



Danish Ministry of the Environment
Environmental Protection Agency

Justification Document for the Selection of a CoRAP Substance

– UPDATE –

Substance Name (public name): Reaction products of phosphoryl trichloride and 2-methyloxirane

EC Number: 807-935-0 (previously 911-815-4)

CAS Number: 1244733-77-4 (previously 1244733-77-4)

Authority: Danish Environmental Protection Agency

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20/03/2018 (1. update)

18/03/2020 (2. update)

Cover Note

This document has been prepared by the evaluating Member State given in the CoRAP update

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1 IDENTITY OF THE SUBSTANCE

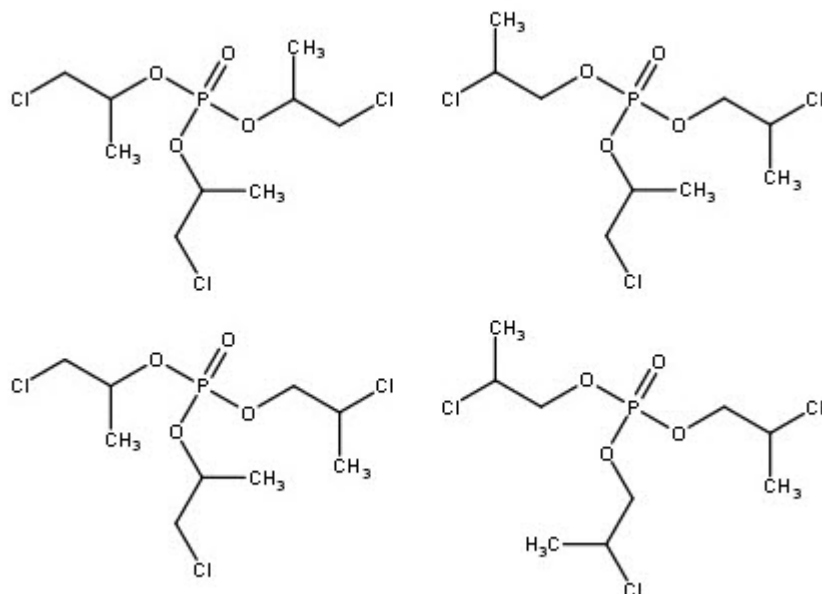
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name (public):	Reaction products of phosphoryl trichloride and 2-methyloxirane
IUPAC name (public):	Phosphorous oxychloride, reaction products with propylene oxide
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	C ₉ H ₁₈ Cl ₃ O ₄ P
Molecular weight or molecular weight range:	327.57
Synonyms:	<ul style="list-style-type: none"> - tris(2-chloroethyl) phosphate (TCEP); tris(2-chloro-1-methylethyl) phosphate (TCPP); 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); Reaction products of phosphoryl trichloride and methyloxirane (TCPP); tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP) - TCPP - <i>Daming Technology</i> - <i>Taizhou Xin`an</i> - <i>WSFR-TCPP</i>

Type of substance Mono-constituent Multi-constituent UVCB

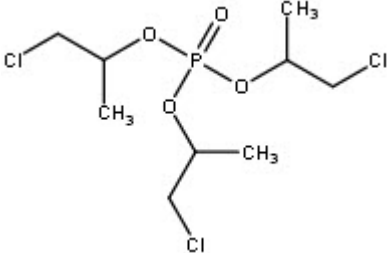
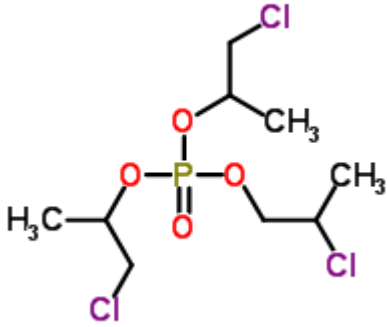
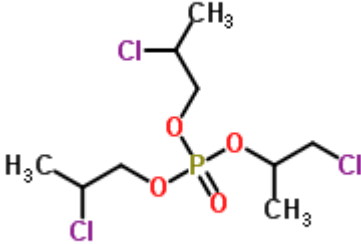
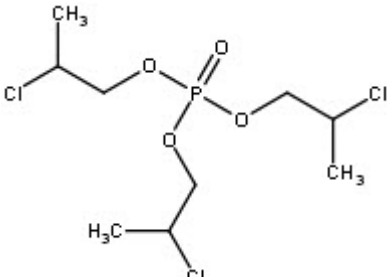
Structural formula:



Above are the structural formulas of the main components of the registered substance. The substance can be regarded as a multi-constituent substance consisting of tris(2-chloro-1-methylethyl) phosphate (main component), bis(2-chloropropyl)-1-chloro-2-propyl phosphate, bis(1-chloro-2-propyl)-2-chloropropyl phosphate and tris(2-chloropropyl) phosphate.

It can be seen from the structural formulas of the constituents that tris(2-chloro-1-methylethyl) phosphate has chiral centres. Therefore the substance is regarded as a mixture of stereoisomers.

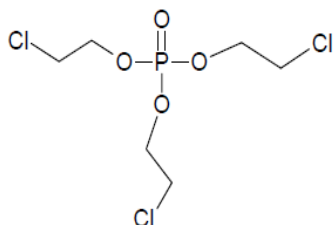
Table: Constituents

Name, CAS number, SMILES	Structural formula
Tris(2-chloro-1-methylethyl) phosphate CAS 13674-84-5 EC 237-158-7	
Bis(1-chloro-2-propyl)-2-chloropropyl phosphate CAS 76025-08-6	
1-chloropropan-2-yl bis(2-chloropropyl) phosphate CAS 76649-15-5	
tris(2-chloropropyl) phosphate CAS 6145-73-9 EC 228-150-4	

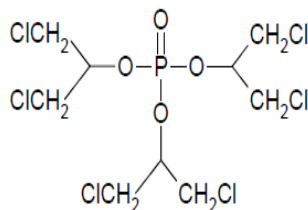
1.2 Similar substances/grouping possibilities

Structural formula:

Tris(2-chloroethyl) phosphate (TCEP)



Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)



2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input checked="" type="checkbox"/> Compliance check, Final decision A compliance check decision on the substance EC 911-815-4 was issued in September 2016 which included a request for identification of constituents. Following this decision, the EC number was updated to the current EC 807-935-0.
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
Restriction	<input checked="" type="checkbox"/> Annex XVII*	
Harmonised C&L	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input checked="" type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)**	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	

Other processes/ EU legislation	<input checked="" type="checkbox"/> Other (provide further details below)***
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*A restriction proposal on “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” was intended on 06/06/2018, but was withdrawn 19/07/2019 while awaiting hazard data from NTP.

**A European Risk Assessment report (under ESR) was published in 2008.

*** The EU Toys Directive 2009/48/EC was amended by 2014/79/EU introducing a specific content limit value of 5 mg/kg (ppm) for each of tris(2-chloro-1-methylethyl) phosphate (TCPP), tris(2-chloroethyl)phosphate (TCEP), and tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP) in toys. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0079&from=EN>

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

There is no harmonised classification available for TCPP.

3.1.2 Self classification

- In the registration for the substance (EC 807-935-0) covering 45 notifiers, the selfclassification in the C&L Inventory was:
Acute Tox. 4 H302: Harmful if swallowed
- Self-classification of the component substance (EC no. 237-158-7)(ECHA C&L inventory database September 2019) according to the CLP regulation (EC) No 1272/2008 (CLP regulation) from 552 notifiers.

International chemical identification	CAS No	Classification		
		Hazard Class and Category Code(s)	Hazard statement Code(s)	Number of notifiers
Tris(2-chloro-1-methylethyl)-phosphate	13674-84-5	Acute Tox. 4	H302	546
		Eye Irrit. 2	H319	4
		Skin Irrit. 2	H315	1
		Aquatic Chronic 3	H412	12
			H413	1
		No classification		1

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

None

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES¹

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site *		
<input type="checkbox"/> 1 - 10 tpa	<input type="checkbox"/> 10 - 100 tpa	<input type="checkbox"/> 100 - 1000 tpa
<input type="checkbox"/> 1000 - 10,000 tpa	<input checked="" type="checkbox"/> 10,000 - 100,000 tpa	<input type="checkbox"/> 100,000 - 1,000,000 tpa
<input type="checkbox"/> 1,000,000 - 10,000,000 tpa	<input type="checkbox"/> 10,000,000 - 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential
*the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11): https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0		

<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<p>The constituent TCPP is an additive flame retardant, i.e. it is physically mixed with the material being treated rather than chemically bound (ECHA, 2008). Over 40,000 tonnes of TCPP were used in the EU in the year 2000, and most of this (> 98%) was used as flame retardant in the production of polyurethane (PUR) for the use in construction (e.g. insulation/ fillers) and furniture (ECHA, 2008).</p> <p>Most TCPP is used in rigid PUR foam (over 80%) mainly for construction applications. The remaining PUR applications are accounted for by flexible foam for automotive applications. However, TCPP has been found in indoor air in cars.</p> <p>Three consumer exposure scenarios from which exposure to TCPP could occur include TCPP-containing flexible PUR foam in furniture; the use of one-component foams; and use of rigid insulation foams and levels in indoor air.</p>			

¹ The dissemination site was accessed in September 2019.

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
 Article 45(5) (Member State priority)

5.2. Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR
 Fulfils criteria as Sensitiser/ Suspected sensitiser
 Fulfils criteria as potential endocrine disruptor
 Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
 Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)
 Fulfils exposure criteria
 Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input checked="" type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ²	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input checked="" type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

² CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

Human hazard

No carcinogenicity studies are available for the substance of concern. However, the EU-RAR considered that there was sufficient information from the structures, physical chemical properties, toxicokinetics and mutagenic profiles of TCEP, TDCP (TCEP and TDCP are both classified as Carc 2 H351) and TCPP to support a qualitative read-across to address the hazard and risk assessment for the carcinogenicity endpoint for TCPP. It was accepted that there were some differences in the metabolism, the target organs and the severity of the effects observed with the three substances. Also, there was no insight into an underlying mode of action for TCEP and TDCP which would make a prediction on relative potency of TCPP possible. Therefore, the EU-RAR concluded that a quantitative read-across approach was not considered sufficiently robust for the purpose of classification and labelling.

The above approach can be considered to be precautionary, in order to complete a risk characterization for this endpoint and was preferred to a situation in which a data gap would trigger the need for a cancer bioassay. However, as the mechanism of tumor formation in either TDCP or TCEP is not understood, and given that the effects seen in the repeated dose toxicity study with TCPP were slight, it was considered that there is not sufficient evidence to classify TCPP for carcinogenicity and therefore no classification for this endpoint was proposed (EU Risk Assessment Committee). Also, it should be noted that since a quantitative read-across was not supported, the starting point for the risk characterisation for carcinogenicity presented in the EU-RAR was the LOAEL derived from the 90-day dietary study for TCPP (LOAEL of 52 mg/kg based on increased liver weights) and not a dose descriptor from either TDCP or TCEP studies.

As the EU-RAR concluded that a quantitative read-across approach was not considered sufficiently robust for the purpose of classification and labelling, further action needs to be considered.

From a 2-generation reproductive toxicity study in rats a LOAEL of 99 mg/kg bw is derived for effects on fertility, based on effects on the uterus weight seen in all dosed females in the F0 generation. A LOAEL of 99 mg/kg bw is derived for developmental toxicity based on the increased number of runts observed in all dose groups of F0 generation, and a decrease in the mean number of pups delivered was observed in the mid dose group of F1 and the high dose groups of both generations. Based on the above, it is possible that TCPP has an effect on developing pups. A possible classification of TCPP would be a classification as toxic to reproduction.

The endocrine disruption potential of TCPP was investigated in an in vitro study with the H295R cell line where testosterone concentration was increased at 1, 10 and 100 mg/L. Furthermore, data from the 2-generation reproductive toxicity study (described above) indicate hormonal disturbance by TCPP due to the findings concerning decreased uterus weight and also prolongation of the oestrus cycle. The results indicate that TCPP could alter the sex hormone balance. This could support a classification as indicated above. However, it remains to be determined whether increased testosterone level also occurs in vivo and whether this could be associated to the decrease in uterus weight. Thus, further verification/studies would be needed to clarify the potential for endocrine disruption of the substance.

Environmental hazard

TCPP is not readily biodegradable according to OECD Guideline no 301. TCPP is expected to have a half-life of at least one year under environmental conditions, based on a standard preliminary hydrolysis test.

While standardized lab-tests indicate a low potential for bioaccumulation, monitoring data shows that the substance can be found in animals far from emission sources, including in white-tailed eagles, common eiders, great-black backed gulls, harbor seals and polar bears. The discrepancy between standardized tests for bioaccumulation and field observations leaves room for doubt about the validity of the measured BCFs. The field measurements indicate a need for reevaluation of the bioaccumulation potential for TCPP, and also the

environmental risk assessment. The measurements also highlight the possibility that there may be some other mechanism involved in bioaccumulation, other than lipophilicity.

TCPP has also been detected in WWTP sludge and effluents in Norway, and a recent study of EU WWTP-effluents demonstrated that TCPP is commonly found in wastewater effluents. These results indicate that TCPP may partition into several environmental compartments and potentially contaminate both sewage sludge and recipient waters. Eggen et al. have recently demonstrated that TCPP, along with TCEP, can accumulate in tissues of important food crops, such as wheat, barley, and carrot. Current practices for land-application of sewage sludge may therefore potentially lead to accumulation of TCPP in plants and subsequent transfer to animals and humans through food.

In the notified classifications to ECHA, 32 out of 596 notifiers have classified the substance as Aquatic Chronic 3; H412. This seems to be a proper classification of the substance since the lowest L(E)C50 values reported for fish and algae are 51 mg/L and 82 mg/L, respectively (i.e. > 10 to ≤100 mg/L) and TCPP is not readily biodegradable and can therefore be classified as Aquatic Chronic 3 classification (Regulation (EC) No 1272/2008 of the Council of 16 December 2008).

With respect to PBT evaluation, TCPP can be considered to meet the screening criterion as persistent (P) or potentially very persistent (vP) based on its ultimate mineralization. The available information on bioaccumulation (measured BCF (fish) of 0.8-4.6) may indicate that TCPP does not meet the bioaccumulation (B) criteria. In case the substance based on new information can be concluded to fulfil the B criterion further studies may be needed in order to conclude whether TCPP fulfils the criteria for toxicity (Teco or Tmammals).

5.4 Preliminary indication of information that may need to be requested to clarify the concern

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

It is stated in the EU RAR: Three consumer exposure scenarios from which exposure to TCPP could occur include TCPP-containing flexible PUR foam in furniture; use of one-component foams; and use of rigid insulation foams and levels in indoor air. Furthermore, TCPP has been found in indoor air in cars.
It seems likely that the use of TCPP may be characterised as "widespread" to "wide dispersive".

5.5 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
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Depending on the outcome of the substance evaluation and a subsequent RMO analysis, it might be relevant to put forward a proposal for harmonized classification, restriction or inclusion in the candidate list.