



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

**Substance Name (public name):** Oxydiethylene dibenzoate

**EC Number:** 204-407-6

**CAS Number:** 120-55-8

**Authority:** LV MSCA

**Date:** 22/03/2016

### **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	4
<b>2</b>	<b>OVERVIEW OF OTHER PROCESSES / EU LEGISLATION</b>	<b>5</b>
<b>3</b>	<b>HAZARD INFORMATION (INCLUDING CLASSIFICATION)</b>	<b>6</b>
3.1	Classification	6
3.1.1	Harmonised Classification in Annex VI of the CLP	6
3.1.2	Self classification	6
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
4.2	Overview of uses	7
<b>5.</b>	<b>JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE</b>	<b>8</b>
5.1.	Legal basis for the proposal	8
5.2.	Selection criteria met (why the substance qualifies for being in CoRAP)	8
5.3.	Initial grounds for concern to be clarified under Substance Evaluation	8
5.4.	Preliminary indication of information that may need to be requested to clarify the concern	9
5.5.	Potential follow-up and link to risk management	9

## 1 IDENTITY OF THE SUBSTANCE

### 1.1 Other identifiers of the substance

**Table: Other Substance identifiers**

<b>EC name (public):</b>	Oxydiethylene dibenzoate
<b>IUPAC name (public):</b>	oxydiethane-2,1-diyl dibenzoate
<b>Index number in Annex VI of the CLP Regulation:</b>	-
<b>Molecular formula:</b>	C <sub>18</sub> H <sub>18</sub> O <sub>5</sub>
<b>Molecular weight or molecular weight range:</b>	
<b>Synonyms:</b>	<i>Benzoflex 2-45</i> <i>Diethylene glycol, dibenzoate</i> <i>Ethanol, 2,2'-oxybis-, dibenzoate</i>

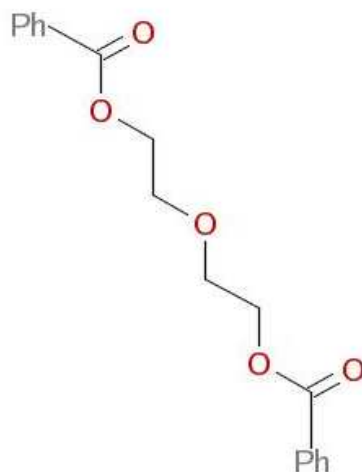
**Type of substance**

Mono-constituent

Multi-constituent

UVCB

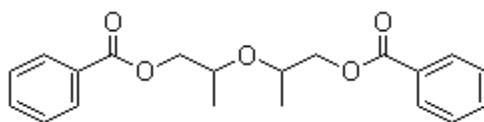
**Structural formula:**



## 1.2 Similar substances/grouping possibilities

<b>EC name (public):</b>	Oxydipropyl dibenzoate
<b>IUPAC name (public):</b>	1-[2-(benzoyloxy)propoxy]propan-2-yl benzoate
<b>Index number in Annex VI of the CLP Regulation:</b>	-
<b>Molecular formula:</b>	C <sub>20</sub> H <sub>22</sub> O <sub>5</sub>
<b>Molecular weight or molecular weight range:</b>	-
<b>Synonyms:</b>	<i>Benzoflex 9-88</i> -

**Structural formula:**



## 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 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
Harmonised C&L	<input 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 type="checkbox"/> Other (provide further details below)	

No ongoing processes identified.

### **3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)**

#### **3.1 Classification**

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

None.

##### **3.1.2 Self classification**

- In the registration:  
The substance is not classified.
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:  
Aquatic Chronic 2, H411  
Eye Irrit. 2, H319

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

None.

## 4 INFORMATION ON (AGGREGATED) TONNAGE AND USES<sup>1</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 type="checkbox"/> 100 – 1000 tpa
<input checked="" 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
<i>Joint submission.</i>		

### 4.2 Overview of uses

Plasticizer for PVC  
 Industrial manufacture of adhesives and sealants  
 Professional use of adhesives and sealants  
 Consumer use of adhesives and sealants  
 Chemical processes for peroxide carrier  
 Manufacture of coatings & inks  
 Professional use of coatings and inks  
 Consumer use of coatings and inks  
 Manufacture of lubricant additives  
 Professional use of lubricant additives  
 Agricultural chemicals (carrier)  
 Consumer use of cosmetics and personal care products  
 Cosmetics & personal care  
 Use as laboratory reagent.

**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 checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Article service life	<input checked="" type="checkbox"/> Closed system
---	---	--	--	--	--	---

<sup>1</sup> 24/08/2015.

## 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 type="checkbox"/> R	Suspected CMR <sup>2</sup> <input type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser <sup>2</sup>	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB <sup>2</sup>	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

<sup>2</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



In the study according to OECD Guideline 414 (Prenatal Developmental Toxicity Study) with the registered substance the Registrant has indicated embryotoxic/teratogenic effects in rats. At 1000 mg/kg/day 4 fetuses (3 litters affected) showed cervical ribs, this incidence being higher than the concurrent Control and marginally outside the current background control data. There was a clearer increase in the incidence of incomplete ossification, principally affecting the cranial centres, sacrocaudal vertebral arches, 5th/6th sternbral centres and pelvic bones compared with the concurrent Control. At 500 mg/kg/day there was a slight increase in the incidence of incomplete ossification of the 5th/6th sternbral centres.

The substance has wide dispersive use with potential exposure to workers, professionals and consumers. While DEGDB is not classified, a risk assessment has not been conducted. Therefore the evident developmental effects should be examined further under SEV in order to decide on the severity of possible risks from the substance and conclude on the further actions.

**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 type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
No exposure assessment and risk characterisation have been performed for the substance. Toxicological information in the registration dossier indicated a potential concern for developmental toxicity.	

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

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
Follow-up actions will be considered taking into account the evaluated information. The above ticked follow-up processes are only indicative.			