



## **Justification Document for the Selection of a CoRAP Substance**

<b>Substance Name (public name):</b>	<b>Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide</b>
<b>EC Number:</b>	<b>278-355-8</b>
<b>CAS Number:</b>	<b>75980-60-8</b>
<b>Authority:</b>	<b>SE MSCA</b>
<b>Date:</b>	<b>22/03/2016</b>

### **Note**

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

## Table of Contents

<b>1</b>	<b>IDENTITY OF THE SUBSTANCE</b>	<b>3</b>
1.1	Other identifiers of the substance	3
1.2	Similar substances/grouping possibilities	3
<b>2</b>	<b>OVERVIEW OF OTHER PROCESSES / EU LEGISLATION</b>	<b>4</b>
<b>3</b>	<b>HAZARD INFORMATION (INCLUDING CLASSIFICATION)</b>	<b>5</b>
3.1	Classification	5
3.1.1	Harmonised Classification in Annex VI of the CLP	5
3.1.2	Self classification	5
3.1.3	Proposal for Harmonised Classification in Annex VI of the CLP	6
<b>4</b>	<b>INFORMATION ON (AGGREGATED) TONNAGE AND USES</b>	<b>7</b>
4.1	Tonnage and registration status	7
4.3	Overview of uses	8
<b>5.</b>	<b>JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE</b>	<b>9</b>
5.1.	Legal basis for the proposal	9
5.2.	Selection criteria met (why the substance qualifies for being in CoRAP)	9
5.3.	Initial grounds for concern to be clarified under Substance Evaluation	9
5.4.	Preliminary indication of information that may need to be requested to clarify the concern	11
5.5.	Potential follow-up and link to risk management	11

## 1 IDENTITY OF THE SUBSTANCE

### 1.1 Other identifiers of the substance

Table: Other Substance identifiers

<b>EC name (public):</b>	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
<b>IUPAC name (public):</b>	(Diphenylphosphinyl)-(2,4,6-trimethylphenyl)methanone
<b>Index number in Annex VI of the CLP Regulation:</b>	015-203-00-X
<b>Molecular formula:</b>	C <sub>22</sub> H <sub>21</sub> O <sub>2</sub> P
<b>Molecular weight or molecular weight range:</b>	348.3747
<b>Synonyms:</b>	

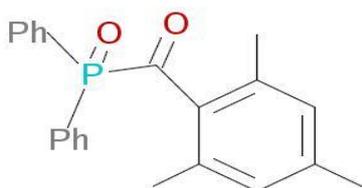
**Type of substance**

Mono-constituent

Multi-constituent

UVCB

**Structural formula:**



### 1.2 Similar substances/grouping possibilities

Not relevant.

## 2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

**Table: Completed or ongoing processes**

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check, Final decision
		<input checked="" type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
Restriction	<input type="checkbox"/> Annex XVII <sup>1</sup>	
Harmonised C&L	<input checked="" type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	
Other processes / EU legislation	<input checked="" type="checkbox"/> Other (further details below)	

<sup>1</sup> Please specify the relevant entry.

Further details	Substance is used in cosmetic products (nail modelling products). It is not regulated under Cosmetics Regulation (EC) No 1223/2009. Due to harmonized Repr. 2 classification, it shall be prohibited as a cosmetic ingredient. However, substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS (Scientific Committee on Consumer Safety) and found safe for use in cosmetic products (Art. 15.1 of the Cosmetics Regulation). The SCCS is of the opinion that substance is safe when used as a nail modelling product at a concentration of at maximum 5.0%, although it is considered a moderate skin sensitizer (SCCS 1528/14).
-----------------	---

### 3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

#### 3.1 Classification

##### 3.1.1 Harmonised Classification in Annex VI of the CLP

**Table: Harmonised classification**

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
015-203-00-X	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	278-355-8	75980-60-8	Repr. 2	H361f (causing atrophy of the testes)		

##### 3.1.2 Self classification

- In the registration:

Repr. 2 classification, which is included in Annex VI of CLP Regulation, is included in the registration as follows:

Repr. 2 H361: Suspected of damaging fertility or the unborn child  
Specific effect: testes atrophy

In addition, the registration contains the following classifications not included in Annex VI of CLP Regulation:

Skin Sens. 1B H317: May cause an allergic skin reaction

Aquatic Acute 2 H401: Toxic to aquatic life.

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

*It is noted that in the CLP Regulation there is no category "Aquatic Acute 2".*

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
  - Aquatic Chronic 1 H410
  - Aquatic Chronic 3 H412
  - Aquatic Chronic 4 H413
  - Eye Irrit. 2 H319
  - Skin Irrit. 2 H315
  - Skin Sens. 1 H317
  - No Hazard Class and Category Code but still Labelling Hazard Statement H317
  - No Hazard Class and Category Code but still Labelling Hazard Statement H411

### **3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP**

No information found.

## 4 INFORMATION ON (AGGREGATED) TONNAGE AND USES<sup>2</sup>

### 4.1 Tonnage and registration status

**Table: Tonnage and registration status**

<b>From ECHA dissemination site</b>		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per 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

---

<sup>2</sup> Please provide here the date when the dissemination site was accessed.

## 4.2 Overview of uses

**Table: Uses**

**Part 1:**

<input checked="" type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
---	---	--	--	---------------------------------------	---	--

**Part 2:**

	<b>Use(s)</b>
<b>Formulation</b>	Formulation of preparations Formulation of inks, coatings and adhesives
<b>Uses at industrial sites</b>	Industrial use, resulting in inclusion into or onto a matrix Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers Industrial use, resulting in inclusion into or onto a matrix
<b>Uses by professional workers</b>	Wide dispersive indoor use of reactive substances in open systems Wide dispersive indoor use of processing aids in open systems Wide dispersive indoor use of reactive substances in open systems

## 5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

### 5.1. Legal basis for the proposal

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

### 5.2. 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

### 5.3. Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	Suspected CMR <sup>3</sup> <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input checked="" type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser <sup>3</sup>	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB <sup>3</sup>	<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 type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input checked="" type="checkbox"/> Other Insufficient documentation of ecotoxicity studies; lack of long-term

<sup>3</sup> 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

		aquatic ecotoxicity studies; lack of terrestrial ecotoxicity studies
<p><b>Reproductive toxicity and endocrine disruption</b></p> <p>The substance has harmonized classification for reproductive toxicity category 2 based on adverse effects in rat testes. In repeated dose toxicity studies (28-day and 90-day), the substance has been shown to cause testicular atrophy in rats at the dose levels lower than 900 mg/kg/day. There are no other studies where reproductive toxicity has been examined and the registrant(s) have provided a waiver that seems to be inadequately justified. Therefore more detailed information is needed to better address this endpoint. This would not only help to clarify how these testicular effects impact reproduction but also enable to better evaluate the concern of endocrine disruption.</p> <p><b>PBT properties</b></p> <p>For persistence, only one screening level test is available for the substance. This test is an OECD 301F ready biodegradability test and showed 0-10% biodegradation. Therefore, the substance fulfills the screening criteria for P. There is no hydrolysis test in the dossier although hydrolysis is a standard information requirement.</p> <p>The available information on bioaccumulation shows that the substance does not fulfill the screening criteria for B (<math>\log K_{OW}</math> values <math>&gt; 4.5</math>) as the available experimental <math>\log K_{OW}</math> value is 3.1 and a QSAR value is 3.87 (<math>K_{OW}</math> = octanol/water partition coefficient). A Fish bioaccumulation study indicates that the bioconcentration factor is below the criterion for B. Therefore, the substance does not indicate a concern for aquatic bioaccumulation. However <math>\log K_{OA}</math> value is high (12.3 estimated by KOAWIN), indicating possibility for terrestrial bioaccumulation (<math>K_{OA}</math> = octanol/air partition coefficient).</p> <p>The substance fulfills the T criterion as it has a harmonized classification for reproductive toxicity category 2.</p> <p><b>Ecotoxicological properties</b></p> <p>There are only acute aquatic ecotoxicity studies for fish, daphnia and algae available for the substance. For all three trophic levels results are <math>&gt; 1</math> mg/l, and the lowest value was obtained for Daphnia (EC50 3.53 mg/l). No long term studies are available. In addition, no terrestrial toxicity studies have been submitted.</p> <p>The risk characterization is based on acute aquatic ecotoxicity studies which are very briefly described. The validity of those studies cannot be evaluated based on the available information i.e. the reliability of the studies should be currently considered with Klimisch score 4 as 'not assignable'. Consequently it is not possible to estimate whether there is a need for long-term fish and aquatic invertebrate studies.</p> <p>In addition, the substance does not have a harmonized CLP classification for aquatic toxicity. Based on the results available for the manual screening the classification as Aquatic Chronic 2 seems warranted. However, based on the available information it is not possible to estimate the adequacy of the ecotoxicity studies for harmonized classification.</p>		

**Exposure**

The substance is registered within 100 - 1000 tpa and has industrial and professional uses. There is wide dispersive indoor use of the substance with respect to human exposure in professional use. Consumer use or use in articles are not indicated in ECHA dissemination site.

**Conclusions**

It is proposed to investigate further the reproductive toxicity and endocrine disrupting properties, persistence, terrestrial bioaccumulation, and ecotoxicological properties.

**5.4. Preliminary indication of information that may need to be requested to clarify the concern**

<input checked="" 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 checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
<p><b>Toxicological properties and endocrine disruption potential</b>                  More information is needed to clarify the concern regarding reproductive toxicity and endocrine disruption.</p> <p><b>Fate and behaviour</b>                  More information is needed to clarify the concerns regarding persistence and terrestrial bioaccumulation.</p> <p><b>Ecotoxicological properties</b>                  More information is needed to assess the validity of the ecotoxicity tests and to verify the environmental risk assessment.</p>	

**5.5. Potential follow-up and link to risk management**

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)