

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

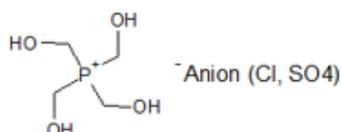
Date: 18/02/2022

Group Name: Tetrahydroxymethyl and tetraalkyl phosphonium salts

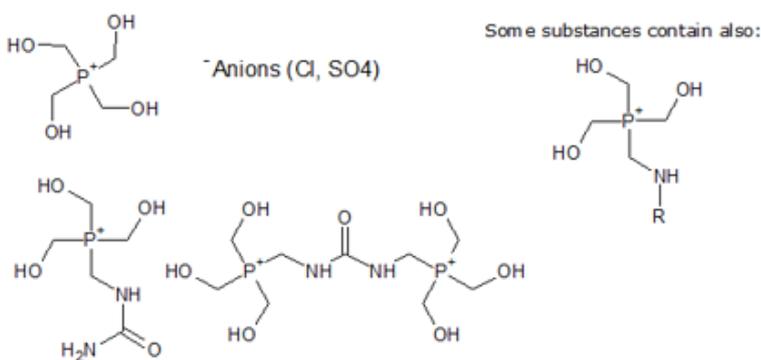
General structure:

Sub-group 1:
 Tetrakis hydroxymethyl phosphonium salts and their condensation products with amines

Tetrakis hydroxymethyl phosphonium salts



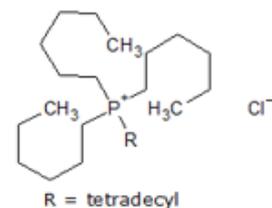
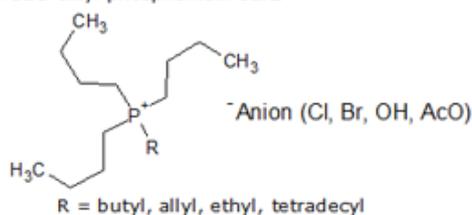
Condensation products



R = tetradecyl or C16-C18 (even numbered) alkyl

Sub-group 2:
 Tetra-alkylphosphonium salts

Tetra-alkyl phosphonium salts

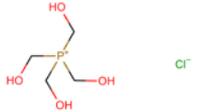
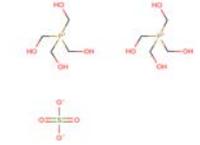
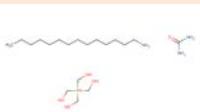
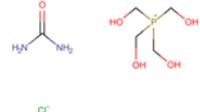
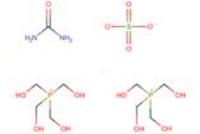
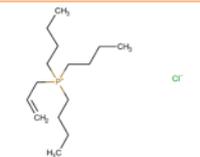


Revision history

ASSESSMENT OF REGULATORY NEEDS

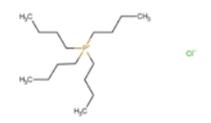
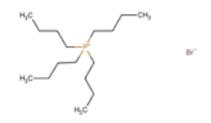
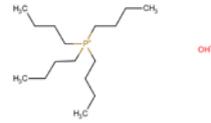
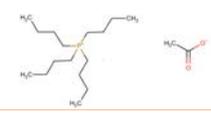
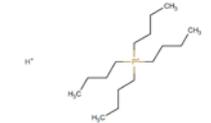
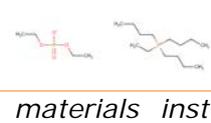
<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	03/05/2022	

Substances within this group:

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
Sub-group 1: Tetrakis(hydroxymethyl) phosphonium salts and their condensation products with amines				
204-707-7	124-64-1	Tetrakis(hydroxymethyl)p phosphonium chloride		OSII or TII
259-709-0	55566-30-8	Tetrakis(hydroxymethyl)p phosphonium sulphate(2:1)		Full, not (publicly) available
422-720-8	166242-53-1	UVCB condensation product of: tetrakis-hydroxymethylphosphonium chloride, urea and distilled hydrogenated C16-18 tallow alkylamine	* 	Cease manufacture
436-230-7	359406-89-6	Reaction products of tetrakis(hydroxymethyl)p phosphonium chloride, urea and tetradecan-1-amine	* 	Full, not (publicly) available
500-057-6	27104-30-9	Tetrakis(hydroxymethyl)p phosphonium chloride, oligomeric reaction products with urea	* 	Full, 100-1000
613-239-6	63502-25-0	Phosphonium, tetrakis(hydroxymethyl)-, sulfate (2:1), polymer with urea	* 	Full, not (publicly) available
Not (publicly) available	Not (publicly) available	Not (publicly) available (referred to as "Substance X" hereinafter)	Not (publicly) available	Full, not (publicly) available
Sub-group 2: Tetra-alkylphosphonium salts				
216-231-7	1530-48-9	Allyltributylphosphonium chloride		Full, not (publicly) available

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>

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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
218-964-8	2304-30-5	Tetrabutylphosphonium chloride		Full, not (publicly) available
221-487-8	3115-68-2	Tetrabutylphosphonium bromide		Full, 10-100
238-528-0	14518-69-5	Tetrabutylphosphonium hydroxide		OSII or TII
250-139-8	30345-49-4	Tetrabutylphosphonium acetate		OSII or TII
279-808-2	81741-28-8	Tributyltetradecylphosphonium chloride		C&L notification
471-140-1	-	Tetrabutylphosphonium hydrogen difluoride		Full, not (publicly) available
684-206-1	258864-54-9	triethyl(tetradecyl)phosphonium chloride		OSII or TII
801-347-8	20445-94-7	tributyl(ethyl)phosphonium diethyl phosphate		Full, not (publicly) available

* This published structure represents the starting materials instead of the composition of the substance.

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

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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 website².

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
RMOA	Regulatory management options analysis
RMM	Risk Management Measures
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern
THP	Tetrakis(Hydroxymethyl)Phosphonium

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of tetrahydroxymethyl and tetraalkyl phosphonium salt moieties. The group is one of several groups built around substances with known use as flame retardants (in this case, featuring especially in subgroup 1).

The group consists of both mono-constituent substances (tetrahydroxymethyl and tetra-alkyl phosphonium salts) and multi-constituent/UVCB substances (condensation products of tetrahydroxymethyl phosphonium salts with amines). The alkyl groups include hydroxymethyl and C3-C18 alkyl groups, and the counter-ions include chloride, bromide, hydroxide, acetate, sulphate, difluoride, and diethyl phosphate.

The 16 substances with 11 full registrations, 4 registrations as intermediates and 1 with C&L notification were divided into the following groups based on structural features, hazard profile and foreseen final regulatory action:

- Subgroup 1 'Tetrakis(hydroxymethyl) phosphonium salts and their condensation products with amines': This subgroup consists of 7 tetrakis(hydroxymethyl) phosphonium salts and their condensation products with amines. The condensation products contain also unreacted tetrakis(hydroxymethyl) phosphonium salts.
- Subgroup 2 'Tetra-alkylphosphonium salts': This subgroup consists of 9 tetra-alkyl phosphonium salts.

Based on information reported in the REACH registration dossiers, the substances have the following uses:

- Subgroup 1: the substances in this subgroup are used at industrial sites as intermediates (precursors) for the manufacture of flame retardants or leather tanning agents or find industrial uses as flame retardants and leather tanning agents; one substance has also article service life. Biocidal uses are also known. These substances have likely low exposure potential for workers and the environment from the industrial use and the use of articles, although their use may be associated with potential skin and inhalation exposure to free formaldehyde;
- Subgroup 2: The substances in this subgroup are mainly used at industrial sites and one substance has also article service life. They are mainly used as catalysts. Other uses include uses as curative agent for rubber, process chemical, metal extraction agent, pH regulating agent in antistatic agents, curing agents for epoxy resins. These substances have either intermediate registrations or full registrations at a low tonnage band and likely have low exposure potential for workers and the environment from their industrial use or the use of articles.

Completed relevant regulatory risk management activities are available for EC 422-720-8 for which there is CLH for Carc. 2, STOT RE 2, Skin Sens. 1, Acute Tox. 4, Skin Corr. 1B, Aquatic Acute 1, Aquatic Chronic 1.; for EC 259-709-0 there is an active substance approval under the Biocidal Products Regulation plus entries in Article 95 Applications .

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 EU regulatory risk management – harmonised classification for carcinogenicity, reproductive toxicity and STOT RE hazards due to the potential for release/ exposure of all subgroup 1 members.

Based on the available hazard information in registration dossiers it is concluded that all members of subgroup 1 are known or potential cat 1B carcinogens (Harmonised classification for EC 422-720-8 as Carc. 2; self-classification as Carc. 1B for ECs 204-707-7, 436-230-7 and 500-057-6), reproductive toxicants 1B, skin sensitisers 1/1A (one substance has CLH as Skin Sens cat 1 and the rest have self-classification for cat 1/1A), and STOT RE 2. It is concluded that these hazards may be extrapolated to all subgroup 1 members based on common structural features (for EC 436-230-7, 500-057-6 and 613-239-6, THPC is reported as constituent), on the basis that the effects are observed with a high number of substances of subgroup 1.

Reproductive toxicity (developmental effects) is observed within subgroup 1 and self-classification is applied, although it is considered that it could be more stringent and more consistent for substances (see EC 259-709-0). Read-across has been applied by the registrants to fulfil this information requirement for example for ECs 613-239-6 (EC 436-230-7 as read-across source). The hazard of developmental toxicity (Repr. 1B) is extrapolated to whole subgroup 1 due to structural similarity to ECs 204-707-7 and 259-709-0.

Formaldehyde is identified as a principal metabolite, indicating potential carcinogenicity. In addition, formaldehyde release is expected in aqueous solution

at least, with uncertainty on the amount of release, and during production of articles which involves irreversible transformation into “flame retardant polymers”. Very limited data exist for carcinogenicity on the substances in the subgroup (only with EC 204-707-7, not showing any tumours, up to 7.5 mg/kg in either sex of F344/N rats, up to 15 mg/kg in male B6C3F1 mice and up to 30 mg/kg in female B6C3F1 mice). ECs 436-230-7 and 500-057-6 are self-classified as Carc. 1B due to formaldehyde presence as constituent. *In vivo* mutagenicity data do not indicate that the substances are mutagenic. It should also be taken into account that a formaldehyde threshold needs to be reached in order to exhibit its hazardous properties and its further metabolism could influence the (lack of) observed effects. Based on the abovementioned uncertainties, carcinogenicity potential cannot be excluded, although it is not currently supported by the data.

All members of this subgroup are skin sensitizers, most of them potent sensitizers, according to the applied self-classification. In addition, some substances (422-720-8, 436-230-7, 500-057-6, 613-239-6, Substance X) show target organ specific toxicity after repeated exposure, more specifically in the liver. For substances that read-across is applied (STOT RE 1 for EC 436-230-7 as source for Substance X; STOT RE 2 for EC 500-057-6 as source for 613-239-6), the same consequences/self-classifications exist as in the source substances.

In addition, substances in subgroup 1 are toxic to the aquatic environment and they are self-classified as such. All the substances are expected to be mobile in the environment as indicated by their respective low LogKow values. The substances are salts and they are expected to disassociate into ions under environmentally relevant pH. All the substances are expected to release the tetrakis(hydroxymethyl)phosphonium ion which can rapidly oxidise into trishydroxymethylphosphine oxide (THPO). PBT/vPvB hazard is for all the substances in the subgroup unlikely as low bioaccumulation potential is expected for all substances. Additionally, while the substances screen as persistent, environmental persistence is not expected. The substances are salts and they are expected to disassociate into ions under environmentally relevant pH. All the substances are expected to release the tetrakis(hydroxymethyl)phosphonium ion which can rapidly oxidise into trishydroxymethylphosphine oxide (THPO). Therefore, substances are not ionisable and they are not surfactants. Biodegradability screening tests are available for all substances and they consistently indicate that the substances are not readily biodegradable.

All substances in subgroup 1 find industrial uses as flame retardant precursors for cellulose (cotton) textiles used as furnishings, furniture coverings, apparel (including Personal Protective Equipment (PPE)), bedding and mattresses, and as leather tanning agents (EC 259-709-0 and 500-057-6)³. In addition, the chloride and sulphate salts of tetrakis(hydroxymethyl)phosphonium can show biocidal activity, which is not reported in registration dossiers⁴.

Article service life requires consideration; the chloride and sulphate salts (both members of subgroup 1) confer flame retardancy only when a nitrogen-containing species (e.g. urea, amines) is used to produce pre-condensates (some of which are members of this subgroup) which are then applied onto textiles via padding. The

³ According to the open literature, the chloride salt (EC 204-707-7) may also be used as a leather tanning agent (<https://smc-global.com/tetrakis-hydroxymethyl-phosphonium-chloride-thpc/>).

⁴ See for example, <https://smc-global.com/tetrakis-hydroxymethyl-phosphonium-chloride-thpc/> and activities under the Biocidal Products Regulation at <https://echa.europa.eu/fi/information-on-chemicals/biocidal-active-substances/-/disas/substance/100.054.263>

THP salt-urea/amine pre-condensate then reacts with ammonia gas forming an insoluble three-dimensional polycondensate which has flame retardancy. Similarly, for leather articles, the hydroxymethyl groups in THP salts may react with the amino groups in collagen; these constitute short and strong cross-bonds by exhibiting a combined tanning property (Bayramoglu *et al*, 2013). Whilst this mode of application indicates a reactive nature for the members of the subgroup, registration data identify article service life as relevant for one subgroup member (EC 500-057-6, in flame retarded textiles), yet not for the others. Therefore, there is uncertainty over the presence of residual substances from this subgroup on the treated articles. Although there is uncertainty, the expectation is that the concentration in articles is low. In addition, breakdown of the flame retardant polycondensate to pre-condensates or the salts themselves is considered unlikely; the flame retardant polymer is described in literature as durable to, e.g., 100 washes at 75 °C and the polymer bonds are likely to be strong enough not to break down, and the condensation reactions used to manufacture the polycondensates are irreversible.

Another consideration relates to the possible presence of free formaldehyde on treated textiles that have been flame retarded with THP salt-based polycondensates⁵; this may give rise to skin exposure during use or inhalation exposure during storage. Therefore, given the widespread use of articles relevant by consumers, professional users and industrial users alike, presence of free formaldehyde (which has a harmonised classification of Carc cat 1B, Muta cat. 2 and Skin sens 1) could be relevant to consider.

The presence of multi-endpoint toxicity including CMR cat 1 supports the proposal for harmonising the hazard classification of these substances. Harmonised classification will have several relevant consequences:

- It will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place;
- It is a prerequisite to restrict the presence of the substances in clothing and other textiles, and footwear articles, by means of the restriction entry 72 of REACH Annex XVII (NB. this restriction includes a concentration limit of 75 ppm for formaldehyde);
- It will affect the authorisation of biocidal products containing the substances if present at concentrations above the relevant specific concentration limits for mixtures.

There is an ongoing restriction proposal on skin sensitisers in textiles, leather, and fur and hide articles. Under the current proposal for the restriction, harmonised classification would be needed for the restriction to apply. This would mean that free formaldehyde (with a harmonised Skin sens 1 classification) would be within the scope of this restriction, but the potential presence of either residual monomer THP salt or pre-condensate would not be covered as the CLH proposed here does not encompass the skin sensitisation endpoint due to (a) the existing skin sensitisation classification of these substances (all being self-classified, except EC 422-720-8 which has CLH for Skin Sens 1) and, (b) the expectation that the residual concentration of subgroup 1 in articles is low.

⁵ A US manufacturer of treated textiles ([http://chicagoprotective.com/pdf/Navy-Whipcord-\(NW\)-DATASHEET.pdf](http://chicagoprotective.com/pdf/Navy-Whipcord-(NW)-DATASHEET.pdf)) and a publication by the representative body of firefighters in Australia (http://volunteerfirefighters.org.au/wp-content/uploads/2015/03/AFACCouncil_IndustrySafetyAdvice_WildlandPPC_2015-02-25.pdf) indicate presence of up to 300ppm in treated textiles (PPE).

The above restrictions on textiles and leather are primarily aimed at addressing risks to consumers. As regards the use of flame retarded textiles, i.e. PPE, by professional and industrial users, safety of such equipment falls under Regulation (EU) 2016/425 which in paragraph 1.2.1.1. of its Annex II prescribes that "*the materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.*" Additionally, in order to be sold and used in the EU, PPEs have to be marked with the CE marking. The application of CE marking requires that the product complies with all applicable EU regulation including the REACH regulation.

Taking the combined effect of all these existing or foreseen provisions into account, the proposed CLH will adequately cover all relevant uses and uses of articles treated with THP-based flame retardants and tanning agents whether exposure is relevant to only residual substance or formaldehyde or both. It is proposed that a CLH proposal is considered at group level and it might also encompass the skin sensitisation (particularly to address skin sensitisation from leather articles which are not within the scope of Restriction entry No 72) and aquatic toxicity of these substances for which self-classification currently exists. Further EU RRM, such as authorisation or restriction, are deemed unnecessary due to the expected low exposure potential.

Based on currently available information, there is a need for EU regulatory risk management – harmonised classification for reproductive toxicity due to the potential for release/ exposure of eight subgroup 2 members.

The reprotoxicity hazard, assumed to be category 1B, is tentatively extrapolated, from subgroup 1 members on the basis of some common structural features across the entire group. In the absence of information, despite the remaining uncertainty from the presence of hydroxyl in subgroup 1 members that is not present in the subgroup 2 members, a reproductive (developmental) toxicity potential is flagged also for subgroup 2 members due to similar conformation around the phosphate.

In addition, as for subgroup 1, substances in this subgroup are toxic to the aquatic environment and they are self-classified as such (hence CLH for this endpoint is not necessary). All the substances are expected to be mobile in the environment as indicated by their respective low LogKow values. PBT/vPvB hazard is unlikely for all the substances in the subgroup. Biodegradability screening tests are available for all substances and they consistently indicate that the substances are not readily biodegradable. The substances are not ionisable, and they are not surfactants. Low bioaccumulation potential is expected for all substances.

Seven of the nine members of the subgroup find industrial uses as catalysts, curative, chelating and pH regulating agents with additional article service life for one substance (EC 216-231-7) in the form of rubber hoses for the automotive sector. An eighth member of the sub-group (EC 279-808-2) is currently not registered, it only has a C&L notification.

CMR category 1 endpoints are a priority for EU-wide action. Harmonisation of classification also takes into consideration the overlap in the applications of these sub-group members which could lead to one being a substitute for the other, thus the importance of adequate and consistent hazard classification is increased and CLH will bring added value. CLH will require company level risk management measures (RMM) under OSH legislation for workers. Further action beyond CLH is not considered necessary at present due to the relatively low volumes shown in the registration dossiers.

Based on currently available information, there is no need for (further) EU regulatory risk management for reproductive toxicity and aquatic toxicity hazards of substance EC 221-487-8 (tetrabutylphosphonium bromide).

The substance is a bromide salt which finds industrial uses as, primarily, a catalyst (NB. registration dossiers refer to uses as catalyst, process chemical and intermediate (precursor)) at relatively low tonnage. Bromide salts have an established Repr. 1B hazard due to a recent harmonised classification of ammonium bromide as Repr. 1B, on the basis of the bromide anion. A previous ARN by ECHA for inorganic bromides has concluded that a generic CLH proposal for Repr. 1B for bromide salts would be beneficial to cover in general all substances that are simple salts and release the bromide ion in contact with water. Thus, additional action under the present ARN for this substance on this endpoint is not needed. As regards the aquatic toxicity of the substance, it is noted that there is existing self-classification for the substance as Aquatic Chronic 2. It is expected that registrants would implement necessary RMMs to ensure safe use. Therefore, there is currently no need for additional EU-wide regulatory risk management.

3 Conclusions and actions

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

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Subgroup 1 204-707-7 259-709-0 500-057-6 422-720-8 436-230-7 613-239-6 Substance X	Known or potential hazard for carcinogenicity, reproductive toxicity, STOT RE and skin sensitisation	Known or potential hazard for aquatic toxicity Known or potential persistence and mobility in the environment	<u>Industrial use</u> as flame retardant precursors for textiles, tanning agents for leather. Known biocidal properties, not reported in registration dossiers. <u>Article service life</u> for EC 500-057-6 (and possibly other subgroup members) in flame retarded textiles. <u>Exposure potential:</u> According to the reported uses, likely low exposure potential for the substances from use of articles; potential skin and inhalation exposure to free formaldehyde	Need for EU RRM: CLH <u>Justification:</u> Harmonised classification should be sufficient to ensure safe use by workers at industrial settings and would also trigger restrictions and other controls on the substances and formaldehyde present on treated articles. Implementation of necessary RMMs should be sufficient to ensure safe use for workers.	First step: CCH (259-709-0 436-230-7 613-239-6 Substance X) Next step: CLH

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
<p><u>Subgroup 2</u> 216-231-7 218-964-8 238-528-0 250-139-8 279-808-2 471-140-1 801-347-8</p>	<p>Known or potential hazard for reproductive toxicity and skin sensitisation</p>	<p>Known or potential hazard for aquatic toxicity Known or potential persistence and mobility in the environment</p>	<p><u>Industrial use</u> as catalysts, curative agent for synthetic rubber, process chemical, metal extraction/chelating agent or pH regulating agent. <u>Article service life</u> for EC 216-231-7 in rubber hoses for the automotive sector</p>	<p>Need for EU RRM: CLH <u>Justification:</u> Harmonised classification should be sufficient to ensure safe use by workers at industrial settings. Implementation of necessary RMMs should be sufficient to ensure safe use for workers.</p>	<p>First step: CCH (216-231-7, 471-140-1) Next step: CLH</p>
<p>684-206-1 (Subgroup 2)</p>	<p>Known or potential hazard for reproductive toxicity and skin sensitisation</p>	-	<p><u>Exposure potential:</u> According to the reported uses, low exposure potential and a limited release to the environment can be assumed</p>		
<p>221-487-8 (Subgroup 2)</p>	<p>Known or potential hazard for reproductive toxicity and skin sensitisation</p>	<p>Known or potential persistence and mobility in the environment</p>		<p>Currently no need for EU RRM <u>Justification:</u> Reproductive toxicity will be addressed through separate generic CLH for bromide salts. Self-classification followed by implementation of necessary RMMs should be sufficient to ensure safe use for workers.</p>	<p>First step: CCH</p>

Annex 1: Harmonised and self-classifications

Data extracted on 8 November 2021.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
Sub-group 1: Tetrakis(hydroxymethyl phosphonium salts and their condensation products with amines					
204-707-7	124-64-1	tetrakis(hydroxymethyl)phosphonium chloride		Repr. 1B H360D Aquatic Chronic 2 H411 Aquatic Chronic 1 H410 Skin Sens. 1 H317 Met. Corr. 1 H290 Acute Tox. 3 H311 Eye Damage 1 H318 Repr. 2 H361 Skin Corr. 1C H314 Carc. 1B H350 Skin Corr. 1B H314 Repr. 2 H361d Acute Tox. 3 H301 Aquatic Acute 1 H400	Acute Tox. 2 H330 Skin Corr. 1 H314 Skin Irrit. 2 H315 Acute Tox. 4 H312 Resp. Sens. 1 H334 Acute Tox. 4 H302
259-709-0	55566-30-8	tetrakis(hydroxymethyl)phosphonium sulphate(2:1)		Repr. 2 H361D Acute Tox. 4 H302 Acute Tox. 3 H331 Acute Tox. 2 H330 Eye Damage 1 H318 Skin Sens. 1A H317 Aquatic Acute 1 H400 Aquatic Chronic 2 H411	Skin Sens. 1 H317 Skin Irrit. 2 H315 Acute Tox. 3 H301 Repr. 2 H361, Acute Tox. 5 H333 Repr. 1B H360 Acute Tox. 5 H313 Aquatic Chronic 1 H410 Skin Corr. 1B H314 STOT Rep. Exp. 2 H373, STOT Single Exp. 3 H335, Repr. 2 H361 Acute Tox. 3 H302
422-720-8	16624-2-53-1	UVCB condensation product of: tetrakis-hydroxymethylphosphonium chloride, urea and distilled hydrogenated C16-18 tallow alkylamine	Acute Tox. 4 H302 Skin Corr. 1B H314 Skin Sens. 1 H317 Carc. 2 H351 STOT RE 2 H373 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	STOT Rep. Exp. 2 H373, Carc. 2 H351 Skin Corr. 1B H314 Aquatic Chronic 1 H410 Skin Sens. 1 H317 Acute Tox. 4 H302	-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
436-230-7	35940 6-89-6	Reaction products of tetrakis(hydroxymethyl)phosphonium chloride, urea and tetradecan-1-amine		Carc. 1B H350 Repr. 2 H361 Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1A H317 STOT Rep. Exp. 1 H372, Aquatic Chronic 2 H411	-
500-057-6	27104 -30-9	Tetrakis(hydroxymethyl)phosphonium chloride, oligomeric reaction products with urea		Met. Corr. 1 H290 Acute Tox. 4 H302 Acute Tox. 5 H313 Skin Corr. 1C H314 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1 H317 Skin Sens. 1A H317 STOT Rep. Exp. 2 H373, Aquatic Chronic 1 H410, M-factor: 10.00 Aquatic Chronic 3 H412 Carc. 1B H350 Repr. 2 H361D Repr. 2 H361,	Acute Tox. 4 H312 Aquatic Chronic 1 H410 Eye Irrit. 2 H319 Repr. 2 H361, Muta. 2 H341
613-239-6	63502 -25-0	613-239-6		Repr. 2 H361 Acute Tox. 3 H301 Eye Irrit. 2 H319 Skin Sens. 1A H317 STOT Rep. Exp. 2 H373 Aquatic Chronic 1 H410, M-factor: 10.00	Acute Tox. 4 H302 Acute Tox. 4 H312 Aquatic Chronic 3 H412 Skin Corr. 1B H314 Aquatic Chronic 1 H410
-	-	Not (publicly) available, Substance X		Repr. 2 H361D Acute Tox. 3 H301 Eye Irrit. 2 H319 Skin Sens. 1A H317 STOT Rep. Exp. 1 H372 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	-
Sub-group 2: Tetra-alkylphosphonium salts					
216-231-7	1530- 48-9	allyltributyl phosphonium chloride		Repr. 1B H360 Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Chronic 2 H411	

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
218-964-8	2304-30-5	tetrabutylphosphonium chloride		Acute Tox. 4 H302 Acute Tox. 3 H311 Acute Tox. 1 H330 Skin Corr. 1C H314 Eye Damage 1 H318 Skin Sens. 1B H317 Aquatic Acute 2 H401 Aquatic Chronic 2 H411	Skin Corr. 1B H314 Acute Tox. 2 H310 Aquatic Chronic 4 H413
221-487-8	3115-68-2	tetrabutylphosphonium bromide		Repr. 2 H361 Met. Corr. 1 H290 Acute Tox. 4 H302 Acute Tox. 3 H311 Eye Damage 1 H318 Skin Sens. 1B H317 Aquatic Chronic 2 H411	Acute Tox. 2 H310 Acute Tox. 4 H332 STOT Single Exp. 3 H335 Skin Irrit. 2 H315 STOT Single Exp. 3 H335 Aquatic Chronic 4 H413 Eye Irrit. 2 H319 Acute Tox. 4 H312
238-528-0	14518-69-5	tetrabutylphosphonium hydroxide		Skin Corr. 1A H314 Aquatic Acute 1 H400 Eye Damage 1 H318	Met. Corr. 1 H290 Aquatic Chronic 2 H411 Skin Corr. 1B H314 Acute Tox. 3 H301
250-139-8	30345-49-4	tetrabutylphosphonium acetate		Eye Irrit. 2 H319 Acute Tox. 4 H302 Skin Irrit. 2 H315	Acute Tox. 3 H311 Skin Corr. 1B H314
279-808-2	81741-28-8	tributyltetradecylphosphonium chloride		-	Eye Damage 1 H318 Skin Corr. 1C H314 Aquatic Acute 1 H400 Acute Tox. 4 H302 Acute Tox. 2 H330 Acute Tox. 1 H330 Skin Corr. 1A H314 Acute Tox. 3 H331 Aquatic Chronic 3 H412 Aquatic Chronic 1 H410 Skin Corr. 1B H314
471-140-1	-	471-140-1		Acute Tox. 4 H302 Skin Corr. 1B H314 Aquatic Chronic 2 H411	-
684-206-1	25886-4-54-9	trihexyl(tetradecyl)phosphonium chloride		Aquatic Chronic 1 H410, M-factor: 10.00 Skin Sens. 1A H317 Skin Corr. 1B H314 Eye Damage 1 H318 Aquatic Acute 1 H400, M-factor: 10.00 Acute Tox. 4 H302	Aquatic Acute 1 H400 Aquatic Chronic 1 H410
801-347-8	20445-94-7	tributyl(ethyl)phosphonium		Acute Tox. 3 H301 Skin Irrit. 2 H315 Eye Damage 1 H318 Skin Sens. 1A H317	Skin Corr. 1B H314 Eye Irrit. 2 H319 Aquatic Chronic 1 H410

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
		diethyl phosphate		Aquatic Chronic 2 H411	Aquatic Acute 1 H400 STOT Single Exp. 3 H335

(*) 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 8 November 2021.

Main types of applications structured by product or article types	613-239-6	422-720-8	221-487-8	259-709-0	238-528-0	216-231-7	Substance X	204-707-7	218-964-8	500-057-6	436-230-7	684-206-1	250-139-8	801-347-8	471-140-1	613-239-6
PC 20: Products such as pH-regulators, flocculants, precipitants, neutralisation agents			I							I						
PC 29: Pharmaceuticals									I							
PC 32: Polymer preparations and compounds			I			F, I, A			I	I						
PC 9a: Coatings and paints, thinners, paint removes			I													
PC 34: Textile dyes, and impregnating products	F, I						F, I			F, I	F, I					F, I
PC 23: Leather treatment products				I												
PC 40: Extraction agents														I		
PC 21: Laboratory chemicals			I													
PC 19: Intermediate	F, I			I	I		I	I		F, I			I			F, I
Uses without specified product category		I	I	F		F				A		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

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

Data extracted on 11 November 2021.

EC/List number	RM OA	Authorisation		Restriction	CLH	Actions not under REACH/CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
259-709-0						Active substance approval (biocide), Article 95 Applications
422-720-8					YES	
436-230-7						NONS, claimed, tpa upgrade
471-140-1						NONS, claimed, tpa upgrade

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