Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Triphenyl phosphate
Chemical Group:	Organic
EC Number:	204-112-2
CAS Number:	115-86-6
Submitted by:	UK CA
Published:	20/03/2013

NOTE

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

Contents

1 IDENTITY OF THE SUBSTANCE

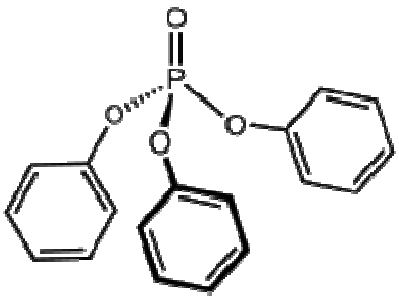
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Triphenyl phosphate
EC number:	204-112-2
EC name:	Triphenyl phosphate
CAS number (in the EC inventory):	115-86-6
CAS number:	115-86-6
CAS name:	Phosphoric acid, triphenyl ester
IUPAC name:	Triphenyl phosphate
Index number in Annex VI of the CLP Regulation	Not applicable
Molecular formula:	C18H15O4P
Molecular weight or molecular weight range:	326.28
Synonyms:	TPP Trade name: Disflamoll TP

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

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None

2.3 Self classification

The following self-classification is given by the registrant (on the dissemination site).

CLP:

Aquatic acute 1; H400: Very toxic to aquatic life

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

DSD:

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

In the Classification and Labelling Inventory notifications vary from no self classification to one or both of the above and additionally:

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

Aquatic chronic 1; H410: Very toxic to aquatic life with long lasting effects

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

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

☒ Article 44(1) (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)	

An Endocrine Disruption screening tool suggests the substance may be an endocrine disruptor (a potential Androgen receptor ligand). There is no 2-generation study available, only a one-generation study, which showed no adverse effects up dose level of 690 mg/kg/day (the highest dose level tested). Given the wide dispersive & consumer use this potential concern should be verified.

The substance is self-classified for the environment based on acute and chronic toxicity in fish (however it is not bioaccumulative and it is readily biodegradable). A previous UK assessment of the substance identified potential risks for all areas of use for surface water (fresh and marine), sediment (fresh and marine) and soil compartments, and for exposure through the terrestrial food chain for one use.

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		

Tonnage band given on the dissemination site.

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

Industrial Use:

Handling of raw materials and formulation of plastic preparations

Production of plastic articles

Consumer use:

General public: service life of articles containing triphenyl phosphate (e.g. adhesives, sealants)

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

☒ Compliance check final decision – under appeal	☐ 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)	

Compliance Check - The following testing was requested in a final decision, but an appeal of the decision has been published;

Sub-chronic toxicity (90-day, rat, oral) – Annex IX, 8.6.2 – EU method B.26 or OECD 408
Developmental toxicity study (rabbit, oral) – Annex X, 8.7.2 – EU method B.31 or OECD 414

As the substance was already on the CoRAP due to endocrine disruption concerns, it was decided not to address any potential deficiencies with respect to the compliance of the dossier with the standard information requirement set out in Annex X, 8.7.3 as this would be covered in the evaluation where the most suitable testing to address these concerns could be requested.

The UK will consider the progress of the update and may revise the year of evaluation accordingly.

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 studies may be required to clarify whether triphenyl phosphate is an endocrine disruptor.

For the environmental risk evaluation, emission estimates could be refined with more specific information for the substance itself. Testing on sediment and terrestrial organisms would allow evaluation for these compartments to be refined. Registered exposure scenarios for the environment should be checked during substance evaluation to ensure that releases from specified uses are below concentrations leading to a potential risk for the environment. The substance is also a major impurity in several phosphate flame retardant products, so evaluation may need to consider how to deal with these potential contributions to release.

3.6 Potential follow-up and link to risk management

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

Any follow-up will depend on the outcome of the evaluation.