Justification Document for the Selection of a CoRAP Substance

Substance Name:	Tetraphenyl m-phenylene bis (phosphate)
EC Number:	260-830-6
CAS Number:	57583-54-7
Authority:	French CA
Date:	20/03/2018

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

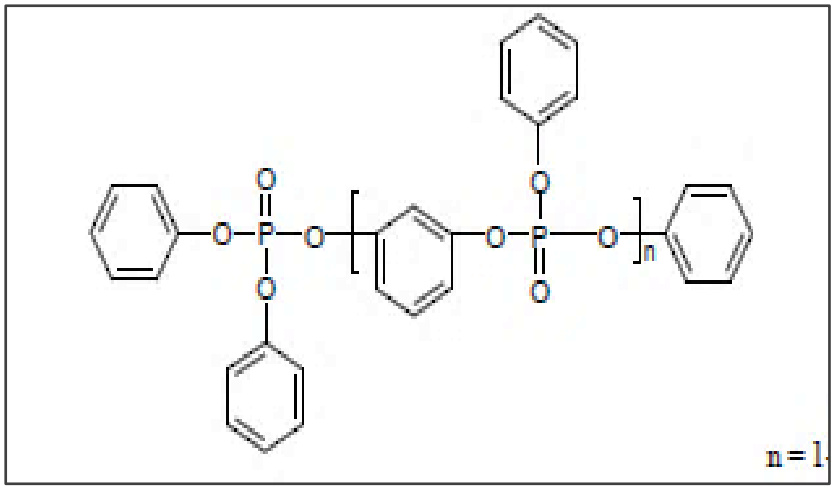
1.1 Other identifiers of the substance

Table 1: Other Substance identifiers

EC name (public):	Tetraphenyl m-phenylene bis (phosphate)
Physical strate	Liquid
IUPAC name (public):	Tetraphenyl 1,3-phenylene bis (phosphate) where n=1
CAS number:	57583-54-7
Index number in Annex VI of the CLP Regulation:	None
Molecular formula:	$C_{30}H_{24}O_8P_2$
Molecular weight or molecular weight range:	574.4543, where n=1
Synonyms:	Resorcinol bis-diphenylphosphate (RDP); Resorcinol bis (biphenylphosphate); Tetraphenyl resorcinol diphosphate;

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

Structural formula where n=1:



1.2 Other relevant information about substance composition

Table 2: Main constituents

Constituent	Typical concentration (w/w)	Concentration range (w/w)	Remarks
Tetraphenyl resorcinol diphosphate n= 1	confidential	confidential	n = 1 p = 2
Tetraphenyl resorcinol diphosphate n= 2	confidential	confidential	n = 2 p = 3
Tetraphenyl resorcinol diphosphate n= 3	confidential	confidential	n = 3 p = 4
Tetraphenyl resorcinol diphosphate n= 4	confidential	confidential	n = 4 p = 5
Tetraphenyl phosphate (TPP) **EC no: 204-112-2**	confidential	confidential	Another flame retardant

n = number of oligomers; p = number of phosphorus atoms

Table 3: Constituent: TPP

EC number:	204-112-2
EC name (public):	Triphenyl phosphate (TPP)
CAS number:	115-86-6
IUPAC name (public):	Triphenyl phosphate
Index number in Annex VI of the CLP Regulation:	None
Molecular formula:	C18H15O4P
Molecular weight or molecular weight range:	326,28

Structural formula

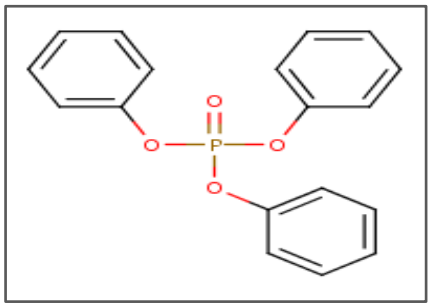
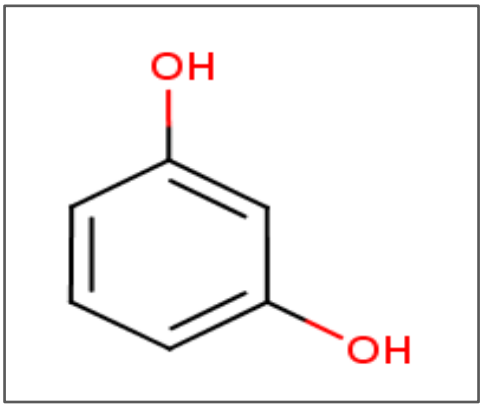


Table 4: Degradation (transformation) product or metabolite

EC number:	203-585-2
EC name (public):	Resorcinol
CAS number:	108-46-3
IUPAC name (public):	Resorcinol, Benzene-1,3-diol
Index number in Annex VI of the CLP Regulation:	604-010-00-1
Molecular formula:	C6H6O2
Molecular weight or molecular weight range:	110.11
Synonyms:	– 1,3-Benzenediol, *m*-Dihydroxybenzene – Resorcine

Structural formula:



2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table 5: Completed or ongoing processes

RMOA	☒ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☐ Testing proposal
		☒ CoRAP and Substance Evaluation The RDP is not on CoRAP but it should be noted that one of its constituent and one of its potential metabolite are on the CoRAP list: - Triphenyl phosphate (constituent) is on the CoRAP 2017 list by UK in particular for potential endocrine disrupting properties concern. - Resorcinol (potential metabolite of the parent compound) was on the CoRAP list 2016 by FI in particular for potential endocrine disrupting properties concern.
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restric -tion	☐ Annex XVII[1]
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)	

[1] Please specify the relevant entry.

(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment
	☐ In relevant Annex
Other processes / EU legislation	☐ Other (provide further details below)

No ongoing activity other than the RMOA conducted by France in the frame of the Franche National Strategy for Endocrine Disruptors (SNPE 2016).

It should be noted that one of its constituent and one of its potential metabolite are on the CoRAP list:

- Triphenyl phosphate (constituent) is listed on CoRAP 2017 by UK in particular for potential endocrine disrupting properties concern.

- Resorcinol (potential metabolite of the parent compound) is listed on CoRAP 2016 by FI in particular for potential endocrine disrupting properties concern.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table 6: 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)		
No current entry							

Self classification

The following hazard classes are notified among the aggregated self classifications in the C&L Inventory:

Table 7: Self classification

Hazard class and category code(s)	Hazard statement code(s)	Number of notifiers
Not classified	/	60
Aquatic chronic 3	H412	61
Aquatic chronic 2	H411	17

17 notifiers indicated that an impurity or an additive present in the substance impacts the notified classification

3.1.2 Proposal for Harmonised Classification in Annex VI of the CLP

There is no current proposal for harmonised classification in Annex VI of the CLP.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

4.1 Tonnage and registration status

Table 8: 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

Table: Uses

Part 1:

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

Part 2:

[2] *The dissemination site was accessed in November 2017*

	Use(s)
Uses as intermediate	
Formulation	PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, palletisation PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles PC 32: Polymer preparations and compounds
Uses at industrial sites	PROC 1: Use in closed process, no likelihood of exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 6: Calendering operations PROC 7: Industrial spraying PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by tabletting, compression, extrusion, palletisation PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles
Uses by professional workers	PROC 21: Low energy manipulation of substances bound in materials and/or articles
Consumer Uses	PC 32: Polymer preparations and compounds
Article service life	AC 1: Vehicles AC 2: Machinery, mechanical appliances, electrical/electronic articles AC 5: Fabrics, textiles and apparel AC 13: Plastic articles

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 (SNPE[3] 2016)

5.3. Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐ C ☐ M ☐ R	Suspected CMR[4] ☐ C ☐ M ☒ R	☒ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[4]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[4]	☐ 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)

[3] French Annual National Strategy for Endocrine Disruptors

[4] 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

The RDP is suspected to be an endocrine disruptor (ED) because of an alert in a 2-generation study, in which a delay in preputial separation and vaginal opening was observed at the two highest tested dose levels. Available data showed a possible neurotoxic effect in different species (3 studies in rat and hen), an increase in weight of the adrenal glands and a possible developmental effect in the rat.

Moreover, one of its metabolites, resorcinol, is toxic for aquatic compartment with a classification as Acute Aquatic tox Cat. 1. and Aquatic Chronic tox cat.2 for the environment. There is also evidence of potential ED effects of resorcinol in the environment as a TPO inhibitor, decreasing ITC4 concentration and having an impact on TGFD (thyroid gland function disruptor).

On the basis of alerts seen in the toxicological and ecotoxicological data provided in the registration dossier, but a lack of sufficient information it was not possible to conclude on the ED properties of this substance.

There is a need to await the final evaluation of resorcinol by the TUKES for environmental data and potential disrupting effects to draw future recommendations.

Additionally, one of the impurities of the RDP, TPP, is also suspected of being an ED for environment based on a fish reproduction study highlighting a significant decrease in fecundity, significant increases of plasma 17β-estradiol (E2) concentrations, vitellogenin (VTG) levels, and E2/testosterone (T) and E2/11-ketotestosterone (11-KT) ratios. Sex-dependent changes in transcriptional profiles of several genes of the hypothalamus-pituitary-gonad (HPG) axis where also observable (US EPA). In another study, TPP significantly increased plasma E2 in fish and T and 11-KT were decreased (1 mg/L). Changes in transcription of steroidogenic genes and vitellogenin gene were also observed (US EPA).

Regarding the RDP, no direct data are available on its ED potential for environment. Based on the presence of TPP as an impurity and the metabolisation of RDP in resorcinol more data are necessary to conclude on the ED concern for both human health and for environment.

Based on ecotoxicological information already available, it is possible to classify the RDP as Aquatic acute tox cat 1 and Aquatic chronic tox 2, which is different from what was proposed in the CSR. Due to uncertainties about water solubility and log Kow parameters reported, there is some concern about the RDP as meeting the PBT criteria. In US EPA EPI suite software, RDP is considered as not readily biodegradable. Moreover, one of the possible hydrolysis degradation product of RDP is diphenyl phosphate, which is predicted as non readily biodegradable by the Danish QSAR database. More data are necessary on the hydrolysis degradation product to ensure that RDP is not meeting the PBT criteria.

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)
Evaluation of hydrolysis degradation products (diphenyl phosphate formation possible, wich is predicted as non readily biodegradable by the Danish QSAR database) Evaluation of fish chronic toxicity Evaluation of n=1 oligomer solubility and log Kow Evaluation of the potential neurotoxicity, reprotoxicity and developmental effects of RDP Evaluation of the ED potential with fish sexual development OECD 234	

5.5. Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
A C&L proposal at least for environment is already foreseen based on the current information available but other proposals may be proposed based on new information requested.			