Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

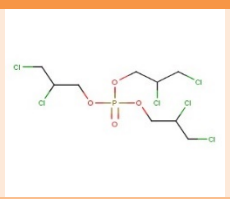
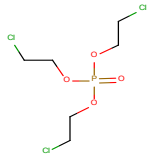
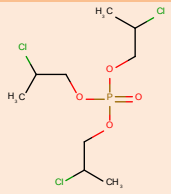
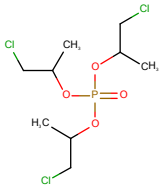
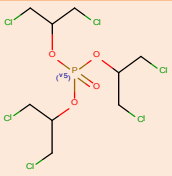
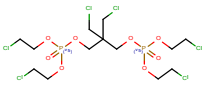
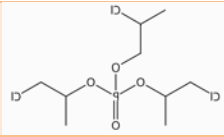
Date: 26.07.2022

Group Name: Chlorinated trialkyl phosphates

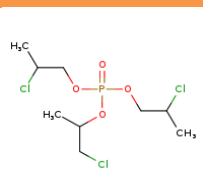
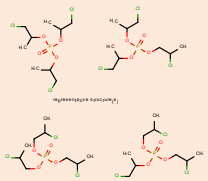
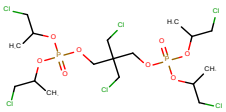
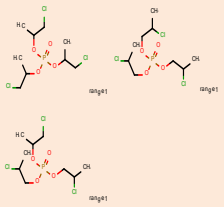
Revision history

Version	*Date*	*Description*
1	26.07.2022	

Substances within this group:

EC / List number	CAS number	Substance name Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
201-117-1	78-43-3	Tris(2,3-dichloropropyl) phosphate (TDCP)		**C&L notification**
204-118-5	115-96-8	Tris(2-chloroethyl) phosphate (TCEP)		**Full, cease manufacture**
228-150-4	6145-73-9	Tris(2-chloropropyl) phosphate (TCPP)		**C&L notification**
237-158-7	13674-84-5	Tris(2-chloro-1-methylethyl) phosphate (TCPP)		**Full, cease manufacture**
237-159-2	13674-87-8	Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)		**Full, 100-1000 t/y**
253-760-2	38051-10-4	2,2-bis(chloromethyl)trimethylene bis(bis(2-chloroethyl)phosphate) (TCDPP, also known as TCDP)		**Full, tonnage not (publicly) available**
616-283-4	76025-08-6	Phosphoric acid, bis(2-chloro-1-methylethyl) 2-chloropropyl ester (TCPP)		**C&L notification**

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

EC / List number	CAS number	Substance name Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
616-366-5	76649-15-5	Phosphoric acid, 2-chloro-1-methylethyl bis(2-chloropropyl) ester (TCPP)		**C&L notification**
807-935-0	1244733-77-4	Reaction products of phosphoryl trichloride and 2-methyloxirane (adapt from 911-815-4) (TCPP)		**Full, >1000 t/y**
809-920-4	1047637-37-5	Phosphoric acid, P,P'-[2,2-bis(chloromethyl)-1,3-propanediyl] P,P,P',P'-tetrakis(2-chloro-1-methylethyl) ester		**Full, tonnage not (publicly) available**
911-815-4	-	Reaction mass of tris(2-chloropropyl) phosphate and tris(2-chloro-1-methylethyl) phosphate and Phosphoric acid, bis(2-chloro-1-methylethyl) 2-chloropropyl ester and Phosphoric acid, 2-chloro-1-methylethyl bis(2-chloropropyl) ester (TCPP)		**Full, cease manufacture (adapted to 807-935-0)**

This table also contains 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 may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

Contents

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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[2].

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

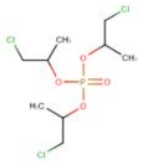
Glossary

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
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

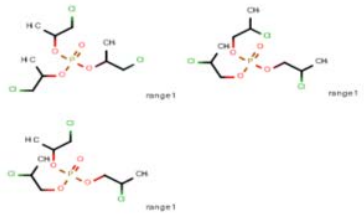
1 Overview of the group

ECHA has grouped together 11 structurally similar chloroalkyl esters of orthophosphoric acid, as shown in the figures below. Four substances have active registrations.

Six of the substances in the group are individual isomers or mixtures of isomers of tris(chloropropyl) phosphates (TCPP) of which only one substance (EC 807-935-0) has an active registration (the understanding is that the two inactive registrations actually concern the same commercial product).

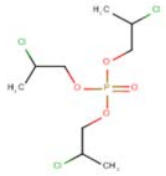


237-158-7, tris(2-chloro-1-methylethyl) phosphate

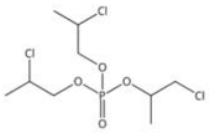


911-815-4, Reaction mass of tris(2-chloropropyl) phosphate and tris(2-chloro-1-methylethyl) phosphate and Phosphoric acid, bis(2-chloro-1-methylethyl) 2-chloropropyl ester and Phosphoric acid, 2-chloro-1-methylethyl bis(2-chloropropyl) ester

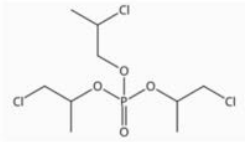
807-935-0, Reaction products of phosphoryl trichloride and 2-methyloxirane (SID adapt from 911-815-4)



228-150-4, tris(2-chloropropyl) phosphate

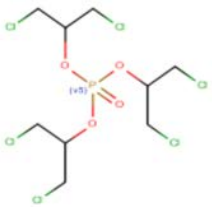


616-366-5, Phosphoric acid, 2-chloro-1-methylethyl bis(2-chloropropyl) ester

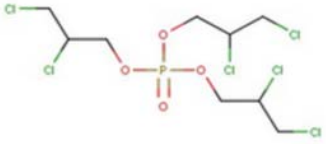


616-283-4, Phosphoric acid, bis(2-chloro-1-methylethyl) 2-chloropropyl ester

Two substances are tris (dichloropropyl) phosphates (TDCP), with only one active registration (EC 237-159-2):

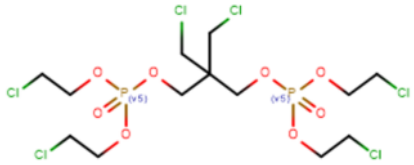


237-159-2, tris[2-chloro-1-(chloromethyl)ethyl] phosphate

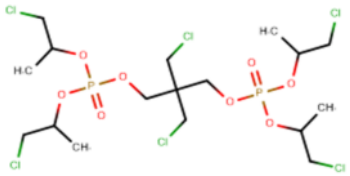


201-117-1, tris(2,3-dichloropropyl) phosphate

Two of the substances are bisphosphates, both registrations are active:

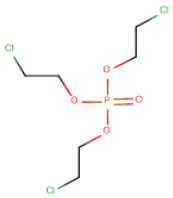


253-760-22, 2-bis(chloromethyl)trimethylene bis(bis(2-chloroethyl)phosphate) (TCDPP, also known as TCDP)



809-920-4, Phosphoric acid, P,P'-[2,2-bis(chloromethyl)-1,3-propanediyl] P,P,P',P'-tetrakis(2-chloro-1-methylethyl) ester

The last substance is tris chloroethyl phosphate (TCEP), which is no longer marketed in the EU:



204-118-5, tris(2-chloroethyl) phosphate

Based on information reported in the REACH registration dossiers, these substances are used as additive flame retardants. External data sources (the PubChem database) confirm that also those substances that have only been notified in the C&L Inventory are flame retardants. The most prominent uses for these flame retardants are in flexible and rigid polyurethane foams, and in different types of flame retardant coatings that have a service life in several article categories (e.g., textiles, metal articles). Therefore, all these substances can be present in a wide range of mixtures and articles used by professionals and consumers, which makes exposure highly relevant. Environmental exposure is not likely to occur before the waste stage of the articles. TCPP has also a reported use as process regulator in (PU foam) sealants used by professionals and consumers, giving rise to potential for exposure.

EC 204-118-5 (TCEP) and EC 237-159-2 (TDCP) have a harmonised classification as Carc. 2 under CLP. TCEP also has a harmonised classification as Repr. 1B (H360F), Acute Tox. 4, and Aquatic Chronic 2. Furthermore, TCEP, TCPP and TDCP have already been identified in ECHA's screening assessment in 2018 as posing a risk from exposure to the substances in flexible polyurethane foams. A restriction proposal was initiated, however, the preparation of the proposal was put on hold, pending the availability of new critical data from the US NTP program. The report of the US NTP studies has not yet been finalised to date.

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 all of the substances in the group for one or more of the following potential properties: **carcinogenicity (all substances, leading effect)**, reproductive toxicity (TCEP, TCPP and TCDPP), neurotoxicity (TDCP and TCEP) or ED for human health (TCPP, TDCP, TCDPP, EC 809-920-4) or the environment.

High exposure potential is expected for consumers and professionals for all four substances with active registrations. Potential for substitution between all substances in the group is expected based on structural similarity and external use information. A group restriction would avoid possible regrettable substitution also for those substances in the group for which information on uses is currently not available or for which the production volume is currently low.

The ECHA Screening report[3] on TCEP, TCPP and TDCP (EC 204-118-5, 237-158-7, 807-935-0, 911-815-4, and 237-159-2) "*identified a risk for children from exposure to TCEP, TCPP and TDCP in flexible polyurethane (PUR) foams in childcare articles and residential upholstered furniture, ECHA recommends an Annex XV restriction dossier is prepared.(…) If a restriction report is prepared, exposure from other uses, article groups and exposure populations will need consideration".*

[3] https://echa.europa.eu/documents/10162/17233/screening_report_tcep_tcpp_td-cp_en.pdf/e0960aa7-f703-499c-24ff-fba627060698?t=1523014289559

Carcinogenicity was considered to be the leading effect in the ECHA Screening report. The Commission requested ECHA to prepare a restriction proposal. The preparation of the proposal[4] was put on hold (19/7/2019), pending the availability of new critical data (US NTP studies on the carcinogenicity of TCPP).

In the ECHA Screening report, risk characterisation was performed for infants exposed to childcare articles and residential upholstered furniture. The report proposes to extend the assessment of exposure from articles also to adults and additional groups of articles, such as automotive applications and furniture, electrical/electronic equipment and additional uses (for example, spraying of insulation foams).

Table 1: Substances covered by the ECHA Screening Report compared to substances assessed under this GMT

EC number	Substance name	Acronym	Substance included in ECHA Screening report?
204-118-5	tris(2-chloroethyl) phosphate	TCEP	YES
237-158-7	tris(2-chloro-1-methylethyl) phosphate	TCPP	YES
(-)	Reaction mass of tris(2- chloropropyl) phosphate and tris(2-chloro-1- methylethyl) phosphate and Phosphoric acid, bis(2-chloro-1- methylethyl) 2- chloropropyl ester and Phosphoric acid, 2-chloro-1-methylethyl bis(2- chloropropyl) ester	TCPP	YES
911-815-4	Reaction mass of tris(2-chloropropyl) phosphate and tris(2-chloro-1-methylethyl) phosphate and Phosphoric acid, bis(2-chloro-1-methylethyl) 2-chloropropyl ester and Phosphoric acid, 2-chloro-1-methylethyl bis(2-chloropropyl) ester	TCPP	YES
807-935-0	Reaction products of phosphoryl trichloride and 2-methyloxirane	TCPP	Indirectly. This EC number is a SID adaptation from EC 911-815-4
228-150-4	Tris(2-chloropropyl) phosphate	TCPP	NO
616-283-4	Phosphoric acid, bis(2-chloro-1-methylethyl) 2-chloropropyl ester	TCPP	NO
616-366-5	Phosphoric acid, 2-chloro-1-methylethyl bis(2-chloropropyl) ester	TCPP	NO
807-935-0	Reaction products of phosphoryl trichloride and 2-methyloxirane (adapt from 911-815-4)	TCPP	YES

[4] The intended scope for the restriction proposal as indicated in the Registry of Intentions: *"Restricting the placing on the market of childcare articles and residential upholstered furniture with PUR foams containing TCEP, TCPP and TDCP. A restriction may cover mattresses for adults and textiles as well"*. https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1829a30b8

EC number	Substance name	Acronym	Substance included in ECHA Screening report?
237-159-2	tris[2-chloro-1-(chloromethyl)ethyl] phosphate	TDCP	YES
201-117-1	Tris(2,3-dichloropropyl) phosphate	TDCP	NO
253-760-2	2,2-bis(chloromethyl)trimethylene bis(bis(2-chloroethyl)phosphate)	TCDPP, also known as TCDP	NO
809-920-4	Phosphoric acid, P,P'-[2,2-bis(chloromethyl)-1,3-propanediyl] P,P,P',P'-tetrakis(2-chloro-1-methylethyl) ester	-	NO

In general, our conclusions are in line with the conclusions and recommendations from the ECHA Screening report. Carcinogenicity appears indeed to be the common potential effect for all the substances in the group and is suggested to be the leading effect in the restriction, as already indicated above. Other effects are relevant as well but appear not to apply to all members of the group, or are difficult to clarify (therefore, no data generation proposed). See section 2.1 on hazard considerations.

In addition, we propose the further inclusion of both bischloroalkylphosphates in a restriction based on their potential carcinogenicity:

- TCDPP (EC 253-760-2), due to its structural similarity to TCEP (EC 204-118-5), predicted formation of several metabolites identical to the metabolites of TCEP (EC 204-118-5, Carc 2), similar uses as flame retardant in PUR foams and coatings.
- EC 809-920-4, based on its structural similarity to TCPP (EC 237-158-7), as well as on the predicted formation of several metabolites identical to the metabolites of TCPP (EC 237-158-7). EC 809-920-4 is also included based on proposed read-across from 253-760-2. Further, the inclusion of EC 809-920-4 will depend on the results from US NTP studies on the carcinogenicity of TCPP.

ECHA, Member States and the Commission are assessing the need for further regulatory management measures on flame retardants in general. The conclusions in the current document may be superseded by the conclusions on flame retardants in general.

To address the potential concern of exposure of workers in the formulation of polyurethane foam products, and workers and consumers using foams and sealants containing these substances, harmonised classification is proposed, if the potential carcinogenicity (or STOT (neurotoxicity) for TCDPP and TCEP) hazards are confirmed. For such uses, even in the absence of a restriction, consistent classification and labelling should limit the exposure and trigger adequate risk management measures. It should be noted that two of the substances already have a harmonised classification: EC 204-118-5 and EC 237-159-2. The harmonised classification as carcinogenic for TCPP could be processed either before or in parallel with the already initiated restriction process. Harmonised classification for other endpoints could take place at any time, once the hazards are confirmed.

Finally, it should be noted that if the ED properties for human health or the environment of any of these substances are confirmed, the identification of those substances as SVHC and extending the scope of the potential restriction based on carcinogenicity to ED properties should be considered.

2.1 Considerations on hazards

TCEP (EC 204-118-5) and TDCP (EC 237-159-2) are suspected of causing cancer and this hazard is reflected in their harmonised classification and labelling as Carc 2. The carcinogenicity of TCPP (EC 237-158-7) is under investigation (ongoing NTP study[5]). It is assumed that the data for EC 237-158-7 is applicable to all the individual isomers or mixtures of isomers that are referred to as "TCPP" (see above) as well as to EC 809-920-4 (see table 1 above). TCDPP (EC 253-760-2) has the structure and the predicted metabolic profile similar to TCEP (EC 204-118-5). However, for TCDPP (EC 253-760-2) and EC 809-920-4 additional evidence, from the ongoing NTP investigation and/or additional search in recent data concerning SAR/mechanism of carcinogenicity, may be needed to clarify their carcinogenic potential.

The mode of action is not known for carcinogenicity but appears not to be mediated by genotoxicity. Therefore, a threshold mode of action was assumed in the ECHA Screening report. According to the ECHA screening report on TCEP, TCPP and TDCP: "*In the event a restriction report will be prepared, any new information regarding the mode of action [*of carcinogenicity] *and the assumption of a threshold will need to be considered.".*

The metabolite of TDCP, 1,3-DCP (1,3-dichloropropan-2-ol, EC no. 202-491-9), has amongst others a harmonised classification as Carcinogenic category 1B under the CLP Regulation.

Reproductive toxicity has been identified for TCEP: the substance has harmonised classification as Repr. 1B (H360). RAC concluded in 2010 that there is insufficient evidence for classification of TDCP (EC 237-159-2) as male reproductive toxicant [6], hence the conclusion that TDCP is unlikely reproductive toxicant. For TCPP (EC 237-158-7), reproductive toxicity is under investigation by US NTP. The Draft EU Risk Assessment report for TCPP (EC 237-158-7) considered the required classification to be a borderline case between classification as Repro Cat 3, R62 for fertility and developmental toxicity and no classification for effects on fertility. There is no harmonised classification for this substance. The ECHA Screening report took for TCPP (EC 237-158-7) into account the effects on uterus weight from a 2-generation study in rats to derive a DNEL for this endpoint. The significance of this finding should be confirmed. In this report, TCPP is considered a potential reproductive toxicant. In summary, even though the effects were not severe enough for some group members to warrant classification as reprotoxic, this concern is taken into account; however, not as a main driver for the restriction.

For neurotoxicity, there was insufficient data in the registration dossiers. Therefore, additional sources were used: the EU RAR for TCEP and the overview by Abou-Donia *et al.*[7]. We concluded that neurotoxicity is a hazard which should be further

[5] https://tools.niehs.nih.gov/cebs3/views/?action=main.dataReview&bin_id=15044

[6] https://echa.europa.eu/documents/10162/26d19254-81a6-f16a-8182-e7824d66bfec

[7] Abou-Donia, M.B., et al. Organophosphorus Flame Retardants (OPFR): Neurotoxicity. (2016) J Environ Health Sci 2(1): 1- 30; https://www.ommegaonline.org/article-details/Organophosphorus-Flame-Retardants-(OPFR)--Neurotoxicity/445

investigated: the conclusion is based on non-standard/non-TG/*in vitro* studies. This is in line with the statement from the ECHA Screening report: "*Neurotoxicity may be a sensitive effect but requires further assessment*." Even if there is no organophosphorus-induced delayed neuropathy (OPIDN, reported for several other organophosphorus flame retardants), indications of other types of neurotoxicity are seen in *in vivo* and *in vitro* studies available from sources outside the registration dossiers. The EU RAR in 2009 identified the brain as one of the main sites of toxicity for TCEP[8]. The neurotoxic effects caused by the group members are hippocampal lesions and impaired learning abilities. These effects could, in theory, be further studied in a 90-day repeated-dose toxicity study. But there are already (sub)chronic studies for the group members, without adverse effects on CNS/behaviour noted. Currently we do not have a strong enough concern, based on available data and SARs, to request additional sub-chronic studies via compliance check or SEv. Therefore, no data generation is proposed. This might change when an additional open-source data is collected for the Restriction Report, as suggested in the ECHA Screening report.

There are indications of ED properties for human health for TCPP (EC 237-158-7 and EC 807-935-0), TCDPP (EC 253-760-2) and EC 809-920-4 (via read-across proposed by the registrants to TCDPP), based on thyroid effects found in repeated dose toxicity studies. There are also indications of endocrine disrupting properties for TDCP (EC 237-159-2), TCDPP (EC 253-760-2) and EC 809-920-4 based on QSARs. We propose the potential ED properties for human health are taken into consideration under the restriction process. We suggest to wait until the DK SEV on TCPP[9] is finalised. One of the initial grounds for concerns listed for this SEV is 'potential endocrine disruptor'. Under this activity data may be generated. Based on those grounds, we do not propose any data generation for ED for other substances in the group. In addition, during the restriction process, analysis of the new open source data on ED will be performed.

No hazard or unlikely hazard for skin sensitisation or genetic toxicity is expected for any the group members.

There is read-across proposed by the registrants from TCDPP (EC 253-760-2) to EC 809-920-4. There are, however, differences in the structures: TCDPP (EC 253-760-2) has structural resemblance to TCEP (EC 204-118-5) and EC 809-920-4 to TCPP (EC 237-158-7). Therefore we advise detailed analysis of this read-across.

The group members are not expected to meet the PBT/vPvB criteria and show no evidence of persistency. Based on the currently available information in the registration dossiers and the EU risk assessment reports, some substances might be mobile in the water phase, while others are unlikely to be highly mobile as the reported adsorption/desorption (log Koc values generally above 3) do not indicate potential for high mobility in soil. The substances in general do not show high aquatic toxicity with the exception of TDCP (EC 237-159-2), which is classified as Aquatic Chronic 1. Based on the potential health hazard ED properties and ED QSAR predictions, the potential environmental ED properties cannot be ruled out. Furthermore, in the justification document for the selection of a CoRAP substance by Germany (2017), TDCP (EC 237-159-2) was concluded to fulfil criteria as a

[8] TCEP EU RAR 2009: https://echa.europa.eu/documents/10162/2663989d-1795-44a1-8f50-153a81133258

[9] https://echa.europa.eu/fi/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ebd7a

potential ED. Germany has confirmed that the substance is in their workplan of 2023[10].

[10] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1812cfe58

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 have also been 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
204-118-5 TCEP **237-158-7** TCPP **807-935-0** TCPP **911-815-4** TCPP **228-150-4** TCPP **616-283-4** TCPP **616-366-5** TCPP **237-159-2** TDCP **201-117-1** TDCP **253-760-2** TCDPP **809-920-4**	Known or potential hazard for reproductive toxicity (TCEP, TCPP, TCDPP) Known or potential hazard for carcinogenicity (TCPP*, TCEP, TDCP, TCDDP, EC 809-920-4*) Known or potential hazard for STOT RE/neurotoxicity (TDCPP (EC 253-760-2) and TCEP (EC 204-118-5)# Known or potential hazard for ED (TCPP, TDCP, TCDDP, EC 809-920-4)$	Known or potential hazard for aquatic toxicity for EC 237-159-2 only Known or potential hazard for ED for the environment for TCPP, TDCP, TCDPP, EC 809-920-4	Flame retardant in polyurethane foams and coatings, with presence in, e.g., plastic and textile articles in vehicles and furniture. High potential for exposure of consumers and professionals. EC 809-920-4 (and 911-815-4) are additionally used in adhesives and sealants. High potential for exposure of consumers and professionals.	Need for EU RRM: Restriction Justification: Restriction is needed to manage risk from exposure to these substances from commonly used articles giving rise to multiple sources of exposure. CLH is proposed for the whole group (note that EC 204-118-5 and 237-159-2 already have CLH as Carc 2) to better manage risk to workers and consumers using mixtures containing these substances.	**First step:** Pending (US NTP studies with TCPP) **Next steps** (if hazard confirmed): Restriction, CLH (with CLH taking place before or parallel to restriction process)

* - Depending on the outcome from the NTP investigation

- Data from outside the registration dossiers, Abou-Donia 2016. This hazard will need further assessment under the restriction process.

$ - Based on thyroid effects from RDT studies and/or QSAR/*in vitro* predictions.

Annex 1: Overview of classifications

C&L inventory checked on 25 of January 2022

Data extracted on 25 November 2021

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
204-118-5	115-96-8	tris(2-chloroethyl) phosphate	Acute Tox. 4 H302, Carc. 2 H351, Repr. 1B H360F, Aquatic Chronic 2 H411	Carc. 2 H351 [Article 10 (inactive)] Repr. 1B H360 [Article 10 (inactive)] Acute Tox. 4 H302 [Article 10 (inactive)] Aquatic Chronic 2 H411 [Article 10 (inactive)]	Muta. 1B H340[1 out of 27] Acute Tox. 3 H301[1 out of 27] Repr. 1B H360, specific effect:May damage fertility[1 out of 27] Repr. 1B H360, specific effect:May damage fertility.[6 out of 27] Repr. 1B H360, specific effect:F[13 out of 27]
228-150-4	6145-73-9	tris(2-chloropropyl) phosphate	-	-	-
237-158-7	13674-84-5	tris(2-chloro-1-methylethyl) phosphate	-	Acute Tox. 4 H302 [Article 10 (inactive)]	Eye Irrit. 2 H319[2 out of 73] Skin Irrit. 2 H315[1 out of 73] Aquatic Chronic 3 H412[3 out of 73]
237-159-2	13674-87-8	tris[2-chloro-1-(chloromethyl)ethyl] phosphate	Carc. 2 H351	Carc. 2 H351 Aquatic Chronic 1 H410, M-factor: 10	Aquatic Chronic 2 H411[10 out of 21] STOT Rep. Exp. 2 H373, affected organs: [3 out of 21] Acute Tox. 4 H332[2 out of 21] Aquatic Chronic 1 H410[1 out of 21] Acute Tox. 3 H331[1 out of 21] Acute Tox. 4 H302[3 out of 21] Skin Irrit. 2 H315[6 out of 21]
253-760-2	38051-10-4	2,2-bis(chloromethyl)trimethylene bis(bis(2-chloroethyl)phosphate)	-	-	-

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
616-366-5	76649-15-5	Phosphoric acid, 2-chloro-1-methylethyl bis(2-chloropropyl) ester	-	-	-
807-935-0	1244733-77-4	Reaction products of phosphoryl trichloride and methyloxirane		Acute Tox. 4 H302	Acute Tox. 4 H302 Aquatic Chronic 3 H412[1 out of 4]
809-920-4	1047637-37-5	2,2-bis(chloromethyl)propane-1,3-diyl tetrakis(1-chloropropan-2-yl) bis(phosphate)	-	-	-

(*) 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 14/01/2022

EC number	204-118-5	237-158-7	237-159-2	253-760-2	807-935-0	809-920-4	201-117-1	228-150-4	911-815-4	616-366-5	616-283-4
PC 15: Non-metal-surface treatment products				P		P					
PC 32: Polymer preparations and compounds		F,I,A	F,I	I,P,A	F,I,P,C,A	I,A	(flame retardant in plastics)		F,I,A		(flame retardant in plastics)
PC 1: Adhesives, sealants					F,I,P,C				(P)		
PC 9a: Coatings and paints, thinners, paint removes	I,P,A		F	F,I,P,A	F,I,P,C						
PC 26: Paper and board treatment products				I,P,A*							
PC 34: Textile dyes, and impregnating products			F	F,I,A	F*,I	I,A					
PC 14: Metal surface treatment products				I,P,A		I					
PC 33: Semiconductors			F								
PC 21: Laboratory chemicals					F,I,P						
Article service life					AC 1,2,4,5,7,11, 13	AC 0, 1 (5)			AC 0, 5		(AC 0)

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

Article categories reported for the substances in the group (as indicated in the table above):
AC 0: Furniture; construction articles and building materials
AC 1: Vehicles
AC 2: Machinery, mechanical appliances, electrical/electronic articles
AC 4: Stone, plaster, cement, glass and ceramic articles
AC 5: Fabrics, textiles and apparel
AC 7: Metal articles
AC 11: Wood articles
AC 13: Plastic articles

*Use indicated as being in the context of AC 1.

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

Data extracted on 02/12/2021.

EC / List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
204-118-5	YES	YES	YES	#	YES	EU RAR[11]
237-158-7	YES			#	(YES)*	EU RAR[12]
237-159-2	YES			#	YES	EU RAR[13]
253-760-2					(YES)*	
807-935-0				#		
911-815-4	YES			#		

*CLH intention, withdrawn (both marked substances)

Restriction proposal under development, on hold

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

[11] EU RAR (2009). European Union Risk Assessment Report Tris(2-chloroethyl) phosphate (TCEP). Final approved version. European Communities, July 2009.

[12] Draft European Union Risk Assessment Report Tris(2-chloro-1-methylethyl) phosphate (TCPP). European Communities, May 2008. Available at https://echa.europa.eu/information-on-chemicals/transitional-measures/annex-xv- transitional-reports?diss=true&search_criteria_ecnumber=237-158- 7&search_criteria_casnumber=13674-84-5&search_criteria_name=Tris%282-chloro-1- methylethyl%29+phosphate

[13] Draft European Union Risk Assessment Report Tris[2-chloro-1- (chloromethyl)ethyl] phosphate (TDCP). European Communities, May 2008. Available at https://echa.europa.eu/information-on-chemicals/transitional-measures/annex-xv-transitional-reports?diss=true&search_criteria_ecnumber=237-158-7&search_criteria_casnumber=13674-84-5&search_criteria_name=Tris%282-chloro-1-methylethyl%29+phosphate