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:	**NL MSCA**
Date:	**22/03/2016**

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Substance identity

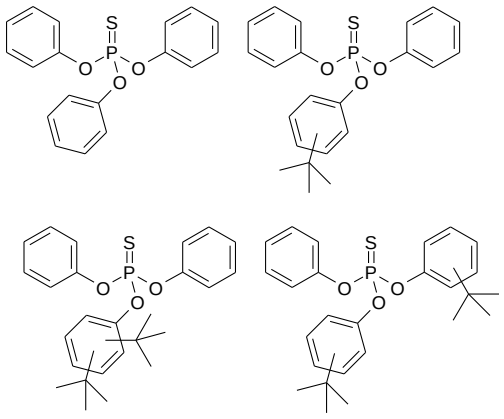
EC name:	A mixture of: triphenylthiophosphate and tertiary butylated phenyl derivatives
IUPAC name:	reaction mass of: triphenylthiophosphate and tertiary butylated phenyl derivatives
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	UVCB: C18H15O3PS, C22H23O3PS, C26H31O3PS
Molecular 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

1.2 Similar substances/grouping possibilities

Tricresylphosphate:
CoRAP 2014; the Netherlands; Suspected PBT
EC nr. 215-548-8
CAS 1330-78-5
Name tris(methylphenyl) phosphate

Structural formula:



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		
☐ 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

☒ Industrial use	☒ Professional use	☐ Consumer use	☒ Closed System
Use in Lubricants, greases, release products, hydrolic fluids (professional, industrial), intermediate, metal working fluid (industrial).			

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 ☐C ☐M ☐R	Suspected CMR[1] ☐C ☐M ☐R	☐ Potential endocrine disruptor
☐ Sensitiser	Suspected Sensitiser[1]	
☐ 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)
P: not readily biodegradable in OECD 301C 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

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

The NL-CA is of the opinion that it is better to wait for the outcome of the substance evaluation of O,O,O-triphenyl phosphorothionate (EC nr 209-909-0), the NL-CA intends to perform. Althought the NL-CA has identified the concerns as described, the NL-CA decided to first perform a substance evaluation of the mono-constituent O,O,O-triphenyl phosphorothionate (EC nr 209-909-0). As this substance is one of the main constituents of the UVCB, the outcome of the mono-constituent will influence the concern regarding the UVCB. Several uncertainties exist on the substance identity of the UVCB and the read-across performed. Therefore, the NL-CA has decided not to evaluate the monoconstituent and the UVCB together.

4.5 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)

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

☐ Harmonised C&L	☐ Restriction	☒ Authorisation	☐ Other (provide further details)

If the evaluation results in a conclusion that the substance is PBT/vPvB it should be substituted by safer alternatives.