baua:
Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
Federal Institute for Occupational Safety and Health

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	Tris[2-chloro-1-(chloromethyl)ethyl] phosphate
EC Number:	237-159-2
CAS Number:	13674-87-8
Authority:	Germany
Date:	21/03/2017

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

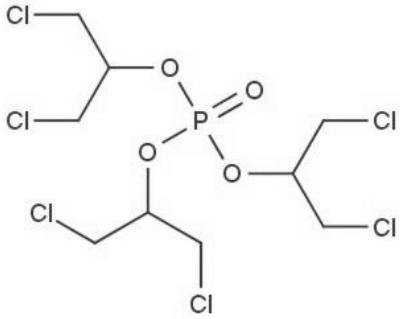
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Tris[2-chloro-1-(chloromethyl)ethyl] phosphate
IUPAC name (public):	tris[2-chloro-1-(chloromethyl)ethyl] phosphate
Index number in Annex VI of the CLP Regulation:	015-199-00-X
Molecular formula:	$C_9H_{15}Cl_6O_4P$
Molecular weight or molecular weight range:	430.90 g/mol
Synonyms:	*TDCP* *Tris(1,3-dichloro-2-propyl) Phosphate* *1,3-dichloro-2-propanol phosphate (3:1)* *2-propanol, 1,3-dichloro-, phosphate (3:1)* *Amgard TDCP* *Antiblaze 195* *Antiblaze TDCP* *FR2* *Fyrol FR-2* *PhireGuard EL-22* *Phosphoric acid, tris(1,3-dichloro-2-propyl)ester* *Tolgard TDCP* *Tolgard TDCP MK1* *tris (1,3-dichloroisopropyl) phosphate* *Tris(1-chloromethyl-2-chloroethyl) phosphate*

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

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2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☒ Compliance check, Final decision
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restric-tion	☐ Annex XVII
Harmonised C&L	☒ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☒ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes / EU legislation	☐ Other	

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
015-199-00-X	tris[2-chloro-1-chloromethyl)ethyl] phosphate	237-159-2	13674-87-8	Carc. 2	H351		

3.1.2 Self classification

- In the registration:
  - Aquatic Chronic 2 H411
  - Carc. 2 H351
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
  - Skin Irrit. 2 H315
  - STOT RE 2 H373
  - Acute Tox. 4 H302
  - Acute Tox. 3 H331

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

No Proposal for Harmonised Classification and Labeling beyond the adopted Harmonised Classification given in section 3.1.1 has been submitted to the Registry of Intentions.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[1]

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☒ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential

4.2 Overview of uses

The substance is used for polymers, manufacture of machinery and vehicles as well as furniture. The substance can be found in complex articles with no intended release such as vehicles. This substance can be found in products with material based on fabrics, textiles, and apparel (e.g. clothing, mattress, curtains or carpets, textile toys), and plastic (e.g. food packaging and storage, toys, mobile phones).
It is used in industrial processing from articles with abrasive technics and long-life articles and materials with low release are wide dispersivly used by consumers in outdoor uses.

Release to the environment of this substance is likely to occur from industrial use: formulation in materials, industrial abrasion processing with low release rate (e.g. cutting of textile, cutting, machining or grinding of metal) and manufacturing of the substance.
In addition, release from service life of the treated articles seems possible.
According to the Risk assessment report performed by Ireland/UK in 2008, calculated PEC values are between 0.02 and 0.3 µg/L. Measured data are in the same range indicating relevant exposure of the environment.

[1] *ECHA disseminiation site accessed in May 2016.*

Table: Uses

Part 1:

☒ Manufacture	☒ Formulation	☒ Industrial use	☐ Professional use	☒ Consumer use	☒ Article service life	☒ Closed system

According to the risk assessment report performed by Ireland/UK in 2008, calculated PEC values are between 0.02 and 0.3 µg/L. Measured data are in the same range indicating relevant exposure of the environment.

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 disrupter

☐ 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 ☐ C ☐ M ☐ R	Suspected CMR[1] ☐ C ☐ M ☐ R	☒ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[2]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure/risk based concerns		
☐ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☐ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ 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

In vitro data from the ToxCast screening program indicate that the substance might have an estrogenic, androgenic, and thyroidal mode of action. *In vivo* data with fish embryos (Wang et al. 2013) and chicken embryos (Amani et al. 2013) shows that the substance interacts with the thyroid pathway and adverse effect observed fit to such an interaction.
As available data on registered uses and measured concentrations in the environment suggest that there is relevant exposure of the environment to the substance, further tests may be required to clarify the concern of endocrine disruption to the environment.

If the concern is verified during substance evaluation, the substance might be conconsidered as SVHC due to its endocrine disrupting properties and further risk mamagement measures (e.g. candidate listing as a further step) would have to be ccoconsidered.

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

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☐ Information on exposure
☒ Information on ecotoxicological properties	☐ Information on uses
☒ Information ED potential	☐ Other (provide further details below)
Information on fish toxicity (e.g. fish sexual development test) or information clarifying a potential thyroid mode of action and potential adverse effects (e.g. a LAGDA (OECD 241) test) might be requested to conclude on the ED properties of the substance.	

5.5. Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☒ Other (provide further details)
If the substance has to be considered an Endocrine Disruptor according to WHO/IPCS definition, SVHC identification and candidate listing might be the first steps that will be further analysed in a risk management option analysis.			

References:

ToxCast screening program: https://www.epa.gov/chemical-research/toxicity-forecaster-toxcasttm-data

Wang Q., Liang K., Liu J., Yang L., Guo Y., Liu C., Zhou B. 2013: Exposure of zebrafish embryos/larvae to TDCPP alters concentrations of thyroid hormones and transcriptions of genes involved in the hypothalamic-pituitary-thyroid axis. Aquat. Toxicol. 15 (126), 207-213.

Amani F., Crump D., Chiu S., Williams K.L., Letcher R.J., Gauthier L.T., Kennedy S.W. 2013: In Ovo effects of two organophosphate flame retardants–TCPP and TDCPP–on pipping success, development, mRNA expression, and thyroid hormone levels in chicken embryos. Toxicol. Sci. 134 (1): 92–102.