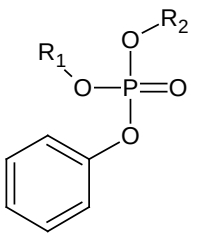
Assessment of regulatory needs

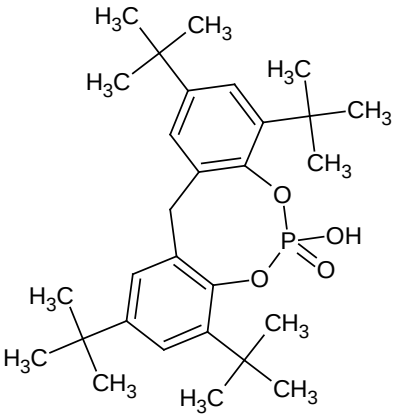
Authority: European Chemicals Agency (ECHA)

Group Name: Alkyl aryl and cyclic diaryl esters of phosphoric acid

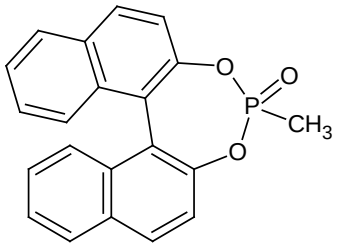
General structure:



R_1, R_2 = alkyl or aryl groups (excluding triarylphosphates)



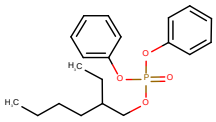
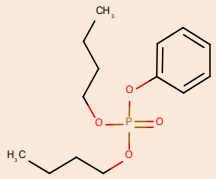
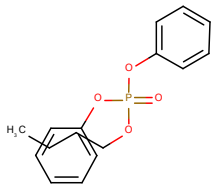
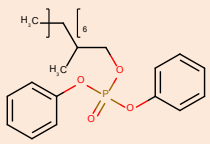
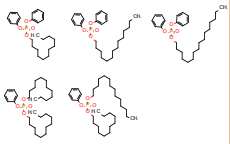
And its salts



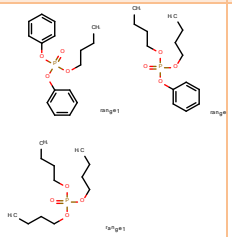
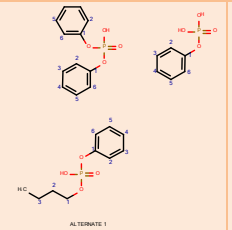
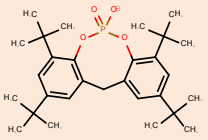
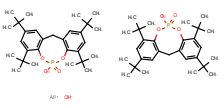
Revision history

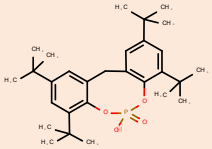
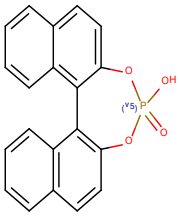
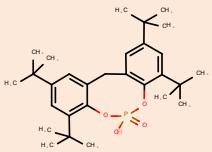
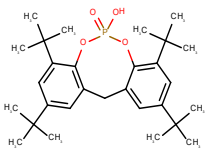
Version	Date	Description
1.0	8 December 2022	

Substances within this group:

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
Subgroup 1 'Alkyl aryl esters'				
214-987-2	1241-94-7	2-ethylhexyl diphenyl phosphate		Full, >1000
219-772-7	2528-36-1	Dibutyl phenyl phosphate		C&L notification
220-398-1	2752-95-6	Butyl diphenyl phosphate		C&L notification
249-828-6	29761-21-5	Isodecyl diphenyl phosphate		Full, not (publicly) available
431-760-5	27460-02-2	dodecyldiphenyl phosphate		NONS

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

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
605-170-5	159002-22-9	(C12-C16 mixed alkyl) diphenyl phosphate	No Structure	C&L notification
907-672-2	-	Reaction mass of butyl diphenyl phosphate and dibutyl phenyl phosphate and tributyl phosphate		Full, not (publicly) available
950-250-8	-	Reaction mass of butyl phenyl hydrogen phosphate and diphenyl hydrogen phosphate and phenyl dihydrogen phosphate		Full, not (publicly) available
Subgroup 2 'Cyclic diaryl esters'				
286-344-4	85209-91-2	2,4,8,10-tetra(tert-butyl)-6-hydroxy-12H-dibenzo[d,g][1,3,2]dioxaphosphocin 6-oxide, sodium salt		Full, 100-1000
430-650-4	151841-65-5	hydroxy aluminium bis(2,4,8,10-tetra-tert-butyl-6-hydroxy-12H-dibenzo[d,g][1.3.2]dioxaphosphocin-6-oxide)		Full, 10-100

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
458-880-0	-	2,4,8,10-tetra(tert-butyl)-6-hydroxy-12H-dibenzo-[d,g][1,3,2]dioxaphosphocin 6-oxide, lithium salt		Full, not (publicly) available
609-734-1	39648-67-4	Dinaphtho[2,1-d:1',2'-f][1,3,2]dioxaphosphepin, 4-hydroxy-, 4-oxide, (11bR)-		OSII or TII
617-688-9 [2]	85209-93-4	12H-Dibenzo(d,g)(1,3,2)dioxaphosphocin, 2,4,8,10-tetrakis(1,1-dimethylethyl)-6-hydroxy-, 6-oxide, lithium salt		C&L notification
829-608-1	106396-29-6	2,4,8,10-tetra(tert-butyl)-6-hydoroxy-12H-dibenzo[d,g][1,3,2]dioxaphosphocin, 6-oxide		Full, not (publicly) available

This table contains also group members that are only notified under the CLP Regulation. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

[2] List number 617-688-9 (which has no registrations) is a duplicate of EC number 458-880-0.

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[3].

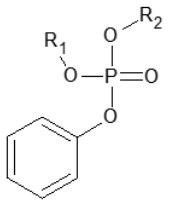
[3] https://echa.europa.eu/understanding-assessment-regulatory-needs

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 structurally similar substances based on the presence of the mixed aryl alkyl phosphate and aryl phosphate moieties shown in the figure below.



R1 and R2 are alkyl or aryl groups.
Includes also cyclic diaryl esters.

Excludes triphenyl phosphates; R1 and R2 cannot both be phenyl

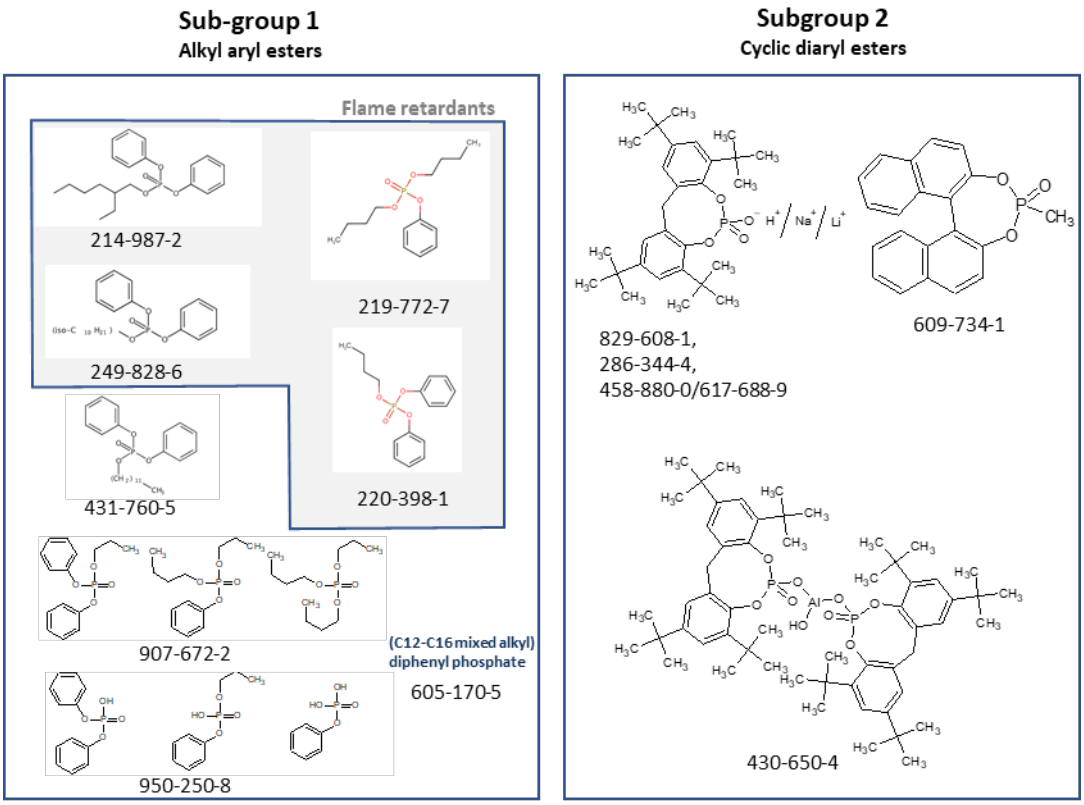
The 14 substances with 8 full registrations, 1 NONS notification, 1 registration as intermediates, and 4 with C&L notification were divided into the following groups based on structural features, hazard profile and foreseen final regulatory action:

- Subgroup 1 ‘Alkyl aryl esters’: This subgroup consists of 8 mixed alkyl aryl phosphate esters where the aryl group is always phenyl. Triphenylphosphate (TPP; EC 204-112-2) is present or assumed to be present in these substances as an impurity.

- Subgroup 2 ‘Cyclic diaryl esters’: This subgroup consists of the cyclic diester 2,2'-methylene-bis-(4,6-di-t-butylphenylene)phosphate, its sodium salt, lithium salt, and triester with aluminium trihydroxide, and one cyclic diester where the aryl group is 1,1'-binaphthalene.

Most of the substances (13) are well-defined mono- and multi-constituent substances, and one of the substances is a UVCB substance.

This group is one of several groups built around substances with known uses as flame retardants (in this case, featuring only in subgroup 1).



Substances in subgroup 1 are used as plasticizers with flame retardant properties. There is clear evidence for use as flame retardants for substances EC 214-987-2, 219-772-7, 220-398-1 and 249-828-6. All the substances in this sub-group are expected to be able to display flame retardant properties based on structural similarities. Other uses include lubricating agent in heat transfer fluids and hydraulic fluids (List No. 907-672-2). These substances are used in the production of plastics, adhesives/sealants, fillers, coatings/paints and leather treatment products. Hence there is potential for exposure relevant to human health and the environment.

Substances in subgroup 2 containing 2,2'-methylene-bis-(4,6-di-t-butylphenylene)phosphates (EC/List 286-344-4, 430-650-4, 458-880-0 and 829-608-1 in table below) are used as nucleating agents in the production of plastics to enhance transparency of the materials (also referred to as clarifying agents). The concentration in the polymeric matrix is low and the resultant polymers are used in a variety of articles.[4] The type of polymers in which these substances are used, and the migration potential of the substances from those materials, is unknown. The registrants claim that low release is expected for these substances, but no data are available in the registration dossiers to confirm this. Consequently, the potential for exposure for human health and the environment cannot be excluded. Overall, it can be anticipated that exposure from uses in articles may be limited. However, there is concern regarding the potential for exposures to EC/List 430-650-4 since this substance has professional uses related to the manufacturing of plastic products.

[4] The reported article categories for those materials are AC 1: Vehicles, AC 2: Machinery, mechanical appliances, electrical/electronic articles, AC 3: Electrical batteries and accumulators, AC 5: Fabrics, textiles and apparel, AC 10: Rubber articles and AC 13: Plastic articles.

Subgroup 2 also contains a substance considered an outlier (List 609-734-1) based on the chemical structure and the use description. This substance is a cyclic phosphate from (R)-1,1'-Binaphthalene-2,2'-diol that is used as intermediate in the production of other chemicals not further specified in the registration dossiers. Further, this substance is registered as a transported isolated intermediate under Art. 18 of REACH and thus strictly controlled conditions are expected to be in place to minimise exposure to human health and environment.

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

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

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

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

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for potential reproductive toxicity due to the potential for release/exposure of the substances EC/List 286-344-4, 430-650-4, 458-880-0, 617-688-9 and 829-608-1 in subgroup 2.

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity all the substances in the group have (potentially) the following human health/environmental hazards: *Reproductive toxicity for* EC/List 286-344-4, 430-650-4, 458-880-0, 617-688-9 and 829-608-1.

This hazard is identified based on a two-generation reproductive toxicity study available for EC/List 286-344-4 showing lower mating index, increased pre-coital time, lower fertility index and significant early embryonic loss leading to 0% gestation index in the high dose group. The severity of effects cannot be explained solely by maternal toxicity.

The substances are either sodium, aluminium, or lithium salts of the same anion (the same organic structure). Therefore, based on structural similarity the reproductive toxicity hazard findings from EC/List 286-344-4 (sodium salt) are extrapolated to the other substances in subgroup 2 with common organic structure and differing only on counter ion (aluminium, or lithium) where there is no information for this endpoint. Furthermore, the lithium cation in EC/List 458-880-0 and 617-688-9 further adds on the reproductive toxicity concern. For several lithium salts (Li2CO3, LiOH, LiCl) the Committee for Risk Assessment (RAC) has adopted an opinion in support of a harmonised classification as Repr. 1B, H360FD, H362, Lact based on the toxicity of the lithium cation[5].

No other potential hazards were identified for human health. These conclusions are based on data available for skin sensitisation, mutagenicity, and repeated dose sub-acute and sub-chronic toxicity for the substances in the subgroup. Some uncertainty remains on the potential of the substance(s) to affect the thyroid system.

In addition to the hazards listed above it is important to note that the substances also fulfil the P/vP criteria and are expected to be mobile in the environment. Together with the hazards identified for human health, the substances may pose an inherent hazard to remote aquatic environments and the sources of drinking water.

For substance EC 430-650-4, professional use of polymer preparations and compounds is reported[6]. Considering the structural similarity between the substances in this sub-group it cannot be completely excluded that the other substances could be used in the same professional settings which would constitute a regrettable substitution. 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.

Although registrants claim that low release is expected for these substances there are no data in the registration dossiers to confirm this hence it is assumed that there is potential for release/exposure from articles containing these substances.

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

CLH and SVHC identification are highly recommended as a step prior to restriction. In addition, SVHC identification brings immediate obligations for suppliers of the substances such as (i) supplying a safety data sheet and communicating on the safe use of the substances, (ii) responding to consumer requests within 45 days and (iii) notifying ECHA if the article they produce contains the substance above regulatory threshold.

Confirmation of the hazard properties via CLH and SVHC identification is not considered sufficient to minimise potential releases of the substances in the environment and exposure to humans. Widespread professional uses are typically non-contained and non-automated leading to releases to environment.

[5] https://echa.europa.eu/sv/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18270066e

[6] No further details on the types of professional uses are available.

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

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

Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

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

Moreover, the exposure potential from articles used by professionals or consumers should be assessed during the preparation of a potential restriction proposal and depending on the exposure potential restricting substances in articles should be considered.

It is suggested to cover possibly also industrial uses as part of the restriction. The need for authorisation might be considered for industrial uses excluded from the scope of the restriction as it may not be proportionate to restrict all uses.

Based on currently available information, there is no need for (further) EU regulatory risk management all the substances in subgroup 1 and substance List 609-734-1 in subgroup 2.

Carcinogenicity for EC/List 907-672-2, 220-398-1, 219-772-7

Substance EC/List 907-672-2 is self-classified as Carc. 2 (H351) based on the harmonised classification available for one of its constituents, i.e. tributyl phosphate. In addition, the repeated-dose toxicity studies available for substances EC/List 907-672-2 and 219-772-7 show effects consistent with those observed in the toxicity studies for tributyl phosphate. In this regard, substance EC 220-398-1 is a constituent of substance List 907-672-2 and, considering the structural similarities, is also concluded that the same potential hazard for that substance cannot be excluded.

Nevertheless, the carcinogenic effects which lead to the classification of tributylphosphate as Carc. 2 consisted of urinary bladder malignant transitional cell carcinoma and squamous cell carcinoma in the presence of a non-dose-related low incidence of urinary crystals. This is also consistent with bladder hyperplasia observed in the toxicity studies for substances EC/List 219-772-7 and 907-672-2.

In line with the CLP Guidance Document (2017) which presents a list of mechanisms of tumour formation (such as urinary bladder tumours due to crystals in the bladder) as non-relevant for humans, the relevance of the harmonised classification of tributyl phosphate has been considered. However, based on available information during CLH process, the mode of action for tributyl phosphate induced urinary bladder hyperplasia and tumours were considered to be related to a non-genotoxic mechanism that involves local damage and cell proliferation rather than the formation of crystals in the urine. In addition, the underlying mechanism for rat sensitivity was not established, and therefore, it is not possible to discount the relevance of the observed urinary tumours for human health. Further, substances classified as Carc. 2 are handled according to Dir 98/24/EC (risks related to

chemical agents at work). Finally, the registrants have applied a correct self-classification.

It is important to note that these substances are not expected to be P/vP or mobile in the environment based on available information on biodegradability and adsorptive properties.

There is potential for exposure to these substances since substances EC 219-772-7 and 220-398-1 are identified flame retardants with plasticiser properties that can be used in the production of plastics, adhesives/sealants, fillers, coatings/paints and leather treatment products. Substance 907-672-2 is used as lubricant in heat transfer and hydraulic fluids by professional workers.

Nevertheless, considering the hazard class (cat 2) and the correct self-classification applied by the registrants for substance List No. 907-672-2 and that there are no registrations for substances EC 219-772-7 and 220-398-1, it is proposed that there is currently no need for EU-wide regulatory risk management.

ED for EC/List 214-987-2, 219-772-7, 220-398-1, 249-828-6, 431-760-5, 907-672-2 and 950-250-8

In substances EC 214-987-2, 219-772-7, 220-398-1, 249-828-6, 431-760-5, 907-672-2 and 950-250-8, triphenylphosphate (TPP; EC 204-112-2) is present or assumed to be present as an impurity. TPP is a suspected endocrine disrupter and is found on the CoRAP list. A fish sexual development test according to OECD TG 234 was requested in the SEV Decision in 2019. Significant effects on the timing of gonad maturation in males and on oestrogen levels in females were reported. However, the study is currently under assessment by the evaluating member states and competent authorities (MSCA). In addition, an Extended One Generation Reproductive Toxicity study for TPP is currently ongoing under US NTP.

There is uncertainty regarding the potential hazard for endocrine disruption, mainly due to ongoing data generation/assessment for TPP, but also because the available human health data does not show clear ED effects. Nevertheless, any potential action should address all substances containing TPP at relevant concentrations and not only focus on the specific substances in this sub-group. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management in this regard at this moment.

Aquatic toxicity

It is expected that registrants, having adequately self-classified the substances, are implementing the necessary RMMs to ensure safe use. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management in this regard.

Unlike subgroup 2, substances in subgroup 1 are not expected to be P/vP or mobile in the environment based on available information on biodegradability and adsorptive properties.

Other hazards

No other potential hazards were identified for human health. These conclusions are based on the available information for skin sensitisation, mutagenicity and repeated dose sub-acute and sub-chronic toxicity studies as well as reproductive toxicity studies for the substances in the subgroup with data generation ongoing for EC 214-987-2.

With regard to substance List 609-734-1, it is registered as a transported isolated intermediate (TII) under strictly controlled conditions (Art. 18 of REACH) and consequently the potential for exposure is low.

Further, there is no hazard data available both for human health and environment.

Since List 609-734-1 is an outlier from this group based on structure is not assumed that it could be used as a substitute for other groups members in the future, hence there is no current concern that it may have future professional uses.

Therefore, no further regulatory action is proposed for this substance.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited.

As indicated in the Restrictions Roadmap[7] ECHA will prepare an overall strategy on flame retardants by 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 will be 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
Subgroup 1 Alkyl aryl esters					
907-672-2 **220-398-1** **219-772-7**	Known or potential hazard for carcinogenicity ED	Known or potential hazard for aquatox ED	Substances 220-398-1 and 219-772-7 are used as plasticiser and flame retardants in plastic products, adhesives, fillers, coatings and leather treatment products. There is potential for exposure/release from professional and consumer uses as well as from articles	Currently no need for EU RRM Justification: It is unclear if carcinogenicity is relevant to humans. CMR Cat. 2 substances are already handled according to Dir 98/24/EC.	**First step:** No action

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

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			manufactured with materials containing these substances. Substance List 907-672-2 is used in hydraulic and heat transfer fluids with potential for exposure in professional uses.	The registrants for substance List No. 907-672-2 have self-classified appropriately for human health and environment. There are no registrations for substances EC No. 220-398-1 and 219-772-7. ED potential is related to the presence of TPP at relevant concentrations. Data on TPP to confirm hazard is on-going. Hazard data available for the substances do not indicate ED concern. Regulatory action should consider all substances containing TPP at relevant concentrations.	

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
214-987-2 **249-828-6** **950-250-8** **431-760-5** **605-170-5**	Known or potential hazard for ED	Known or potential hazard for aquatox Known or potential hazard for ED	Substances are used as plasticisers and flame retardants in plastic products, adhesives, fillers, coatings and leather treatment products. There is potential for exposure/release from professional and consumer uses as well as from articles manufactured with materials containing these substances.	Currently no need for EU RRM Justification: ED potential is related to the presence of TPP at relevant concentrations. Data on TPP to confirm hazard is on-going. Hazard data available for the substances do not indicate ED concern. Regulatory action should consider all substances containing TPP at relevant concentrations.	**First step:** CCH for 249-828-6 to confirm unlikely hazard for mutagenicity and skin sensitisation
Subgroup 2 Cyclic diaryl esters					
286-344-4 **430-650-4** **458-880-0 (617-688-9)** **829-608-1**	Known or potential hazard for reproductive toxicity	Known or potential hazard for aquatox Known or potential PMT	For EC 430-650-4 professional uses are also reported related to the manufacture of	Need for EU RRM: Restriction Justification: Professional uses are widespread (at many sites and many	**First step:** CLH **Next steps (if hazard confirmed):** Restriction

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			plastic products.[8] Considering the structural similarity between the substances in this subgroup it cannot be completely excluded that the other substances could be used in the same professional settings which would constitute a regrettable substitution. These substances are present in articles manufactured with plastics containing these substances. The potential for exposure for human health and the environment cannot be excluded.	users) with potentially relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. Potential exposure from articles needs further investigation, restriction for use in articles to be considered together	

[8] No further details on the types of professional uses are available.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			Further, there is no indication that these substances are used as flame retardants and the chemical structure differs significantly from the substances in subgroup 1.	with the restriction of professional uses.	
609-734-1	Inconclusive hazard	Inconclusive hazard	Transported isolated intermediate under strictly controlled conditions	Currently no need for EU RRM Justification: Transported isolated intermediate under strictly controlled conditions and no hazard data available.	**First step:** No action

Annex 1: Overview of classifications

Data extracted on 28.02.2022.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
Non-cyclic phosphate esters					
214-987-2	1241-94-7	2-ethylhexyl diphenyl phosphate	-	-	*Aquatic Chronic 2 H411[2 out of 30]* *Acute Tox. 4 H332[2 out of 30]* *Aquatic Chronic 1 H410[11 out of 30]* *Aquatic Acute 1 H400[12 out of 30]*
249-828-6	29761-21-5	Isodecyl diphenyl phosphate	-	-	*Aquatic Chronic 4 H413[3 out of 13]* *Aquatic Acute 1 H400[1 out of 13]* *Aquatic Chronic 1 H410[1 out of 13]*
907-672-2	-	Reaction mass of butyl diphenyl phosphate and dibutyl phenyl phosphate and tributyl phosphate	-	*Carc. 2 H351* *Aquatic Chronic 3 H412*	-
950-250-8	-	Reaction mass of butyl phenyl hydrogen phosphate and diphenyl hydrogen phosphate and phenyl dihydrogen phosphate	-	*Flam. Liquid 3 H226* *Skin Corr. 1 H314* *Eye Damage 1 H318*	-
431-760-5	27460-02-2	Dodecyldiphenyl phosphate	*Skin Irrit. 2 H315* *Aquatic Chronic 3 H412*	-	*Skin Irrit. 2 H315[1 out of 1]*
220-398-1	2752-95-6	Butyl diphenyl phosphate	-	-	-
219-772-7	2528-36-1	Dibutyl phenyl phosphate	-	-	*Eye Irrit. 2 H319[2 out of 7]* *Acute Tox. 4 H312[2 out of 7]* *STOT Single Exp. 3 H335, affected organs: Respiratory tract[1 out of 7]* *Acute Tox. 4 H332[2 out of 7]* *STOT Single Exp. 3 H335, affected organs: Respiratory tract [1 out of 7]* *Acute Tox. 4 H302[2 out of 7]* *Skin Irrit. 2 H315[2 out of 7]*
605-170-5	159002-22-9	(C12-C16 mixed alkyl)	-	-	*Aquatic Chronic 1 H410[1 out of 4]*

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
		diphenyl phosphate			*Aquatic Acute 1 H400[1 out of 4]*
Cyclic phosphate esters					
286-344-4	85209-91-2	2,4,8,10-tetra(tert-butyl)-6-hydroxy-12H-dibenzo[d,g][1,3,2]dioxaphosphocin 6-oxide, sodium salt	-	*Acute Tox. 4 H332 Aquatic Chronic 2 H411*	*Repr. 2 H361[1 out of 12] Aquatic Chronic 3 H412[7 out of 12]*
430-650-4	151841-65-5	Hydroxy aluminium bis(2,4,8,10-tetra-tert-butyl-6-hydroxy-12H-dibenzo[d,g][1.3.2]dioxaphosphocin-6-oxide)	*Aquatic Chronic 2 H411*	*Acute Tox. 4 H332*	*Aquatic Chronic 2 H411[4 out of 4]*
458-880-0	-	Lithium (1+) 5,7,13,15-tetra-tert-butyl-10-oxo-9,11-dioxa-10lambda5-phosphatricyclo[10.4.0.0^{3,8}]hexadeca-1(12),3,5,7,13,15-hexaen-10-olate	-	*Acute Tox. 4 H332 Aquatic Chronic 3 H412*	-
829-608-1	106396-29-6	2,4,8,10-tetra-tert-butyl-12H-dibenzo[d,g][1,3,2]dioxaphosphocin-6-ol 6-oxide	-	*Aquatic Chronic 3 H412*	-

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers, therefore the number may differ from the C&L inventory which displays number of notifiers.

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

Data extracted on 28.03.2022

Main types of applications structured by product or article types	EC 214-987-2	EC 249-828-6	EC 286-344-4	EC 430-650-4	EC 458-880-0	List 609-734-1	List 829-608-1	List 907-672-2	List 950-250-8
PC 16: Heat transfer fluids								P	
PC 17: Hydraulic fluids								I, P	
PC 32: Polymer preparations and compounds	F, I, P, C, A	F, I, P, C, A	F, I, A	F, I, P, A	F, I, A		F, I, A		
PC 1: Adhesives, sealants	F, I, P, C, A	F, I, P, A							
PC 9b: Fillers, putties, plasters, modelling clay	F, I, P, A	F, I, P, A							
PC 9a: Coatings and paints, thinners, paint removes	F, I, P, C, A	F, I, P, A							F, I, A
PC 23: Leather treatment products	F, I, P, A	F, I, P, A							
PC 21: Laboratory chemicals								I, P	
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 17.03.2022.

EC / List number	RMOA	Authorisation		Restriction *	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
430-650-4	-	-	-	-	YES	-
431-760-5	-	-	-	-	YES	NONS, not claimed
458-880-0	-	-	-	-	-	NONS, tpa upgrade

*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).

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