

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name): Trixylyl phosphate

Chemical Group:

EC Number: 246-677-8

CAS Number: 25155-23-1

Submitted by: Italy

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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

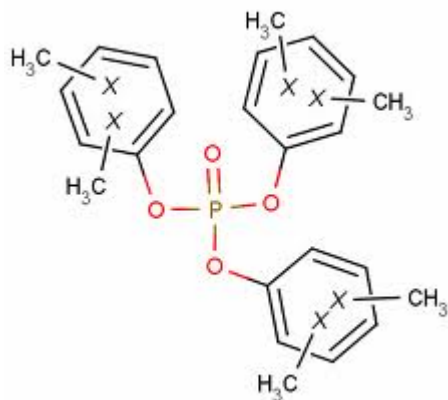
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Trixylyl phosphate
IUPAC name:	Phenol, dimethyl-, 1,1',1''-phosphate
Index number in Annex VI of the CLP Regulation	015-201-00-9
Molecular formula:	C ₂₄ H ₂₇ O ₄ P
Molecular weight or molecular weight range:	410.45
Synonyms/Trade names:	Reaction product of phosphorous oxytrichloric acid and xylenols containing tris (dimethylphenyl and/or ethylphenyl) phosphates Trixylenylphosphate Dimethylphenol phosphate (3:1) Phenol, dimethyl-, phosphate (3:1) Phosphoric acid, trixylyl ester Xylenol, phosphate (3:1) Tri-dimethyl phenyl phosphate Tris (dimethylphenol) phosphate Kronitex TXP (Trade name) Phosflex TXP (Trade name)

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

Major aryl phosphate ester products used in Europe (Reference Science Report Trixylenyl phosphate, Environmental agency UK)

Substance name	EC number	Molecular formula	Molecular Weight
Triphenyl phosphate	204-112-2	C18H15O4P	326.29
Tricresyl phosphate	215-548-8	C21H21O4P	368.36
Cresyl diphenyl phosphate	247-693-8	C19H17O4P	340.31
Tris(isopropylphenyl) phosphate	248-147-1	C27H33O4P	452.54
Isopropylphenyl diphenyl phosphate	248-848-2	C21H21O4P	368.37
Tertbutylphenyl diphenyl phosphate	260-391-0	C22H23O4P	382.39
2-Ethylhexyl diphenyl phosphate	214-987-2	C20H27O4P	362.40
Isodecyl diphenyl phosphate	249-828-6	C22H31O4P	390.45
Tetraphenyl resorcinol diphosphate	260-830-6	C30H24O8P2	574.57

Structural formula: *If group of similar substance, give examples*

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Reproduction toxicity labeling is assigned on the basis of COMMISSION REGULATION (EU) No 618/2012 of 10 July 2012 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labeling and packaging of substances and mixtures, index number 015-201-00-9.

Harmonised classification in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) ATP03.

Repr. 1B; H360F: May damage fertility.

2.2 Self classification

- In the registration (in addition to the harmonised)
 - STOT Rep. Exp. 2 H373 : May cause damage to organs through prolonged or repeated exposure.

Affected organs: adrenals, testes, epididymides, ovaries, liver (females only)
Route of exposure: Oral

- Aquatic Acute 1; H400: Very toxic to aquatic life.
- Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects.
M-factor = 10
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
Reproductive toxicity: Repr. 1B; H360
Repr. 2; H361
Eye Irritation 2; H319: Causes serious eye irritation.
Skin Sens.1; H317: May cause allergic skin reaction.
Hazardous to the aquatic environment: M-factor = 1 (many) or 100 (3 notifiers)
Aquatic Acute 1; H400
Aquatic Chronic 1 H410
Not classified

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

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3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa	
<input checked="" type="checkbox"/> 1000 – 10,000 tpa	<input 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	
<i>Please provide further details if appropriate</i>			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
PC 17: Hydraulic fluids PC 24: Lubricants, greases, release products PC 25: Metal working fluids PC 32: Polymer preparations and compounds			

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

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

4.2 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

4.3 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 type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	Suspected Sensitiser ¹	
<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 type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input checked="" type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

¹ 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

P criterion: Due to being not readily biodegradable and having no significant mechanism of hydrolysis, the substance is considered to be persistent by the registrant. As such, the substance fulfils the requirements of Annex XIII, Para 1.1 based on evaluation of available data, and can be considered to be **"P" and "vP"** based on this data.

B criterion: The available information on Bioaccumulation suggests that the substance is close to fulfil the B criterion. However, experimental data are not lipid normalised, the steady state is not reached in one of the study (Bengtsson et al., 1985) and the available dietary study is difficult to interpret. Therefore the QSAR/ Read-across results for the B/vB assessment reported by the registrant do not allow concluding on the B criterion. As a consequence, the substance should be considered **potentially B**.

T criterion: The substance is classified as having concern for reproductive toxicity. Harmonised classification in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) ATP03 COMMISSION REGULATION (EU) No 618/2012 of 10 July 2012:

Repr. 1B H360F

According to Regulation (EC) No 1272/2008 the substance is also self-classified:

STOT RE 2; H373 , Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 with M=10

As such, the substance can be considered as **"T"** for the requirements of Annex XIII, Para 1.3 based on evaluation of available data.

Summarising: on the basis of data available in the dossier, trixylyl phosphate has to be considered as:

- Potentially persistent ("P"/ "vP") based on screening approach
- Potentially B
- T (Harmonised Classification as Repr. 1B)

4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input checked="" type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input checked="" type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	

It is noted that the substance has been included in the Candidate list on 16 December 2013 as toxic for reproduction (Article 57 c);

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

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

4.6 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>The substance has been included in the Candidate list on 16 December 2013 as toxic for reproduction (Article 57 c); the potential listing also as PBT could be relevant for the inclusion in Annex XIV.</p>			