

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	A mixture of: triphenylthiophosphate and tertiary butylated phenyl derivatives
Chemical Group:	
EC Number:	421-820-9
CAS Number:	192268-65-8
Submitted by:	The Netherlands
Published:	26/03/2014

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

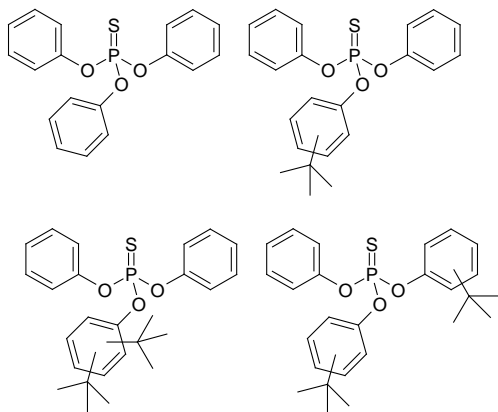
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	A mixture of: triphenylthiophosphate and tertiary butylated phenyl derivatives
IUPAC name:	reaction mass of: triphenylthiophosphate and tertiary butylated phenyl derivatives
Index number in Annex VI of the CLP Regulation	607-501-00-9
Molecular formula:	UVCB: C18H15O3PS, C22H23O3PS, C26H31O3PS
Molecular weight or molecular weight range:	342.35; 398.46; 454.57
Synonyms/Trade names:	CD 28-0132; IRGALUBE 232

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

Tricresylphosphate:

CoRAP 2014; the Netherlands; Suspected PBT

EC nr. 215-548-8

CAS nr. 1330-78-5

Name: tris(methylphenyl) phosphate

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Aquatic Chronic 4; H413: May cause long lasting harmful effects to aquatic life.

2.2 Self classification

- In the registration: (Environmental hazard)

The classification in the registration is identical with the harmonized classification in Annex VI of the CLP

Precautionary statements:

P273: Avoid release to the environment.

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

None, except that one aggregated notification has given the M-factor=10 for the chronic environment hazard.

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 checked="" type="checkbox"/> 100 – 1000 tpa	
<input 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	
In addition there is a confidential tonnage in a NONS registration.			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Closed System
Use in Lubricants, greases, release products, hydraulic fluids (consumer, professional, industrial), intermediate, metal working fluid (industrial).			
Closed system for professional and industrial use Wide dispersive use for the consumer uses			

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 disruptor
- 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 type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
P: not readily biodegradable in OECD301C and D (0% degradation after 28 days). Degradability of one component in an OECD302 B (Zahn Wellens) inherent biodegradability test. B: O,O,O-triphenyl phosphorothioate (main component) BCF 842 – 2508 T: Lowest NOEC (rainbow trout) 0.0044 mg/l (based on growth rate)		

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

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 type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input 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)	
<i>Please provide further details when relevant.</i>	

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

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input 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)

Persistence will have to be further examined. The information in the dossier is indicating that the main and bioaccumulating component (triphenylthiophosphate) of the UVCB, would be inherently biodegradable in an OECD302 (Zahn-Wellens) test. This test result cannot be translated to an environmental half-life; therefore it is not possible to conclude that the component would be not P. Further evaluation of the dossier data is required, and possibly further testing (simulation testing) of the UVCB substance and/or individual components might be necessary.

The B-criterion seems to be fulfilled with BCF values of up to 2508 for the main component.

The T criterion seems to be fulfilled with a chronic fish test.

Use information will be necessary (volumes for different uses) to evaluate the relevance of different uses for PBT assessment.

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)
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Due to several wide dispersive uses and the PBT properties of the substance, authorization seems to be the appropriate risk management.
Authorisation would drive for substitution with non-PBT substance and minimize emissions.