

## Justification for the selection of a substance for CoRAP inclusion

<b>Substance Name (Public Name):</b>	oxydipropyl dibenzoate
<b>Chemical Group:</b>	organic
<b>EC Number:</b>	248-258-5
<b>CAS Number:</b>	27138-31-4
<b>Submitted by:</b>	Latvia
<b>Date:</b>	17/03/2015

### Note

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

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## 1 IDENTITY OF THE SUBSTANCE

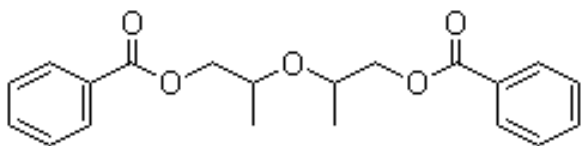
### 1.1 Other identifiers of the substance

Table 1: Substance identity

<b>EC name:</b>	Oxydipropyl dibenzoate
<b>IUPAC name:</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>	342.389
<b>Synonyms/Trade names:</b>	<i>Benzoflex 9-88</i> <i>Benzoflex 9-88 SG</i> <i>Benzoflex TPU 405</i>

**Type of substance**     Mono-constituent     Multi-constituent     UVCB

**Structural formula:**

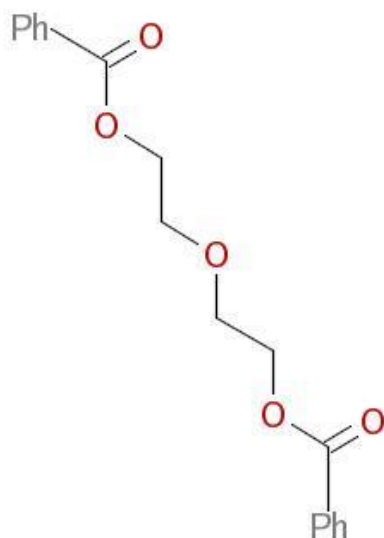


### 1.2 Similar substances/grouping possibilities

Table 2: Similar substance identity

<b>EC name:</b>	Oxydiethylene dibenzoate
<b>IUPAC name:</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>	314.3325
<b>Synonyms/Trade names:</b>	<i>Benzoflex 2-45</i> <i>Diethylene glycol, dibenzoate</i> <i>Ethanol, 2,2'-oxybis-, dibenzoate</i> <i>Ethanol, 2,2'-oxybis-, dibenzoate</i>

**Structural formula:**



## 2 CLASSIFICATION AND LABELLING

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

No harmonised classification.

### 2.2 Self classification

- In the registration

Classification and labelling according to CLP/GHS

Aquatic Chronic 3; H412: Harmful to aquatic life with long lasting effects.

P273: Avoid release to the environment.

P501: Dispose of contents/container to...

Classification and labelling according to Directive 67/548/EEC

N; R51/53 - toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

S60 - this material and its container must be disposed of as hazardous waste

S61 - avoid release to the environment. refer to special instructions/safety data sheets

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

Repr. 2; H361

Aquatic Chronic 2; H411

Eye Irrit. 2; H319

### 2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None

### 3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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	
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
Plasticizer for PVC Adhesives & sealants Coatings & Inks Agricultural chemicals (carrier) Cosmetics & personal care			

### 4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

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

### 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 disruptor
- 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>1</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>1</sup>	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB <sup>1</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 checked="" type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

<sup>1</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

16 notifiers have notified oxydipropyl dibenzoate (DPGDB, EC 248-258-5) as Repr. 2 in C&L inventory.

In a study according to OECD Guideline 414 (Prenatal Developmental Toxicity Study) with the substance the registrant has indicated embryotoxic/teratogenic effects in rats.

An association between treatment at 1000 and 500 mg/kg/day and the greater number of fetuses with incomplete ossification of the 5th and or 6th sternbrae cannot be discounted particularly since a delay in ossification would be expected to be the most sensitive marker of an effect on pre-natal development where treatment has continued through to the day before sacrifice (treatment period: Days 6 to 19 of gestation). The assessment of fetal ossification on Day 20 of gestation represents a snapshot in time as the ossification will continue as the animals grow and mature. Although the relationship of these findings to treatment is uncertain they are considered to be transient in nature rather than representing permanent structural changes and therefore are considered to be of no long-term toxicological importance.

The increase in cervical ribs at 1000 mg/kg/day is considered to be of greater toxicological significance as it occurred at a dosage which has not produced any detectable signs of maternal toxicity however cervical ribs were only found in a small number of fetuses (10/155) at the limit dosage of 1000 mg/kg/day and there was no concomitant change in vertebral configuration.

This endpoint should be further examined and clarified under SEV.

Additionally the substance has wide dispersive use with potential exposure to workers, professionals and consumers. DPGDB is not classified for human health end-points therefore a human health risk assessment was not conducted. Local soil, sediment and water compartment RCSs are close to 1 for some ESs. Exposure considerations should also be taken into account under SEV.

#### 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)

#### 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)