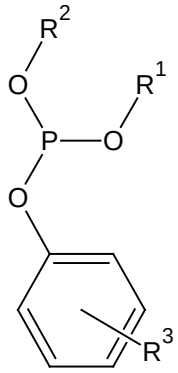
Assessment of regulatory needs

Authority: ECHA

Date: 28/01/2022

Group Name: “Triphenylphosphites” (Triphenylphosphite and its derivatives)

General structure[1]:

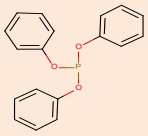
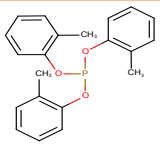
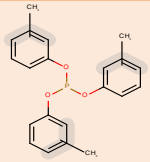
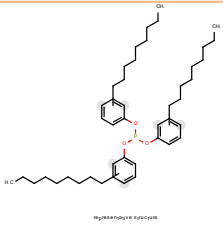
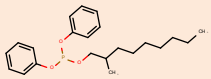
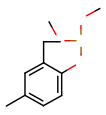


Revision history

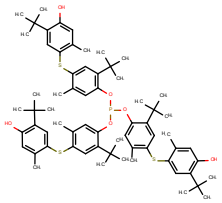
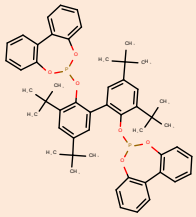
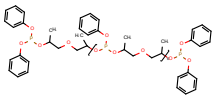
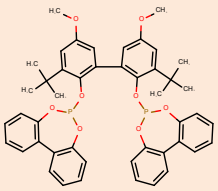
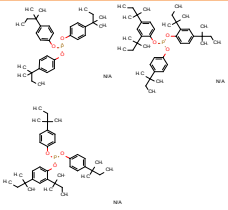
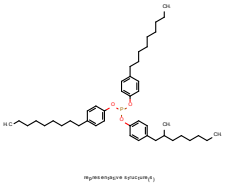
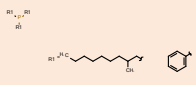
Version	*Date*	*Description*
1	11.02.2022	

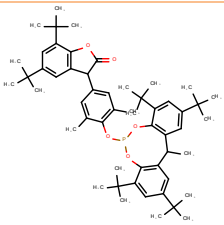
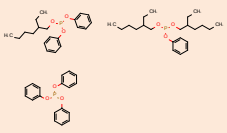
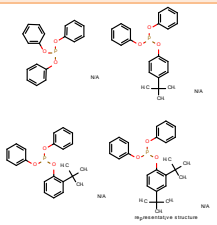
[1] To be provided only when feasible

Substances within this group:

EC/List number	CAS number	Substance name or abbreviation	Chemical structures or link to ECHA substance information	Registration type (full, OSI or TII, NONS), highest tonnage band among all the registrations (t/y) [2]
202-908-4	101-02-0	Triphenyl phosphite (TPP)		Full, 100-1000
220-068-7	2622-08-4	Tri-o-tolyl phosphite		C&L notification
247-119-6	25586-42-9	Tris(methylphenyl) phosphite		OSII or TII
247-759-6	26523-78-4	Tris(nonylphenyl) phosphite		Now registered as "tris (4-nonylphenol, branch) phosphorous acid ester" (see below in this table)
247-777-4	26544-23-0	Isodecyl diphenyl phosphite		Now registered under list number 701-341-4 (see below in this table)
250-709-6	31570-04-4	Tris(2,4-ditert-butylphenyl) phosphite		Full, >1000
437-390-0	–	BNTCP	https://echa.europa.eu/substance-information/-	NONS

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

			/substanceinfo/100.103.473	
439-690-7	310903-37-8	Reaction mixture of phosphorous trichloride and 4,4'-thiobis(2-(1,1-dimethylethyl)-5-methylphenol)		NONS
482-400-9	138776-88-2	Dibenzo[d,f][1,3,2]dioxaphosphepin, 6,6'-[[3,3',5,5'-tetrakis(1,1-dimethylethyl)[1,1'-biphenyl]-2,2'-diyl]bis(oxy)]bis-		OSII or TII
601-420-2	116265-68-0	Poly (dipropyleneglycol) Phenyl phosphite		Full, not (publicly) available
700-178-6	121627-17-6	6,6'-[(3,3'-di-tert-butyl-5,5'-dimethoxybiphenyl-2,2'-diyl)bis(oxy)]bis(dibenzo[d,f][1,3,2]dioxaphosphepine)		cease manufacture
700-485-5	939402-02-5	Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters		Full, not (publicly) available
Not (publicly) available)	–	Phosphorus acid, alkyl substituted [1,1'-biphenyl]-2,2'-diyl-tetra-aryl ester	https://echa.europa.eu/substance-information/-/substanceinfo/100.223.195	Full, not (publicly) available
701-028-2	–	tris (4-nonylphenol, branch) phosphorous acid ester		Full, >1000
701-341-4	–	Reaction products of triphenyl phosphite and isodecanol (1:1)		Full, 100-1000

817-187-7	1803088-15-4	5,7-Di-t-butyl-3-[3,5-dimethyl-4-[(1,3,7,9-tetra-t-butyl-5-methyl-5H-benzo[d][1,3,2]benzodioxaphosphocin-11-yl)oxy]phenyl]-3H-benzofuran-2-one		Full, not (publicly) available
905-728-0	–	2-ethylhexyl diphenyl phosphite		Full, not (publicly) available
Not (publicly) available)	–	[No public or meaningful name is available]	https://echa.europa.eu/substance-information/-/substanceinfo/100.226.420	OSII or TII
Not (publicly) available)	–	di-tert-butyl-dimethoxy-({3,3',5,5'-tetramethyl-2'-[(tetramethyldisubstitutedheteropolycyclyl)oxy]biphenyl-2-yl}oxy) disubstituted heteropolycycle	https://echa.europa.eu/es/substance-information/-/substanceinfo/100.233.591	OSII or TII
941-802-9	–	Reaction products of phosphorous trichloride with phenol, 2-tert-butylphenol and 4-tert-butylphenol		OSII or TII

This table contains also group members that are not registered (yet) but have a C&L notification under the CLP Regulation. However, the list is currently non-exhaustive. Once further regulatory risk management action on one or more registered substances is being considered, ECHA will make an extensive search for related C&L notified substances to be included in the group and develop a regulatory strategy for them.

Contents

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

Foreword

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

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

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

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

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

For more information on Assessment of regulatory needs please consult ECHA website[3].

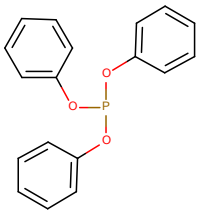
[3] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

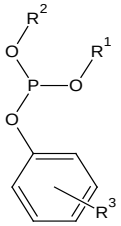
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSI or TII	On-site isolated intermediate or transported isolated intermediate
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 moiety similar to triphenylphosphite (EC 202-908-4), shown in the figure below.



triphenylphosphite (EC 202-908-4)



indicative general structure for the group

Based on information reported in the REACH registration dossiers, many substances of this group are used as intermediates and/or as stabilisers in the manufacture of e.g., lubricants, grease, release products; polymer preparations and compounds such as rubber products, plastic products; adhesive and selants; coating and paints; and/or in electrolytes for batteries. Widespread exposure of professionals and/or consumers occurs for many substances of this group. Releases to the environment are expected to occur from products or via article service life.

In general, phosphites can undergo hydrolysis when exposed to humidity with rates of hydrolysis depending on pH and molecular weight of the substance. Undergoing hydrolysis the substances in this group will release alkylated phenols. In this regard, it is important to note that ECHA has grouped structurally related hydrocarbylphenols (i.e. phenols with any kind of saturated or unsaturated hydrocarbon substituent(s) on the phenol ring). Some hydrocarbylphenols have already been scrutinised by Member State Competent Authorities. For some others, regulatory activities are ongoing. The use of hydrocarbylphenols as such, as a constituent/impurity, in mixtures or articles with (potential) endocrine properties (ED), toxicity to reproduction and/or PBT/vPvB properties and potential exposure to human health and the environment is of concern. ECHA is currently assessing the regulatory needs of several groups of hydrocarbylphenols.

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 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 STOT RE (neurotoxicity) hazards due to the potential for release/ exposure of the substance EC 202-908-4 in the group.

Triphenyl phosphite (TPP, EC 202-908-4) has widespread uses reported including professional and consumer use, pointing to high exposure potential. Triphenyl phosphite, which is the core structure of this group underwent substance evaluation (UK, 2019)[4], recommending that a CLH proposal for Skin Sens. 1A (H317) and STOT RE 2 (H373; nervous system) should be proposed. With regards to reproductive toxicity, genotoxicity and endocrine disruption (for human health) the initial suspected hazards were not substantiated under the substance evaluation. Nevertheless, there is a data gap for a 90-day repeated-dose toxicity study which is a standard info requirement. The data from this study could justify a more stringent classification as STOT RE 1. Since the CLH process was not yet initiated, compliance check and generation of the missing data is proposed as first step.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as STOT RE 1.

CLH (i) will require company level risk management measures (RMM) under the OSH legislation for workers to be in place, ii) is needed or highly recommended for further regulatory processes under REACH (e.g restriction).

[4] https://interact-toolbox.echa.europa.eu/wopihost-generic-module/OWA?fileID=090236e183d94aa9&application=ACT

Exposure to consumers is expected. The following professional uses (e.g. lubricants, grease, release products; adhesive and sealants; coating and paints) are expected to be widespread (at many sites and by many users). Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation.

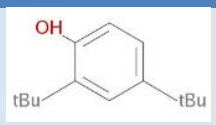
Consumers may be co-exposed to the substances used by professionals (e.g. lubricants, coating and paints, adhesives). Therefore, a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by consumers and professionals** is suggested after CLH**.**
Restriction of professional 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 neurotoxic substances by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability.[5]

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

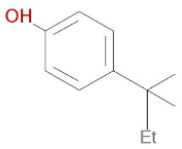
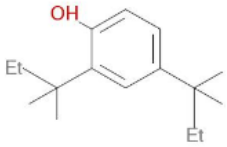
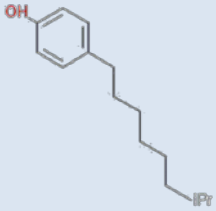
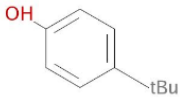
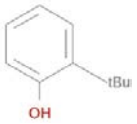
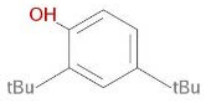
Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for potential Repro. 1B, ED and PBT/vPvB properties, of substances EC 701-028-2 (247-759-6), 250-709-6, 700-485-5 and 941-802-9 and/or their hydrolysis products due to the potential for release/exposure.

In general, phosphites can undergo hydrolysis when exposed to humidity with rates of hydrolysis depending on pH and molecular weight of the substance. This is clear from the data available for EC 202-908-4 (TPP) which, according to the lead registrant, can be "
".

Based on ECHA's assessment, substances EC 701-028-2, 250-709-6, 700-485-5 and 941-802-9 have potentially ED properties. Although the rate of hydrolysis for those substances is unknown due to lack of data, hydrolysis of those substances is anticipated and will yield alkylphenols with already known ED properties for environment and/or under assessment for ED properties for human health and environment. In addition, those alkylphenols are already present in those substances as impurities in concentrations above 0.1%.

EC /List number	CAS Number	Substance name	Relevant impurities/Hydrolysis products	Notes
250-709-6	31570-04-4	Tris(2,4-ditert-butylphenyl) phosphite	 2,4-di-tert-butylphenol EC 202-532-0	2,4-di-tertbutylphenol is under assessment in SEv for reproductive toxicity, ED properties for human health and environment. It is also part of the group

[5] European Commission, , available at https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

EC /List number	CAS Number	Substance name	Relevant impurities/Hydrolysis products	Notes
700-485-5	939402-02-5	Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters	 4-tert-pentylphenol EC 201-280-9  2,4-di-tert-pentylphenol EC 204-439-0	4-tert-pentylphenol is currently in the candidate list for endocrine disrupting properties to the environment 2,4-di-tert-pentylphenol is currently not under assessment for reproductive toxicity and ED properties but it is structurally related to 2,4-di-tert-butylphenol
701-028-2	-	tris (4-nonylphenol, branch) phosphorous acid ester	 Phenol, 4-nonyl-, branched EC 284-325-5	4-nonylphenol (linear or branched) is currently in the candidate list for endocrine disrupting properties to the environment tris (4-nonylphenol, branch) phosphorous acid ester is also in the candidate list due to the presence of 4-nonylphenol above 0.1%
941-802-9	–	Reaction products of phosphorous trichloride with phenol, 2-tert-butylphenol and 4-tert-butylphenol	 4-tert-butylphenol EC 202-679-0  2-tert-butylphenol EC 201-807-2  2,4-di-tert-butylphenol EC 202-532-0	2-tert-butylphenol is currently in the candidate list for endocrine disrupting properties to the environment. 4-tert-pentylphenol is currently in the candidate list for endocrine disrupting properties to the environment 2,4-di-tertbutylphenol is under assessment in SEv for reproductive toxicity, ED properties for human health and environment

Furthermore, EC 250-709-6 and 701-028-2 are currently under PBT EG and SEv , respectively, for PBT clarification. In addition, those substances are potentially toxic to reproduction as well as substance EC 700-485-5 based on the presence and potential release via hydrolysis of 2,4-di-tert-butylphenol (EC 202-532-0) and 2,4-di-tert-pentylphenol (EC 204-439-0). 2,4-di-tert-butylphenol is currently under assessment for reproductive toxicity under SEv and part of the group and 2-4-di-tert-pentylphenol is structurally related.

Compliance check is proposed to clarify the potential reprotoxic properties of the substances (EC 250-709-6, 700-485-5, 701-028-2). Potential PBT/vPvB of 700-485-5 is also to be clarified via compliance check, while for the remaining

substances (EC 250-709-6 and 701-028-2), PBT EG and SEv conclusions are awaited. For EC 701-028-2, the test should be performed with the registered substance with 4-nonylphenol, branched < 0.1% w/w. Note that if it is not possible to clarify the properties via compliance check, substance evaluation may be considered at a later stage.

For the other substances it is suggested to wait for compliance check and the PBT assessment for substances EC 250-709-6 and 701-028-2.

From the exposure/release potential point of view substances EC 250-709-6 and 701-028-2 have wide dispersive professional and consumer uses reported in the registration dossiers and article service life from which releases to the environment and exposure to humans is likely. Note that substance EC 250-709-6 is also listed in Annex I of EC 10/2011 in food contact materials.

For substance EC 700-485-5 only formulation in polymeric materials such as rubber and plastics have been reported in the registration dossiers. In the absence of further data, it is assumed potential exposure/release from articles manufactured with those materials.

Substance List No. 941-802-9 is only registered as an intermediate under alleged strictly controlled conditions. Nevertheless, it could have the same use profile considering the structural similarity with the other substances. Thus, to avoid potential regrettable substitution, this substance should also be considered within the scope of the proposed restriction.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard for the substances as such and/or the hydrolysis products and/or constituents/impurities via harmonised classification (CLH) as Repro. 1B and/or SVHC identification and inclusion on the Candidate List as PBT/vPvB, ED (HH or ENV).

CLH i) will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 28, 29, 30.

SVHC identification is required (Authorisation) or highly recommended for further regulatory processes under REACH (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.

However, confirmation of the hazard properties via SVHC identification is not considered sufficient to minimise potential releases of the substances in the environment and exposure to humans. A restriction is seen as the most appropriate option as potential for exposure/releases 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 (e.g. lubricant, adhesives, coatings and paints) are typically non-contained and non-automated leading to releases to the environment and frequent exposures to workers with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation.

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, industrial workers, is suggested after SVHC identification, with the aim to minimise exposure and emissions to humans and the environment. Moreover, restricting substances used in articles is also proposed.

The use of reprotoxic, PBT/vPvB and ED substances by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[6].

It is suggested to cover possibly also industrial uses as part of the restriction. However, 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.

Before proceeding with the suggested restriction it should be considered that ECHA is currently assessing the regulatory needs of several groups of hydrocarbylphenols and the fact that other carbylphenol-containing substances might have similar use profiles. Thus, a wider restriction could be applicable on a larger group of substances for some specific uses that would mitigate the risk of regrettable substitution.

Based on currently available information, there is no need for (further) EU regulatory risk management for the remaining substances in the group.

Based on ECHA's assessment of information available in the registration dossiers, some substances of this group have either known or potential hazards for skin sensitisation 1. Depending on the alcohol moieties some substances may also have potential aquatic toxicity.

Some substances have correct self-classification for Skin Sens 1, those are: EC 247-119-6, 482-400-9, EC 439-690-7, EC 601-420-2, EC 701-341-4 (same as EC 247-777-4), EC 817-187-7 and EC 905-728-0.

Some substances are concluded not skin sensitisers: EC 700-485-5 and Phosphorus acid, alkyl substituted [1,1'-biphenyl]-2,2'-diyl-tetra-aryl ester (EC not (publicly) available).
All of the substances with available data are negative for any type of mutagenicity, except for the substance Phosphorus acid, alkyl substituted [1,1'-biphenyl]-2,2'-diyl-tetra-aryl ester, which has a positive result for the Mammalian Cytogenicity test, however this result was possibly due to the insolubility of the substance. Overall, the substances are not expected to be mutagenic. Furthermore, there is not enough evidence as well to argue potential reproductive toxicity or ED properties for these substances.

For industrial and professional uses, sufficient and consistent self-classification by registrants should trigger adequate risk management measures according to workplace legislation. Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing substance.

However, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory

[6] European Commission, , available at https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

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

Environmental self-classification is also in place for EC 601-420-2, EC 701-341-4 (same as EC 247-777-4), EC 905-728-0, EC 700-178-6, EC 941-802-9 and EC 482-400-9 however, for some substances the self classifications are questionable (EC 601-420-2, EC 701-341-4 and 905-728-0). CCH will be initiated to clarify the hazard properties of EC 601-420-2, EC 700-485-5, EC 701-341-4 and 905-728-0. It is expected that following data generation for aquatic toxicity registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

In addition for some substances it is not possible to clarify the hazard for the following reasons and therefore, for the time being there is no need for EU RRM action on those:

- not registered (EC 220-068-7),
- cease of manufacture (EC 700-178-6),
- intermediates (no public or meaningful name EC not (publicly) available, di-tert-butyl-dimethoxy-({3,3',5,5'-tetramethyl-2'-[(tetramethyldisubstitutedheteropolycyclyl)oxy]biphenyl-2-yl}oxy) disubstituted heteropolycycle EC not (publicly) available, and EC 941-802-9),
- NONs (EC 437-390-0),
- or Annex VII (EC 817-187-7), due to limited standard information requirements.

The potential for exposure is expected to be low for most of those substances for the time being. If the registration status changes for the non-registered substances and the substances subject to NONS registration, data generation and potential follow up actions will be re-considered when the assessment will be revisited.

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

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
202-908-4 Triphenyl phosphite, TPP	Known or potential hazard for skin sensitisation for STOT RE	Known or potential hazard for aquatic toxicity	Widespread exposure of professionals and/or consumers to many products and/or articles containing the substances used as stabilisers in e.g., lubricants, grease, release products; polymer preparations	**Need for EU RRM: Restriction** Justification: The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with	**First step:** CCH **Next steps (if hazard confirmed):** CLH Restriction

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			and compounds; adhesive and sealants; coating and paints; and/or in electrolytes for batteries	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. Specific restriction for use in articles as	

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				potential exposure from articles cannot be excluded.	

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
250-709-6 **700-485-5** **701-028-2 (previously 247-759-6)** **941-802-9**	Known or potential hazard for ED, skin sensitisation, reproductive toxicity Likely hydrolysis into alkylphenols with ED properties for environment and/or under assessment for ED properties for human health and environment and PBT/vPvB properties	Known or potential hazard for aquatic toxicity for PBT/vPvB, ED Likely hydrolysis into alkylphenols with ED properties for environment and/or under assessment for ED properties for human health and environment and PBT/vPvB properties	Widespread exposure of professionals and/or consumers to many products and/or articles containing the substances used as stabilisers in e.g., lubricants, grease, release products; polymer preparations and compounds; adhesive and sealants; coating and paints; and/or in	**Need for EU RRM: restriction** <u>Justification:</u> Releases to the environment from consumer and widespread professional uses cannot be avoided. Widespread professional uses are typically non-contained and non-automated leading to releases to the environment. Potential	**First step:** CCH for 250-709-6, 700-485-5 and 701-028-2 Await for data and PBT assessments for 250-709-6 and 701-028-2 for the other substances **Next steps:** CLH SVHC identification Restriction

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			electrolytes for batteries	releases to the environment from articles cannot be excluded. Restriction with the aim to minimise exposure to human and releases to the environment. 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	

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				placing on the market rather than at the level of uses. Industrial uses to be considered as part of the restriction	

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
601-420-2, **701-341-4** (previously registered as EC 247-777-4) **905-728-0**	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity Inconclusive hazard for aquatic toxicity for 601-420-2 and 817-187-7		**Currently no need for EU RRM** Justification: All substances are self-classified as Skin Sens 1. Adequate self-classification of the substances should be sufficient to	**First step:** CCH for 601-420-2, 701-341-4 and 905-728- **Next steps (if hazard confirmed):** No action

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
247-119-6[+] **439-690-7**[^] **482-400-9**[+] **817-187-7**			[+]Industrial only [^]NONS	ensure safe use at the workplace. However, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern. Work is ongoing on	No action

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				this generic issue by both Member States and ECHA which may affect the regulatory actions on the substances in this group.	
Phosphorus acid, alkyl substituted [1,1'-biphenyl]-2,2'-diyl-tetra-aryl ester **EC not (publicly) available**	No hazard or unlikely hazard	Inconclusive hazard for aquatic toxicity	Industrial uses only	**Currently no need for EU RRM** Justification: Overall, no or unlikely hazard that would lead to concern for the	No action

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				reported uses	
700-178-6*	Inconclusive hazard *No hazard or unlikely hazard	Inconclusive hazard	Cease of manufacture	**Currently no need for EU RRM** Justification: **Currently not possile to clarify hazards due to the registration status.** If the registration status changes for the non-registered substances and the substances subject to NONS registration, data generation	No action
220-068-7			Not registered (only C&L notification)		
437-390-0			NONS		
No public or meaningful name EC not (publicly) available			Intermediates		
di-tert-butyl-dimethoxy-({3,3',5,5'-tetramethyl-2'-[(tetramethyldisubstitutedheteropolycyclyl)oxy]biphenyl-2-yl}oxy) disubstituted heteropolycycle **EC not (publicly) available**					

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				and actions will be re-considered when the assessment will be revisited.	

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

Data extracted on 16/07/2021

EC/List number	CAS number	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
202-908-4	101-02-0	Triphenyl phosphite	Skin Irrit. 2 H315 C ≥ 5 % Eye Irrit. 2 H319 C ≥ 5 % Aquatic Acute 1 H400 Aquatic Chronic 1 H410	Skin Irrit. 2 H315 [intermediate (active)] **STOT Rep. Exp. 2 H373, affected organs: Nervous System** [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] **Skin Sens. 1B H317 [intermediate (active)]** Acute Tox. 4 H302 Skin Irrit. 2 H315, specific concentration: >=5 Eye Irrit. 2 H319, specific concentration: >=5 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: Nervous system Aquatic Acute 1 H400 Aquatic Chronic 1 H410	STOT Single Exp. 2 H371, affected organs: Central nervous system, Central nervous system[1 out of 109] Eye Irrit. 2 H319, specific concentration: >=5-<100[2 out of 109] STOT Rep. Exp. 2 H373, affected organs: [8 out of 109] Skin Irrit. 2 H315, specific concentration: >=5-<100[2 out of 109] Skin Sens. 1A H317[5 out of 109] Skin Corr. 1B H314[1 out of 109] Acute Tox. 4 H332[2 out of 109] STOT Single Exp. 2 H371, affected organs: Central nervous system[1 out of 109] STOT Rep. Exp. 2 H373, affected organs: nervous system[1 out of 109]
220-068-7	2622-08-4	Tri-o-tolyl phosphite	-		Eye Irrit. 2 H319[1 out of 2] Skin Irrit. 2 H315[1 out of 2]
247-119-6	25586-42-9	Tris(methylphenyl) phosphite	-	**Skin Sens. 1 H317 [intermediate (active)]** Acute Tox. 4 H302 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)]	Eye Irrit. 2 H319[1 out of 2] Skin Sens. 1A H317[1 out of 2] Acute Tox. 4 H312[1 out of 2] Met. Corr. 1 H290[1 out of 2]
247-759-6	26523-78-4	Tris(nonylphenyl) phosphite	**Skin Sens. 1 H317** Aquatic Acute 1 H400 Aquatic Chronic 1 H410	- (pre-registered)	Acute Tox. 4 H332[1 out of 86] Skin Corr. 1B H314[1 out of 86] Repr. 1B H360[1 out of 86] Aquatic Chronic 1 H410[45 out of 86] STOT Single Exp. 3 H336, affected organs: [1 out

EC/List number	CAS number	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
					of 86] Acute Tox. 3 H311[1 out of 86] Repr. 2 H361, specific effect:H361fd[1 out of 86] Aquatic Chronic 4 H413[7 out of 86] STOT Single Exp. 3 H335, affected organs: [1 out of 86] Skin Sens. 1 H317[63 out of 86] Aquatic Acute 1 H400[51 out of 86] Aquatic Chronic 2 H411[4 out of 86] Aquatic Chronic 1 H410, M-factor: 10.00[5 out of 86] Eye Damage 1 H318[2 out of 86] Eye Irrit. 2 H319[6 out of 86] Skin Irrit. 2 H315[19 out of 86] Acute Tox. 4 H302[3 out of 86] Skin Sens. 1 H317, specific concentration: ca..1[1 out of 86] Aquatic Acute 1 H400, M-factor: 10.00[5 out of 86] Repr. 2 H361[3 out of 86]
247-777-4	26544-23-0	Isodecyl diphenyl phosphite	**-**	-	Acute Tox. 4 H332[1 out of 31] **Skin Sens. 1 H317[20 out of 31]** Acute Tox. 4 H302[1 out of 31] Aquatic Chronic 3 H412[2 out of 31] Aquatic Chronic 2 H411[14 out of 31] STOT Rep. Exp. 2 H373, affected organs: [2 out of 31] Eye Irrit. 2 H319[4 out of 31] **STOT Rep. Exp. 2 H373, affected organs: nervous system[1 out of 31]** Aquatic Chronic 1 H410[2 out of 31] Skin Irrit. 2 H315[9 out of 31] Aquatic Acute 1 H400[1 out of 31] Acute Tox. 4 H312[1 out of 31]
250-709-6	31570-04-4	Tris(2,4-ditert-butylphenyl) phosphite	-	-	Aquatic Chronic 3 H412[21 out of 122] Aquatic Chronic 4 H413[1 out of 122] Eye Irrit. 2 H319[2 out of 122]

EC/List number	CAS number	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
					Aquatic Chronic 2 H411[2 out of 122] Acute Tox. 4 H312[3 out of 122] Skin Irrit. 2 H315[3 out of 122]
437-390-0	–	BNTCP			
439-690-7	310903-37-8	Reaction mixture of phosphorous trichloride and 4,4'-thiobis(2-(1,1-dimethylethyl)-5-methylphenol)	-	-	**Skin Sens. 1 H317[2 out of 2]**
482-400-9	138776-88-2	Dibenzo[d,f][1,3,2]dioxaphosphepin, 6,6'-[[3,3',5,5'-tetrakis(1,1-dimethylethyl)[1,1'-biphenyl]-2,2'-diyl]bis(oxy)]bis-	-	**Skin Sens. 1B H317 [intermediate (active)]** Aquatic Chronic 4 H413 [intermediate (active)]	Skin Sens. 1 H317[2 out of 2]
601-420-2	116265-68-0	Poly (dipropyleneglycol) Phenyl phosphite	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 **Skin Sens. 1 H317** **STOT Rep. Exp. 2 H373, affected organs: nervous system** Aquatic Chronic 2 H411	STOT Single Exp. 3 H335, affected organs: [1 out of 2] Aquatic Chronic 4 H413[1 out of 2]
700-178-6	121627-17-6	6,6'-[(3,3'-di-tert-butyl-5,5'-dimethoxybiphenyl-2,2'-diyl)bis(oxy)]bis(dibenzo[d,f][1,3,2]dioxaphosphepine)	**-**	Aquatic Chronic 3 H412 [intermediate (inactive)]	Skin Irrit. 2 H315[2 out of 2] Eye Irrit. 2 H319[2 out of 2] STOT Single Exp. 3 H335, affected organs: Respiratory system[2 out of 2]

EC/List number	CAS number	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
700-485-5	939402-02-5	Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl) phenyl and 4-(1,1-dimethylpropyl) phenyl triesters	-	-	-
- EC not (publicly) available	- CAS not publicly available	**Phosphorus acid, alkyl substituted [1,1'-biphenyl]-2,2'-diyl-tetra-aryl ester**		-	Not classified [1 out of 1]
- EC not (publicly) available	-	**tris (4-nonylphenol, branch) phosphorous acid ester**		**Repr. 2 H361, specific effect:H361fd** Acute Tox. 4 H302 Skin Corr. 1B H314 **Skin Sens. 1 H317** Aquatic Acute 1 H400 Aquatic Chronic 4 H413 Aquatic Chronic 1 H410	
701-341-4	–	Reaction products of triphenyl phosphite and isodecanol (1:1)	-	Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: nervous system Aquatic Chronic 2 H411	-
817-187-7	1803088-15-4	5,7-Di-t-butyl-3-[3,5-dimethyl-4-[(1,3,7,9-tetra-t-butyl-5-methyl-5H-benzo[d][1,3,2] benzodioxaphos	-	**Skin Sens. 1B H317**	-

EC/List number	CAS number	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
		phocin-11-yl)oxy]phenyl]-3H-benzofuran-2-one			
905-728-0	**–**	2-ethylhexyl diphenyl phosphite	-	**Skin Sens. 1 H317** Aquatic Chronic 2 H411	-
- EC not (publicly) available	-	**[No public or meaningful name is available]**		Not published Skin Irrit. 2 H315 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)]	
- EC not (publicly) available	-	**di-tert-butyl-dimethoxy-({3,3',5,5'-tetramethyl-2'-[(tetramethyl disubstitutedheteropolycyclyl)oxy]biphenyl-2-yl}oxy) disubstituted heteropolycycle**		Eye Irrit. 2 H319 [intermediate (active)]	
941-802-9	–	Reaction products of phosphorous trichloride with phenol, 2-tert-butylphenol and 4-tert-butylphenol	-	Aquatic Chronic 3 H412 [intermediate (active)]	-

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

Data extracted on 16/07/2021

Main types of applications structured by product or article types	202-908-4	247-119-6	250-709-6	482-400-9	601-420-2	700-178-6	700-485-5	Phosphorus acid, alkyl substituted [1,1'-biphenyl]-2,2'-diyl-tetra-aryl ester	701-028-2	701-341-4	817-187-7	905-728-0	No public or meaningful name is available]	i-tert-butyl-dimethoxy-({3,3',5,5'-tetramethyl-2'-[(tetramethyldi substituted heteropolycycly)oxy]biphenyl-2-yl}oxy) disubstituted heteropolycycle	941-802-9
Washing and cleaning			I												
Pharmaceuticals	I														
Lubricants, grease, release products	F, I, P, C		F, I, P, A						F, I, P						
Metal woring fluids	P														
Hydraulic fluids	F, I								F, I, P						
Polymer preparations and compounds	F, I, P, A		F, I, P, C, A		F, I, A		F		F, I, C, A	F, I, A	F, I, A	F, I, A			
Adhesives, sealants	F, I, P, C		F, I, P, C, A						F, P, C	F, P, C					
Coatings and paints, thinners, paint removes	F, I, P, C, A		F, I, P, C, A						F, P, C	F, P, C					
Ink and toners			C							F					
Welding and soldering products, flux products			A												
intermediate	F, I, P	I	F, I	I		I							I	I	I
Electrolytes for batteries	I, P														

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 27/08/2021

Tris(nonylphenol)phosphite (EC 247-759-6) underwent harmonised classification in 2010[7] and was classified for Skin Sens. 1, H317 and Aquatic chronic 4, H413. This substance is now registered as **Tris (4-nonylphenol, branch) phosphorous acid ester (EC 701-028-2)**. Focus of further regulatory risk management activities were related to the impurity 4-nonylphenol. The substance 'Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)' was identified as SVHC[8] and was included in the candidate list for authorisation[9] in the year 2019. The concern is 'Endocrine disrupting properties (Article 57(f) - environment)'.

Table: Overview of completed or ongoing regulatory risk management activities

EC/List number or name	RMOA	Authorisation		Restriction	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
247-759-6 (now registered as 'Tris (4-nonylphenol, branch) phosphorous acid ester')		See 'Tris (4-nonylphenol, branch) phosphorous acid ester'			YES	
701-028-2	SVHC identification (related to the presence of 4-nonylphenol as impurity ≥ 0.1% w/w))	YES (related to the presence of 4-nonylphenol as impurity ≥ 0.1% w/w))				

[7] https://echa.europa.eu/pact?p_p_id=disspact_WAR_disspactportlet&p_p_lifecycle=0&_disspact_WAR_disspactportlet_substanceId=100.043.402&_disspact_WAR_disspactportlet_jspPage=%2FdetailsPage%2Fview_detailsPage.jsp

[8] https://echa.europa.eu/registry-of-svhc-intentions/-/dislist/details/0b0236e1825f37c5

[9] https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1833efad1

Annex 4: Non-exhaustive list of substances in the C&L inventory that may fall into the group definition (optional)

Tri-o-tolyl phosphite (EC 220-068-7, CAS 2622-08-4) is not registered under REACH but has notifications for self-classification.