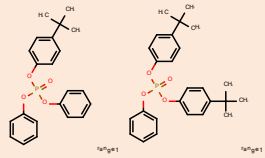
Justification Document for the Selection of a CoRAP Substance

EC/List number	CAS RN	Public Substance name	Chemical structure	Registration type (t/y) [1]
939-505-4	-	tert-butylphenyldiphenyl phosphate (tBuTPP)		Full 100-1000

Authority: France

Date: 21 March 2023

Revision history

Version	*Date*

Cover Note

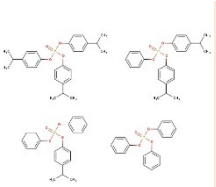
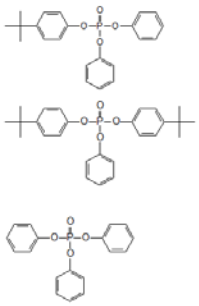
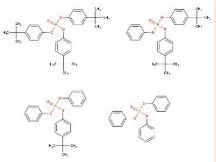
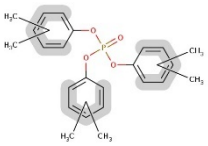
This document has been prepared by the evaluating Member State given in the CoRAP update.

[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

1. Background

1.1 Analogue substances: triphenylphosphate derivatives with one phosphate group with poly-alkylated or branched-alkylated phenols

The most relevant triphenylphosphate derivatives with one phosphate group include but may not be restricted to the following substances (with poly-alkylated or branched-alkylated phenols):

EC/List number	CAS RN	Public Substance name	Chemical structure	Registration type (t/y)
273-066-3	68937-41-7	Phenol, isopropylated, phosphate (3:1)		Full, 1 000 - 10 000
700-990-0	-	Reaction mass of 4-tert-butylphenyl diphenyl phosphate and bis(4-tert-butylphenyl) phenyl phosphate and triphenyl phosphate		Full, 1 000 - 10 000
273-065-8	68937-40-6	Phenol, isobutylenated, phosphate (3:1)		-
246-677-8	25155-23-1	trixylyl phosphate		Full, 100-1000
946-992-7	-	Reaction product of 2,4-bis(2-methylbutan-2-yl)phenol and phosphorous pentoxide	Not available	1-10

1.2 Overview of ongoing / completed / other processes & other EU legislation

EC / List number	Evaluation			CLH	Restriction	Authorisation
	CCH	TPE	Previously on CoRAP	Annex VI (CLP)	Annex XVII*	Candidate List/ Annex XIV
939-505-4	X					

**Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40)*

2. Classification

You can find information on classification in the ECHA C&L Inventory database, which includes both harmonised classification (when available) and the notified self-classifications. (http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database].
The CLP Regulation and all published ATPs are available on ECHA website: http://echa.europa.eu/web/guest/regulations/clp/legislation .

EC/ List No	CAS RN	Public Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
939-505-4	-	tert-butylphenyldiphenyl phosphate	No Harmonised classification	None	None

(*) 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.

3. Tonnage and uses

3.1 Aggregated Tonnage

EC/ List No	Aggregated tonnage (as per ECHA dissemination website)*
939-505-4	100-1000

** The total tonnage band has been calculated by excluding the intermediate uses,- See also the Manual for Dissemination and Confidentiality under REACH (section 2.6.11): https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0*

3.2 Overview of the Uses

Main types of applications	EC 939-505-4 Key information
Manufacture	
Industrial use	Coatings and paints, thinners, paint removes, Polymer preparations and compounds Lubricants, greases, release products Metal working fluids
Professional use	Coatings and paints, thinners, paint removes, Polymer preparations and compounds Hydraulic fluids Lubricants, greases, release products Metal working fluids
Consumer Use	None
Article service life	Textile dyes, and impregnating products Coatings and paints, thinners, paint removes Polymer preparations and compounds Hydraulic fluids
Intermediate use (if TII)	
Formulation	Coatings and paints, thinners, paint removes, Polymer preparations and compounds Hydraulic fluids Lubricants, greases, release products Metal working fluids

4. Justification for inclusion on the CoRAP

4.1 Legal basis

☒ Article 44(2)[2]

☐ Article 45(5)[3]

4.2 Identification of initial grounds of concern

Hazard-based concerns	
Suspected CMR	☐ Carcinogenic ☐ Mutagenic ☐ Reproductive toxicant
Potential ED	☒ Human Health ☒ Environment
Suspected Sensitiser	☐ Respiratory ☐ Skin
Specific target organ toxicity – repeated (STOT RE)	☐ (as defined in section 4.3 below)
Suspected PBT/ vPvB Suspected PMT/ vPvM	☐ Persistent ☐ Bioaccumulative ☐ Mobile ☐ Toxic (as defined in section 4.3 below) ☐ very Persistent ☐ very Bioaccumulative ☐ very Mobile
Other human health hazard(s)	☐ (as defined in section 4.3 below)
Other environmental hazard(s)	☐ (as defined in section 4.3 below)
Exposure / risk-based concerns	
Wide dispersive use	☐
Consumer use	☐
Exposure of workers	☐
Exposure of sensitive populations	☐
Exposure of environment	☒
Cumulative exposure	☐
High RCR	☐
High (aggregated) tonnages	☐
Others (to be specified)	☐

[2] "The Agency shall use the criteria in paragraph 1 […]. Substances shall be included if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment."

[3] "A Member State may notify the Agency at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is a priority for evaluation. […]".

4.3 Justification of the concern(s) – to be clarified under Substance evaluation

Existing data supporting the hazard-based concern

Several alerts exist leading to a concern for possible ED properties for tBuTPP:

- triphenyl phosphate (TPP , EC 204-112-2) is an impurity of the substance present at relevant concentrations. TPP is currently under Substance Evaluation by France in relation to a concern for ED properties based on evidence from *in silico, in vitro,* and *in vivo* studies.
- Based on *in silico* modelling (DEREK) and a publication (Heitkamp *et al.*, 1986)[4] p-tert-butylphenol (PTBP, EC 202-679-0) seems to be a degradation product/metabolite of (tBuTPP). PTBP has been identified as an SVHC according to article 57(f) of REACH for its ED properties for the environment.
- Additionally, *in vitro* studies indicate that tBuTPP can impact steroidogenesis (Schang *et al*; 2016)[5]

Therefore, the potential ED properties of the substance needs to be clarified in order to adequately manage the hazards and risks of the substance.
The assessment will mainly focus on ED properties for the environment but ED properties for human health may be considered in a comprehensive approach.

Other relevant information to justify the inclusion in CoRAP

The substance has a potential for environmental exposure due to its uses.

Information to be potentially requested

The most appropriate study to clarify the concern will be considered during SEv and may include in vivo studies to investigate the ED properties of the substance in vivo.

Possible follow-up (demonstrating the improvement of risk management measures)

EC/ List number	Harmonised C&L	Restriction	Authorisation	Other
939-505-4	☒	☒	☒	☐

[4] Heitkamp MA, Freeman JP, Cerniglia CE. Biodegradation of tert-butylphenyl diphenyl phosphate. Appl Environ Microbiol. 1986 Feb;51(2):316-22. doi: 10.1128/aem.51.2.316-322.1986.

[5] Schang G, Robaire B, Hales BF. Organophosphate Flame Retardants Act as Endocrine-Disrupting Chemicals in MA-10 Mouse Tumor Leydig Cells, Toxicological Sciences, Volume 150, Issue 2, April 2016, Pages 499–509, https://doi.org/10.1093/toxsci/kfw012