Justification for the selection of a candidate CoRAP substance

– UPDATE –

Substance Name (Public Name):	Tris(methylphenyl)phosphate
Chemical Group:	
EC Number:	215-548-8
CAS Number:	1330-78-5
Submitted by:	NL-CA
Published:	20/03/2013 Update 26/03/2014

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

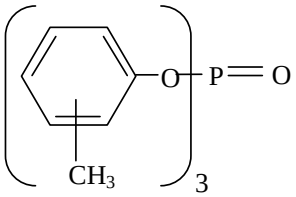
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Tris(methylphenyl)phosphate
EC number:	215-548-8
EC name:	Tris(methylphenyl) phosphate
CAS number (in the EC inventory):	1330-78-5
CAS number:	1330-78-5
CAS name:	-
IUPAC name:	Tris(4-methylphenyl)phosphate
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	$C_{21}H_{21}O_4P$
Molecular weight or molecular weight range:	368.36
Synonyms:	Kronitex TCP, TCP , Kronitex TCP-S, Durad 125, From CO Reofos 908, From CO TCP/TXP, PHOSPHORIC ACID, TRIS(METHYLPHENYL) ESTER , PHOSPHORIC ACID TRICRESYL ESTER , PHOSPHORIC ACID, TRITOLYL ESTER, TRICRESYL PHOSPHATE , TRITOLYL PHOSPHATE , Disflamoll TKP , Disflamoll TKP-P.

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

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not classified.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self classification

By the registrants

According to CLP

Repr. 2 H361: Suspected of damaging fertility or the unborn child.

Specific effect: Testicular effects - Sperm concentration, motility
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.

According to DSD:

Repr. Cat. 3; R62 Possible risk of impaired fertility.

N; R50/53 Dangerous for the environment; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

In addition are the following classifications notified to the Classification and Labelling Inventory:

Repr. 1B; H360: May damage fertility or the unborn child.

Skin Sens. 1; H317: May cause allergic skin reaction.

Eye Irrit. 2; H319: Causes serious eye irritation.

STOT SE 1; H370: Causes damage to organs.

Some give Spec. Conc. limits: STOT SE 1: C ≥ 1% ; STOT SE 2: C ≥ 0,2%

STOT SE 2; H371: May cause damage to organs through prolonged or repeated exposure.

STOT RE 1; H372: Causes damage to organs through prolonged or repeated exposure.

STOT RE 2; H373: May cause damage to organs.

Acute Tox. 4; H302: Harmful if swallowed.

Acute Tox. 4; H312: Harmful in contact with skin.

Acute Tox. 4; H332: Harmful if inhaled.

Aquatic Chronic 2; H411: Toxic to aquatic life with long lasting effects.

Aquatic Acute 1 H400/Aquatic Chronic 1 H410 with M-factor = 100 or 10.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

☐ Article 44(2) (refined prioritisation criteria for substance evaluation)

☒ Article 45(5) (Member State priority)

3.2 Grounds for concern

☐ (Suspected) CMR	☒ Wide dispersive use	☐ Cumulative exposure
☐ (Suspected) Sensitiser	☐ Consumer use	☐ High RCR
☒ (Suspected) PBT	☐ Exposure of sensitive populations	☒ Aggregated tonnage
☐ Suspected endocrine disruptor	☒ Other (provide further details below)	

The P status of the substance is uncertain. In the only biodegradation study available, 24.2% degradation was observed in a 28-day ready biodegradation test. The screening criteria for potential Biowin6 <0.5 AND Biowin3<2.2 are just barely not met since although the Biowin6 predicts 0.0098, then Biowin3 predicts 2.3. The screening criteria for potential P of Biowin 2 <0.5 AND Biowin 3 <2.2 are not met. The screening criteria would suggest that the substance is potential P.

The substance fulfills the screening criteria for B. The log Kow value is 5.9, measured according to a non-guideline study. KOWWIN predicts a log Kow of 6.3.

The substance does fulfill the T criteria as it is classified as Repr 2 and STOT RE 2. It is suggested to prioritise this substance for CORAP, given the uncertainty if the ultimate criteria for P will be met.

For human health, our primary concern relates to the potential neurotoxic effects of (isomers of) TCP, especially due the use of TCP as additive in oils used in airplane engines and subsequent exposure of TCP, or breakdown products, to cabin crew, pilots and passengers.

3.3 Information on aggregated tonnage and uses

☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☒ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	
☐ 100,000 – 1000,000 tpa	☐ > 1000,000 tpa	
☐ Confidential		

☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Closed System

Given the wide range of applications, emissions and exposure are considered to be likely.

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

☐ Compliance check final	☐ 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
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	
Long-term toxicity to fish; Bioaccumulation: aquatic / sediment;	

3.5 Information to be requested to clarify the suspected risk

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☒ Information on fate and behaviour	☐ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Other (provide further details below)	

More information about the biodegradation of the substance would make it possible to draw a definitive conclusion for the P status (it should be noted that the registrant waives additional testing on degradation based on the conclusion that the substance is likely to be persistent on basis of the available study).

When ultimate criteria for P are fulfilled, also the bioaccumulative properties of the substances should be further tested (it should be noted that the registrant indicates that a BCF-study in fish is planned).

Information on toxicological properties, use and exposure may be needed to clarify the concern on, amongst others, the neurotoxic potential of (isomers of) TCP and other potential neurotoxic substances formed during intended use of TCP as additive in oils used in airplane engines. Furthermore, there is (amongst others) as yet insufficient information in the dossier regarding the exposure of air cabin crew, pilots and passengers to TCP, or breakdown products, during intended use of TCP as additive in oils used in airplane engines.

3.6 Potential follow-up and link to risk management

☐ Restriction	☐ Harmonised C&L	☒ Authorisation	☐ Other (provide further details)
A potential follow-up regulatory action would be authorisation of the substance, if the substance turns out to be PBT.			