-66-9	Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-, phosphate		C&L notification
609-691-9	39464-70-5	2-phenoxyethanol; phosphoric acid	 representative structure(s)	Full, not (publicly) available
610-044-8	42612-52-2	Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-		C&L notification

[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

		hydroxy-, phosphate, sodium salt		
614-291-2	68130-47-2	C8-10 Alkyl alcohol ethoxylate (4EO), phosphate ester		C&L notification
616-610-0	78330-24-2	Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, mono-C11-14-isoalkyl ethers, C13-rich, phosphates		C&L notification
[**X4**] Not (publicly) available	-	Sodium salts of Mono- and di-[reaction products of dodecyl alcohol and ethylene oxide]phosphates		Full, not (publicly) available
947-738-8	-	Phosphoric acid, mixed esters with alcohols, C7-9-iso-, C8-rich and alcohols, C11-14-iso-, C13-rich, ethoxylated, potassium salt		Full, not (publicly) available
947-763-4	-	Alcohols, C16-18 and ethoxylated C16-18 , phosphates (20 moles ethoxylation)		Full, not (publicly) available
[**X6**] Not (publicly) available	-	[No public or meaningful name is available]		Full, not (publicly) available
947-833-4	-	Alcohols, C18-unsatd and ethoxylated C18-unsatd., phosphates (5 moles ethoxylation)		Full, not (publicly) available
948-017-0	-	Esterification product of Alcohols, C12-13, ethoxylated, and Alcohols, C16-18 and butan-1-ol with diphosphorus pentaoxide		OSII or TII

Sub-group 2: Hydrocarbylphosphinic acids and salts				
224-305-5	4297-95-4	Sodium phenylphosphinate		Full, not (publicly) available
280-445-7	83411-71-6	Bis(2,4,4-trimethylpentyl)phosphinic acid		Full, 100-1000
420-450-5	86552-32-1	(4-phenylbutyl)phosphinic acid		NONS
428-310-5*	225789-38-8	Aluminium tridiethylphosphinate		Full, >1000
433-860-4	2135911-34-9	potassium m-toluenephosphonate;potassium p-toluenephosphonate;reaction mass of: potassium o-toluenephosphonate		NONS
434-510-3	176316-86-2	Exolit OP 940		NONS
457-580-7	284685-45-6	Phosphinic acid, P,P-diethyl-, zinc salt (2:1)		Full, not (publicly) available

607-114-5*	225789-38-8	Phosphinic acid, P,P-diethyl-, aluminum salt (3:1)		C&L notification
609-080-7	35160-38-4	Phosphinic acid, P,P-diethyl-, sodium salt (1:1)		Full, not (publicly) available
[**X2**] Not (publicly) available	-	Alkyl-[2-(alkyl-substituted-phosphinoyl)-alkyl]-phosphinic acid		Full, not (publicly) available
[**X3**] Not (publicly) available	-	Dialkyl phosphinic acid		Full, not (publicly) available
Sub-group 3: Hydrocarbylphosphinic acids substituted with carboxylic acids and esters				
411-200-6	14657-64-8	3-(hydroxyphenylphosphinyl)propanoic acid		Full, 10-100
412-170-7*	83623-61-4	((4-phenylbutyl)hydroxyphosphoryl)acetic acid		NONS
416-050-5	87460-09-1	Benzyl [hydroxy-(4-phenylbutyl)phosphinyl] acetate		NONS
443-950-5	-	NALCO 73280		Full, >1000
[**X1**] Not (publicly) available	-	Reaction mass of [3-(2-hydroxyethoxy)-3-oxopropyl]arylphosphinic acid and 3-(hydroxyarylphosphinyl)propanoic acid and ethane-1,2-diol		OSII or TII

809-489-2*	83623-61-4	[No public or meaningful name is available]		C&L notification
Sub-group 4: Phosphinic acid esters				
402-090-0	87025-52-3	A mixture of: pentyl methylphosphinate; 2-methylbutyl methylphosphinate		NONS
612-366-4	6172-80-1	Phosphinic acid, P-methyl-, butyl ester		OSII or TII
[**X5**] Not (publicly) available	-	E17-194T, (P,P-diethyl, monoester with 1,2 propanediol)_		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: List number 809-489-2 and EC number 412-170-7, and List number 607-114-5 and EC number 428-310-5. In general EC numbers take precedence over List numbers.

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.

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 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[2].

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

Glossary

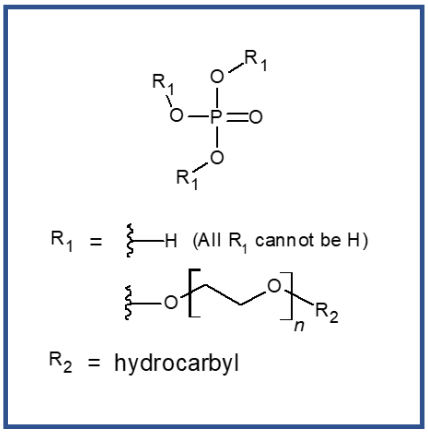
ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
PMT/vPvM	Persistent, mobile and toxic/very persistent and very mobile
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 structurally similar substances based on the presence of the ethoxylated alcohol phosphates and phosphinic acid derivatives with reported use as flame retardants.

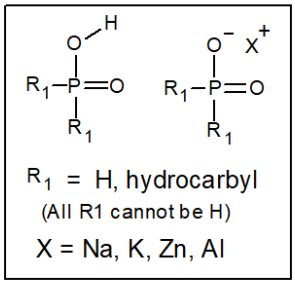
The 34 substances of the group (including 19 substances with full registrations, 6 NONS substances, 3 substances with intermediate registrations, and 6 substances with only C&L notifications) have been further subdivided in 4 subgroups considering structural similarities: one containing phosphates with ethoxylated alcohols (14 substances, subgroup 1) and the other three containing phosphinic acid derivatives. The phosphinic acid derivatives cover Hydrocarbylphosphinic acids and salts (11 substances, subgroup 2), Hydrocarbylphosphinic acids substituted with carboxylic acids and esters (6 substances, subgroup 3) and Phosphinic acid esters (3 substances, subgroup 4) as shown in the figure below:

Ethoxylated alcohol phosphates (subgroup 1)

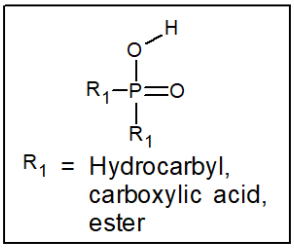


Phosphinic acid derivatives

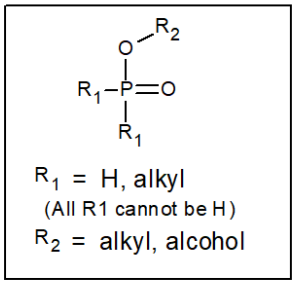
Subgroup 2: Hydrocarbylphosphinic acids and salts



Subgroup 3: Hydrocarbylphosphinic acids substituted with carboxylic acids and esters



Subgroup 4: Phosphinic acid esters



The Ethoxylated alcohol phosphates (subgroup 1) include esters and their salts with ethoxylated alcohols that have relatively long alcohol carbon chain lengths. 'Tris(2-butoxyethyl) phosphate' (EC No. 201-122-9) is a triester with a relatively short carbon chain length.

The Hydrocarbylphosphinic acids and salts (sodium, aluminium, potassium, zinc) (subgroup 2) include substances with various alkyl substituents, including aromatic groups.

The Hydrocarbylphosphinic acids substituted with carboxylic acids and esters (subgroup 3) include mostly substances with aromatic substituents.

The Phosphinic acid esters (subgroup 4) include substances with relatively short alkyl chains (one with a hydroxyl group).

In general, the chemical diversity of the substances in this group is also reflected on the diversity of uses reported for the substances. Nevertheless, some patterns have been identified for different subgroups:

- **Ethoxylated alcohol phosphates (subgroup 1)**

  This subgroup contains surface active substances that are used as surfactants, lubricants and anti-scaling agents in a wide range of applications such as cosmetics and personal care products, washing and cleaning products, polymer preparations and compounds, adhesives and sealants, coatings and paints. There are professional and consumers uses and article service life associated to most of the applications and consequently high exposure potential.

  In addition, substance EC No. 201-122-9 is also used as an additive plasticising flame retardant in the production of plastic and rubber products with potential exposure/release via article service life.

- **Phosphinic acid derivatives (subgroups 2, 3 and 4)**

  In general, phosphinates seem to be reactive substances and consequently most are used as intermediates in the preparation of other substances or polymers or reactive flame retardants that are incorporated covalently in a matrix in the production of flame-retarded polymers and textiles.

    - **Subgroup 2: Hydrocarbylphosphinic acids and salts**

  Diethylphosphinic acid and methylethylphosphinic acid and their salts (EC/List No. 428-310-5 (607-114-5), 434-510-3, 457-580-7, 609-080-7) are reported to be used as reactive flame retardants in the production of flame-retarded polymers in industrial settings. The same uses have been reported for substances X2 and X3. Potential exposure from article service life is limited considering they would be covalently incorporated in the polymers. In addition, substance EC No. 428-310-5 (607-114-5) is also used as flame retardant in heat transfer fluids and adhesives/sealants in industrial settings with article service life.

  Phenyl-substituted substances like EC No. 433-860-4 and 224-305-5 are reported to be used in the production of Nylon 66 as antioxidant or nucleating agents in industrial settings. Potential exposure from article service life is limited considering the low concentration required.

  As for the rest of the substances, EC No. 280-445-7 is used as an extraction agent due to its chelating properties and EC No. 420-450-5 as an intermediate in the production of pharmaceuticals.

- **Subgroup 3: Hydrocarbylphosphinic acids substituted with carboxylic acids and esters**

In this subgroup, substances EC No. 411-200-6 and X1 are reported to be used as reactive flame retardants in the production of flame-retarded polymers and textiles. Potential exposure from article service life is limited considering they would be covalently incorporated in the matrices.

As for the other substances, EC No. 416-050-5 and 412-170-7 (809-489-2) are reported to be used as intermediates in the production of pharmaceuticals. In addition, substance EC No. 443-950-5 is reported to be used as a corrosion inhibitor and anti-scaling agent in water treatment chemicals, washing and cleaning products and paper treatment products in industrial settings.

- **Subgroup 4: Phosphinic acid esters**

In this subgroup substance X5 is reported to be used as a reactive flame retardant in the production of polyurethane foams. Thus, potential exposure from article service life is limited considering they would be covalently incorporated in the matrix.

Substances EC/List No. 402-090-0 and 612-366-4 are reported to be used as intermediates in the production of agrochemicals.

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

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

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

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

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for ED hazards due to the potential for release/exposure of the substance Tris(2-butoxyethyl) phosphate (TBEP) (EC No. 201-122-9) in the subgroup 1: ethoxylated alcohol phosphates.

Based on ECHA's assessment of hazard information currently available in publicly available scientific literature, substance Tris(2-butoxyethyl) phosphate (TBEP) (EC No. 201-122-9) in the subgroup 1 (ethoxylated alcohol phosphates) has (potentially) the following hazard: ED for human health and environment.

The ED hazard is identified based on *in vitro* evidence in human cell lines[3] as well as *in vivo* evidence in fish.[4] For example, TBEP significantly increased oestradiol (E2) and testosterone (T) production in H295R cells and increased the E2/T ratio (no binding affinity to oestrogen receptor in MVLN luciferase assay). TBEP showed also effects on transcriptomics related to steroid hormone biosynthesis in TM3 Leydig cells[5] and in liver HepG2 cells.[6] Increased expression of steroidogenic genes following exposure to TBEP has also been reported from *in vivo* studies in fish[4,7]. Xu *et al* (2017) also observed increased plasma concentrations of E2 in both sexes of fish, and increased testosterone levels in male fish; inhibition of oocyte maturation in females and delayed spermiation in males; as well as decreased egg production, hatching success and survival rates in offspring following TBEP exposure (Xu *et al*., 2017). Another study by Sun *et al*. (2016)[8] reported evidence of developmental neurotoxicity in Japanese medaka exposed to TBEP as well as decreased hatchability, delayed time to hatch, and increased occurrence of gross abnormalities. No *in vivo* studies are available in the dossier addressing sensitive endocrine parameters in rodents such as sexual maturation, anogenital distance or nipple retention.

Based on ECHA's assessment, ED hazard is not extrapolated to other ethoxylated

[3] Liu et al., 2012. Endocrine disruption potentials of organophosphate flame retardants and related mechanisms in H295R and MVLN cell lines and in zebrafish. Aquatic Toxicology 114-115, 173-181. Accessed 28/10/2022 at https://www.sciencedirect.com/science/article/pii/S0166445X12000690?via%3Dihub

[4] Xu et al., 2017. Reproduction impairment and endocrine disruption in adult zebrafish (Danio rerio) after waterborne exposure to TBOEP. Aquat. Toxicol., 182, 163-171. Accessed 28/10/2022 at https://pubmed.ncbi.nlm.nih.gov/27912163/

[5] Jin et al., 2016. Effects of TBEP on the induction of oxidative stress and endocrine disruption in Tm3 Leydig cells. Environ Toxicol 10, 1276-86.Accessed 28/10/2022 at https://pubmed.ncbi.nlm.nih.gov/25808963/

[6] Krivoshiev et al., 2018. Toxicogenomics of the flame retardant tris (2-butoxyethyl) phosphate in HepG2 cells using RNA-seq. Toxicology in Vitro, 46, 178–188. Accessed 28/10/2022 at https://www.sciencedirect.com/science/article/pii/S0887233317303089?via%3Dihub#bb0470

[7] Arukwe A, Carteny CC, Möder M, Bonini A, Maubach MA, Eggen T. Differential modulation of neuro- and interrenal steroidogenesis of juvenile salmon by the organophosphates - tris(2-butoxyethyl)- and tris(2-cloroethyl) phosphate. Environ Res. 2016 Jul;148:63-71. doi: 10.1016/j.envres.2016.03.020. Epub 2016 Mar 26. PMID: 27019041.

[8] Sun L., Tan H., Peng T., Wang S., Xu W., Qian H., Jin Y., Fu Z. Environ. Toxicol. Chem. 2016;35(12):2931–2940. https://doi.org/10.1002/etc.3477

alcohol phosphates considering structural dissimilarities supported by the available data for ethoxylated alcohols other than TBEP. Thus, TBEP (EC No. 201-122-9) is considered an outlier among the ethoxylated alcohol phosphates in the group.

There is also uncertainty for the reproductive toxicity of the TBEP as no information is available in the dossier on the potential effects on the sexual function and fertility and only limited information on the pre-natal developmental toxicity.

The potential to request further data for TBEP to clarify the ED hazard and reduce the uncertainty in the potential for the TBEP to cause reproductive toxicity can be evaluated in CCH proposed for the substance. In case no data generation can be requested under dossier evaluation, SEv may be proposed for the substance based on potential ED hazard and high exposure potential.

No other hazards for human health have been identified for TBEP. This conclusion is based on *in vitro* mutagenicity studies in bacteria and mammalian cells, *in vivo* experimental studies on skin sensitisation and repeated dose sub-chronic studies.

Based on ECHA's assessment of hazard information currently available in the registration dossiers TBEP is unlikely to fulfil the PBT/vPvB screening criteria, or to be persistent and mobile, because it is readily biodegradable. This conclusion is based on the results of a ready biodegradability study.

The substance is used in a wide range of applications as surface active agent, lubricating agent, anti-scaling agent, corrosion inhibitor including professional and consumer uses. The substance is also used as an additive plasticising flame retardant in the production of plastic and rubber products with potential exposure/release via article service life.

Confirmation of the hazard properties via SVHC identification is not considered sufficient to minimise potential releases of the substances in the environment. A restriction is seen as the most appropriate option as potential for exposure is expected from consumer uses, professional uses, article service and industrial uses.

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. Consumers may be co-exposed to the substances used by professionals in e.g. washing and cleaning services. Furthermore, potential for exposure and releases to the environment from articles is uncertain based on available information.

Therefore, a **restriction of the substances as such or in mixtures (concentration limit in mixtures) used by consumers, professional workers and industrial workers** is suggested after SVHC identification, with the aim to minimise exposures and emissions to humans and the environment.

The use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[9] which aims to extend to professional users under REACH the level of protection granted to consumers.

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

Moreover, **restricting substances in articles** used by professionals or consumers should be considered in the context of the restriction as potential exposure from articles needs further investigation first.

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for PBT hazards due to the potential for release/exposure of the substances EC/List No. 500-155-9, 500-295-0, 947-763-4, 947-833-4 and X6 in the subgroup 1 (ethoxylated alcohol phosphates).

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety substances EC/List No. 500-155-9, 500-295-0, 947-763-4, 947-833-4 and X6 in the subgroup 1 (ethoxylated alcohol phosphates) have (potentially) the following hazard: PBT. Compared to these substances, the remaining members of this subgroup do not screen for the combined hazards of persistence and bioaccumulation, which may correlate with their relative alkyl chain lengths and levels of ethoxylation.

Based on ECHA's assessment of currently available hazard information, the substances fulfil the PBT/vPvB screening criteria[10]:

- these substances are potentially persistent or very persistent (P/vP) as:
  - they are not readily biodegradable (*i.e.,* <60/70% degradation in an OECD 301B);
- and these substances are potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - they either have a high potential to partition to lipid storage (*e.g.,* log K_{ow} > 4.5): EC No. 500-155-9, 500-295-0;
  - or are surface active and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid as other partitioning mechanisms may drive bioaccumulation (e.g., binding to protein/cell membranes); List No. 947-763-4, X6 and 947-833-4
- they currently do not meet the T criteria set in Annex XIII: NOEC or EC_{10} < 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 there are some aquatic toxicity data gaps.

Therefore, the substances are considered as potential PBT/vPvB substances. Data generation via CCH is foreseen for all the substances to clarify the hazards.

There is known or potential aquatic toxicity hazards for EC/List No. 500-155-9, 500-295-0, 947-763-4, 947-833-4 and X6 in the subgroup 1. This is based on the fact that these substances have some form of aquatic toxicity classification applied based on available data. Overall, there is a lack of long-term aquatic toxicity data available for the subgroup 1, as well as questions regarding the reliability of some existing aquatic toxicity data. The CCHs for EC/List No. 500-155-9, 500-295-0, 947-833-4 and X6 can be used to fill long-term aquatic toxicity data gaps, to assess overall data reliability, and to confirm the correct aquatic toxicity classifications are applied. Although List/EC No. 947-763-4 is assessed as a potential PBT and having aquatic toxicity no further data generation is currently possible.

Based on ECHA's assessment of currently available hazard information, no or low

[10] 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)

hazard potential were identified for human health. These conclusions are based on good coverage of *in vitro* mutagenicity studies in bacteria and mammalian cells and *in vitro/in vivo* experimental studies on skin sensitisation. Some uncertainty remains for repeated dose and reproductive toxicity due to low data coverage. However, available sub-chronic and screening studies indicate low toxicity for these ethoxylated alcohol phosphates, supported by low toxicity potential of ethoxylated alcohols (>C6).

The substances are used in a wide range of applications considering their surface active and lubricating properties including professional and consumer uses.

Confirmation of the hazard properties via SVHC identification is not considered sufficient to minimise potential releases of the substances in the environment. A restriction is seen as the most appropriate option as potential for exposure is expected from consumer uses, professional uses, article service and industrial uses.

Releases to the environment from consumer uses cannot be avoided.

Widespread professional uses are typically non-contained and non-automated leading to releases to the environment.

Furthermore, potential for exposure and releases to the environment from articles is uncertain based on available information.

Therefore, a **restriction of the substances as such or in mixtures (concentration limit in mixtures) used by consumers, professional workers and industrial workers** is suggested after SVHC identification, with the aim to minimise exposures and emissions to humans and the environment.

The use of PBT and vPvB substances by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability.[9]

Moreover, **restricting substances in articles** used by professionals or consumers should be considered in the context of the restriction of consumer/professional uses as potential exposure from articles needs further investigation first.

Based on currently available information, there is no need for (further) EU regulatory risk management for vPvM hazards of the substances EC/List No. 428-310-5, 457-580-7, 607-114-5, 434-510-3, 609-080-7, 280-445-7, 420-450-5, and X3 in the subgroup 2: Hydrocarbylphosphinic acids and salts.

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety (i.e. all are alkylphosphinic acid derivatives) all the substances have (potentially) the following environmental hazards: vPvM. The rest of the substances in the subgroup (two arylphosphinic acid derivatives and a diphosphinate) are structurally different and do not screen as very persistent and very mobile and are of low toxicity.

Based on ECHA's assessment of currently available hazard information, all the substances fulfil the following screening criteria for persistence:

- these substances are potentially persistent or very persistent (P/vP) as:
  they are not readily biodegradable (*i.e.,* <60/70% degradation in OECD 301 series tests).

The conclusion on mobility is based on the values for Log K_{ow} which are well below 4.5 (Log K_{ow} range from -2.3 to 1.83) indicating that all the substances would be expected to be mobile in the environment. Log K_{oc} values are available for three substances in this subgroup: EC No. 428-310-5 (607-114-5), EC No. 280-445-7 and EC No. 420-450-5 (unclaimed NONs) with Log K_{oc} being -0.55, 1.83, and 2.2, respectively. These Log K_{oc} values indicate high mobility can be expected (i.e. vM) hence these substances are potential vPvM substances.

Substance EC No. 428-310-5 (607-114-5) is an Annex X substance with high release potential to surface waters, soil and ground water due to the use in washing and cleaning products and in adhesive/sealants and compliance check is proposed to clarify the potential persistency and mobility of the substance. The results can be extrapolated to substances 434-510-3 and 609-080-7 since they share the same organic moiety. Substance EC/List No. 280-445-7 is also potentially vP and is expected to be very mobile in the environment. However, widespread environmental releases are not expected based on the reported use pattern for this substance (industrial uses only; extraction solvent for metal mining/recycling applications) although some level of environmental releases cannot be excluded. Compliance check is proposed for this Annex IX substance to clarify potential vPvM properties as well as long-term aquatic toxicity. Compliance check is proposed also to clarify the potential persistency and mobility of substance X3.

EC/List No. 420-450-5 (unclaimed NONs) also screens for vPvM however no data generation is possible for this substance at this time. In addition, structural differences do not support direct read across from group members where data generation is possible. Further data generation on this substance may be possible in the future if the situation changes.

However, for the time being no EU regulatory risk management is proposed for these substances until confirmation of the hazard properties which should help identifying what the main protection goals are for the specific substances.

Based on ECHA's assessment of currently available hazard information, no or low hazard potential were identified for human health. These conclusions are based on good coverage of *in vitro* mutagenicity studies in bacteria and mammalian cells and *in vitro/in vivo* experimental studies on skin sensitisation as well as in vivo short-term/sub-chronic repeated dose toxicity studies. Some uncertainty remains for reproductive toxicity due to low data coverage. However, available reproductive toxicity studies indicate low toxicity for these substances, and further assessment to confirm low hazard is proposed for EC No. 280-445-7 (compliance check). EC No. 420-450-5 has harmonised classification as Carc. 2. However, based on the available information, this classification is based on the presence of an impurity (impurity present only in inactive registration).

Substances EC/List No. 428-310-5, 607-114-5, 434-510-3, 609-080-7 and X3 are used as reactive flame retardants in the production of polymers in industrial settings. In addition, substance EC 428-310-5 is also used as flame retardant in heat transfer fluids and adhesives/sealants in industrial settings with article service life.

Based on currently available information, there is no need for (further) EU regulatory risk management for low potential hazards of the substances EC/List No. 609-689-8, 609-691-9, 610-044-8, 614-291-2, 616-610-0, X4, 947-738-8, 948-017-0 in the subgroup 1, substances EC/List No. 224-305-5, 280-445-7, 420-450-5, 433-860-4, X2 and X3 in the subgroup 2 and substances EC/List No. 411-

200-6, 416-050-5, 443-950-5, X1, 412-170-7 (809-489-2), 402-090-0, 612-366-4 and X5 in the subgroups 3 and 4.

Based on ECHA's assessment of currently available hazard information in the registration dossiers, no or low hazard potential were identified for human health. These conclusions are based on good coverage of *in vitro* mutagenicity studies in bacteria and mammalian cells and *in vitro/in vivo* experimental studies on skin sensitisation. Some uncertainty remains for repeated dose and reproductive toxicity due to low data coverage. However, available short-term/sub-chronic and reproductive toxicity studies indicate low toxicity for these substances. Substance EC No. 412-170-7 (809-489-2) is a substance notified under NONs with a harmonised classification as Skin Sens. 1 and STOT RE 2.

The substances are unlikely to fulfil the PBT/vPvB screening criteria, because they are readily biodegradable and/or have a low potential for bioaccumulation, and all are unlikely to fulfil the T criterion. Based on available data the aquatic toxicity hazards for most of the above listed substances are relatively low. Substance List No. 609-691-9 from subgroup 1 and all the above listed substances from subgroups 2 and 3 have low aquatic toxicity based on available data and do not have aquatic toxicity classifications. A few of the above listed substances have aquatic toxicity classifications i.e. X4 and List No. 947-738-8 from subgroup 1 are classified as Aquatic Acute 1 and Aquatic Acute 3, respectively, and EC No. 280-445-7 from subgroup 2 is classified as Aquatic Chronic 2. No aquatic toxicity data are available for List No. 609-689-8, 610-044-8, 614-291-2, 616-610-0, and 948-017-0 (notified substances / isolated intermediates) and no further data generation is possible for these substances. Classification for aquatic toxicity followed by implementation of necessary RRMs should be sufficient to ensure safe use for environment.

Conclusion on P and B is based on ready biodegradability test results, as well as available data on bioaccumulation potential based on Log Kow (used to assess potential for bioaccumulation via lipid partitioning) and/or surface activity (based on surface tension data) of the substances (used to assess potential for bioaccumulation via other mechanisms), and experimental data for group members present in the dossiers. Based on the available data persistence and bioaccumulation were not identified as concomitant hazards for any of these substances.

Substances in subgroup 1 have a range of applications as surfactants and lubricants including professional and/or consumer uses. Low potential for exposure is expected for the other substances that are mainly intermediates or only used in industrial settings.

Although substance EC 412-170-7 (809-489-2) is classified as Skin Sens. 1 and STOT RE 2, it is still proposed no further EU regulatory risk management because the substance is used as an intermediate in the production of other chemicals in industrial settings and the current classification will already require adequate risk management measures in place according to workplace legislation.

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.

As indicated in the Restrictions Roadmap[11] ECHA has prepared an overall strategy on flame retardants[12] in 2022, which will support the Commission when it decides to request ECHA to prepare (a) restriction dossier(s). The substances in scope are in principle all flame retardants, and there is particular focus on brominated flame retardants and their prioritisation for restrictions.

The overall strategy on flame retardants may bring new perspectives and may result in a need to revise some of the conclusions in this ARN.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Tris(2-butoxyethyl) phosphate (EC No. 201-122-9) in subgroup 1	Known or potential hazard for ED	Known or potential hazard for ED	The substance is used in a wide range of applications as surface active agent, lubricating agent, anti-scaling agent, corrosion inhibitor including professional and consumer uses. The substance is also used as an additive plasticising flame	**Need for EU RRM: Restriction** <u>Justification:</u> Releases to the environment from consumer and widespread professional uses cannot be avoided. Widespread	**First step:** CCH Substance evaluation **Next steps (if hazard confirmed):** SVHC identification Restriction

[11] https://ec.europa.eu/docsroom/documents/49734

[12] https://echa.europa.eu/documents/10162/ec392d86-7bfe-1eca-0f65-44c65b2c417f

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			retardant in the production of plastic and rubber products with potential exposure/release via article service life.	professional uses are typically non-contained and non-automated leading to releases to the environment.	
500-155-9 500-295-0 947-763-4 947-833-4 **X6** in subgroup 1	No hazard or unlikely hazard	Known or potential hazard for PBT/vPvB for aquatic toxicity	The substances are used in a wide range of applications considering their surface active and lubricating properties including professional and consumer uses and article service life.	Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses. Industrial uses to be considered as part of the restriction.	**First step:** CCH (except 947-763-4) **Next steps (if hazard confirmed):** SVHC identification Restriction
428-310-5 (607-114-5) 457-580-7 434-510-3 609-080-7 280-445-7	No hazard or unlikely hazard	Known or potential hazard vPvM Known or potential hazard for aquatic toxicity for EC 428-310-5 (Aquatic chronic 3), EC 457-580-7 (Aquatic chronic 1),	The substances are used as reactive flame retardants in the production of polymers in industrial settings. In addition, substance EC 428-310-5 is also used as flame retardant in heat transfer fluids and adhesives/	**Currently no need for EU RRM** <u>Justification:</u> The need for EU RRM will be further investigated once the hazard properties will be clarified after data generation.	**First step:** CCH for EC 428-310-5 & 280-445-7

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
420-450-5 X3 in subgroup 2		EC 280-445-7 (Aquatic chronic 2)	sealants in industrial settings with article service life.	Classification for aquatic toxicity followed by implementation of necessary RRMs should be sufficient to ensure safe use for environment.	
609-689-8, 609-691-9, 610-044-8, 614-291-2, 616-610-0, X4, 947-738-8, 948-017-0 in the subgroup 1 224-305-5, 420-450-5, 433-860-4, X2 and X3 in the subgroup 2 411-200-6, 416-050-5, 443-950-5, X1, 412-170-7 (809-489-2), 402-090-0, 612-366-4 and X5 in the subgroups 3 and 4.	No hazard or unlikely hazard except for X1 for STOT RE EC No. 412-170-7 (809-489-2); subgroup 3 for STOT RE for skin sensitisation	No hazard or unlikely hazard with the following exceptions: Known or potential hazard for aquatic toxicity for X4 (Aquatic acute 1); List No. 947-738-8 (Aquatic chronic 3) in subgroup 1, and EC No. 280-445-7 (Aquatic Chronic 2) in subgroup 2 Inconclusive hazard for vPvM for EC/List No. 609-691-9, 224-305-5, 433-860-4, and X2	Substances in subgroup 1 have a range of applications as surfactants and lubricants including professional and/or consumer uses. Low potential for exposure is expected for the other substances that are mainly intermediates or only used in industrial settings.	**Currently no need for EU RRM** <u>Justification:</u> Overall, no or unlikely hazard that would lead to concern for the reported uses. Substance EC No. 412-170-7 (809-489-2) is used as an intermediate in the production of other chemicals in industrial settings and the current classification will already require adequate risk management measures in place	No action

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				according to workplace legislation. Classification for aquatic toxicity followed by implementation of necessary RRMs should be sufficient to ensure safe use for environment.	

Annex 1: Overview of classifications

Data extracted on 28 September 2022

EC Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
201-122-9	78-51-3	tris(2-butoxyethyl) phosphate	-	-
224-305-5	4297-95-4	sodium phenylphosphinate	-	Eye Damage 1 H318
280-445-7	83411-71-6	bis(2,4,4-trimethylpentyl)phosphinic acid	-	Eye Irrit. 2 H319 Aquatic Chronic 2 H411
411-200-6	14657-64-8	3-(hydroxyphenylphosphinyl)propanoic acid	Index number: 015-167-00-5 Hazard Category: Eye Dam. 1 Hazard Statement: H318	Eye Damage 1 H318
416-050-5	87460-09-1	benzyl [hydroxy-(4-phenylbutyl)phosphinyl] acetate	Index number: 607-442-00-9 Hazard Category: Eye Dam. 1 Hazard Statement: H318	Eye Damage 1 H318
420-450-5	86552-32-1	(4-phenylbutyl)phosphinic acid	Index number: 015-198-00-4 Hazard Category: Eye Dam. 1 Hazard Statement: H318 Carc. 2 Hazard Statement: H351	Carc. 2 H351 [intermediate (inactive)] Eye Damage 1 H318
428-310-5	-	Aluminium tridiethylphosphinate	-	-
434-510-3	-	Exolit OP 940	-	-
443-950-5	-	NALCO 73280	-	-

457-580-7	-	Phosphinic acid, P,P-diethyl-, zinc salt (2:1)	-	Eye Damage 1 H318 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
500-155-9	62362-49-6	Octadecan-1-ol, ethoxylated, phosphates	-	Aquatic Chronic 4 H413
500-295-0	106233-09-4	Alcohols, C16-18, ethoxylated, phosphates	-	Eye Damage 1 H318
607-114-5	225789-38-8	Phosphinic acid, P,P-diethyl-, aluminum salt (3:1)	-	-
609-080-7	35160-38-4	Phosphinic acid, P,P-diethyl-, sodium salt (1:1)	-	-
609-689-8	39464-66-9	Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-, phosphate	-	-
609-691-9	39464-70-5	2-phenoxyethanol; phosphoric acid	-	Eye Irrit. 2 H319
610-044-8	42612-52-2	Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-, phosphate, sodium salt	-	-
612-366-4	6172-80-1	Phosphinic acid, P-methyl-, butyl ester	-	Skin Corr. 1C H314 Aquatic Chronic 3 H412
614-291-2	68130-47-2	C8-10 Alkyl alcohol ethoxylate (4EO), phosphate ester	-	-
616-610-0	78330-24-2	Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, mono-C11-14-isoalkyl ethers, C13-rich, phosphates	-	-
[**X1**] Not (publicly) available	-	Reaction mass of [3-(2-hydroxyethoxy)-3-oxopropyl]arylphosphinic acid and 3-(hydroxyarylphosphinyl)propanoic acid and ethane-1,2-diol	-	STOT Rep. Exp. 2 H373, affected organs: Kidney (Niere) Eye Damage 1 H318 Aquatic Chronic 4 H413

[**X2**] Not (publicly) available	-	Alkyl-[2-(alkyl-substituted-phosphinoyl)-alkyl]-phosphinic acid	-	Eye Damage 1 H318
[**X3**] Not (publicly) available	-	Dialkyl phosphinic acid	-	Skin Corr. 1A H314 Eye Damage 1 H318
[**X4**] Not (publicly) available	-	Sodium salts of Mono- and di-[reaction products of dodecyl alcohol and ethylene oxide]phosphates	-	Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Acute 1 H400
809-489-2	83623-61-4	[No public or meaningful name is available]	Index number: 015-177-00-X STOT RE 2 Hazard Statement: H373 (Minimum classification; No information to prove exclusion of certain routes of exposure) Hazard Category: Eye Dam. 1 Hazard Statement: H318 Skin Sens. 1 Statement: H317	-
[**X5**] Not (publicly) available	-	E17-194T, (P,P-diethyl, monoester with 1,2 propanediol)_	-	-
947-738-8	-	Phosphoric acid, mixed esters with alcohols, C7-9-iso-, C8-rich and alcohols, C11-14-iso-, C13-rich, ethoxylated, potassium salt	-	Skin Corr. 1A H314
947-763-4	-	Alcohols, C16-18 and ethoxylated C16-18 , phosphates (20 moles ethoxylation)	-	Eye Damage 1 H318 Aquatic Chronic 2 H411

[**X6**] Not (publicly) available	-	[No public or meaningful name is available]	-	Eye Damage 1 H318
947-833-4	-	Alcohols, C18-unsatd and ethoxylated C18-unsatd., phosphates (5 moles ethoxylation)	-	Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
948-017-0	-	Esterification product of Alcohols, C12-13, ethoxylated, and Alcohols, C16-18 and butan-1-ol with diphosphorus pentaoxide	-	Skin Corr. 1B H314 Eye Damage 1 H318

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

Data extracted on 28 September 2022

Subgroup 1: Ethoxylated alcohol phosphates

Main types of applications structured by product or article types	201-122-9	500-155-9	500-295-0	609-691-9	X4	947-738-8	947-763-4	X6	947-833-4	948-017-0
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents		I	F, I	F, P						
PC 27: Plant protection products	F, P, C									
PC 35: Washing and cleaning products	F, I, P, C, A		I, C	P			F, I, P, C			
PC 8: Biocidal products (e.g. disinfectants, pest control)			I				F, I, P, C			
PC 28: Perfumes, fragrances			F, I, P, C							
PC 3: Air care products							F, C			
PC 39: Cosmetics, personal care products			F, I, P, C		F, C		F, P, C	F, P, C	F, P, C	
PC 31: Polishes and wax blends	F, I, P, C, A						F, P, C			
PC 24: Lubricants, greases, release products	F, I, P		F, I, P, C							
PC 25: Metal working fluids	F, I, P		F, I, P							
PC 17: Hydraulic fluids	F, I, P									
PC 32: Polymer preparations and compounds	F, I, A	I, A	F, I, C, A							
PC 1: Adhesives, sealants	F		I			F, I, P, C				
PC 9a: Coatings and paints, thinners, paint removes	F, P, C, A		F, I, C, A			F, I, P, C				
PC 18: Ink and toners			F, I			F, P, C				
PC 26: Paper and board treatment products	F, I, A		I							
PC 34: Textile dyes, and impregnating products	F, I		F, I, A							
PC 23: Leather treatment products			F, I							
PC 14: Metal surface treatment products	F, I						I, A			
PC 21: Laboratory chemicals			F, I	F, P						
PC 19: Intermediate	F, I, P		I							I

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

Subgroup 2: Hydrocarbylphosphinic acids and salts

Main types of applications structured by product or article types	224-305-5	280-445-7	420-450-5	428-310-5	457-580-7	609-080-7	X2	X3
PC 35: Washing and cleaning products				I				
PC 16: Heat transfer fluids				I, P, A				
PC 32: Polymer preparations and compounds	F, I, A			I, A*	I, A*	I, A*	I, A*	I, A*
PC 1: Adhesives, sealants				F, I, P, A				
PC 19: Intermediate			I				I	I
PC 40: Extraction agents		F, I						

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release
*Not present in use description. Based on the description of the uses and extrapolation from similar substances (potential alternatives).

Subgroup 3: Hydrocarbylphosphinic acids substituted with carboxylic acids and esters

Main types of applications structured by product or article types	411-200-6	416-050-5	443-950-5	X1
PC 37: Water treatment chemicals			F, I	
PC 35: Washing and cleaning products			I	
PC 32: Polymer preparations and compounds	I, A			I, A
PC 26: Paper and board treatment products			I	
PC 34: Textile dyes, and impregnating products				I, A
PC 19: Intermediate	I	I		I

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

Subgroup 4: Phosphinic acid esters

Main types of applications structured by product or article types	612-366-4	X5
PC 32: Polymer preparations and compounds		F, I, A
PC 19: Intermediate	I	

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

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

Data extracted on 7 September 2022

EC/List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
402-090-0				YES	YES	NONS
411-200-6				YES	YES	
412-170-7						NONS
416-050-5				YES	YES	NONS
420-450-5				YES	YES	NONS
433-860-4						NONS
434-510-3						NONS
457-580-7						NONS
809-489-2				YES	YES	

*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).