

## Justification for the selection of a candidate CoRAP substance

<b>Substance Name (Public Name):</b>	4,4'-[(isopropylidene)bis(p-phenyleneoxy)]diphthalic dianhydride.
<b>Chemical Group:</b>	Benzofuran
<b>EC Number:</b>	253-781-7
<b>CAS Number:</b>	38103-06-9
<b>Submitted by:</b>	Germany
<b>Published:</b>	20/03/2013

### 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

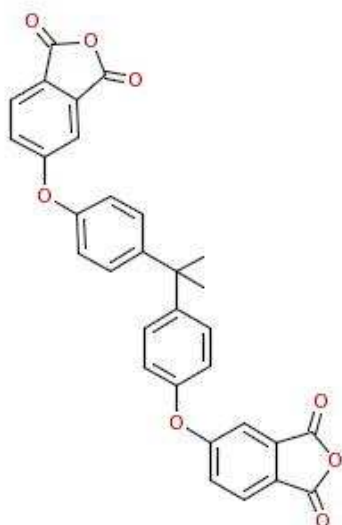
### 1.1 Name and other identifiers of the substance

**Table 1: Substance identity**

<b>Public Name:</b>	4,4'-[(isopropylidene)bis(p-phenyleneoxy)]diphthalic dianhydride.
<b>EC number:</b>	253-781-7
<b>EC name:</b>	4,4'-((Isopropylidene)bis(p-phenyleneoxy))diphthalic dianhydride
<b>CAS number (in the EC inventory):</b>	38103-06-9
<b>CAS number:</b>	38103-06-9
<b>CAS name:</b>	1,3-Isobenzofurandione, 5,5'-((1-methylethylidene)bis(4,1-phenyleneoxy))bis-
<b>IUPAC name:</b>	5,5'-(Propane-2,2-diylbis(4,1-phenyleneoxy))bis(2-benzofuran-1,3-dione)
<b>Index number in Annex VI of the CLP Regulation</b>	-
<b>Molecular formula:</b>	C <sub>31</sub> H <sub>20</sub> O <sub>8</sub>
<b>Molecular weight or molecular weight range:</b>	520.4857
<b>Synonyms:</b>	-

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

**Structural formula:**



## 2 CLASSIFICATION AND LABELLING

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

n.a.

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

n.a.

### 2.3 Self classification

The lead registrant did not classify the substance; therefore, there is no self classification. However, the notifiers under C&L inventory included the following classifications.

<b>Classification</b>	
<b>Hazard Class and Category Code(s)</b>	<b>Hazard Statement Code(s)</b>
Skin Irrit. 2	H315: Causes skin irritation.
Eye Irrit. 2	H319: causes serious eye irritation.
Resp. Sens. 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
STOT SE 3	H335: may cause respiratory irritation.

## 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

<input type="checkbox"/> (Suspected) CMR	<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> (Suspected) Sensitiser	<input type="checkbox"/> Consumer use	<input type="checkbox"/> High RCR
<input checked="" type="checkbox"/> (Suspected) PBT	<input type="checkbox"/> Exposure of sensitive populations	<input checked="" type="checkbox"/> Aggregated tonnage
<input type="checkbox"/> Suspected endocrine disruptor	<input type="checkbox"/> Other (provide further details below)	

Based on the available data in the registration dossier 4,4'-[(isopropylidene)bis(p-phenyleneoxy)]diphthalic dianhydride (BPA-DA) fulfills the screening levels of the PBT criteria according to Annex XIII section 3.1 of the REACH regulation. There is a concern that BPA-DA also fulfills the PBT criteria according to annex XIII section 1.2 of the REACH regulation and consequently might be identified as SVHC substance.

BPA-DA is not readily biodegradable (0% degradation in 28 d).

No measured partition coefficient n-octanol/water (log Pow) for BPA-DA is included in the registration dossier. A read-across to the primary hydrolysis product (4,4-Bisphenol A Tetra-Acid, BPA-TA, CAS 38103-05-8) was made by the registrant. The respective log Pow of BPA-TA ranges from 5.02 to < -2.2 depending on pH. The estimated log Pow of 6.851 for BPA-DA is higher and independent on pH. Consequently, the read across to the BPA-TA seems not to be reasonable. A log Pow > 4.5 indicates a high potential for bioaccumulation and according to Annex IX a bioaccumulation study is necessary.

### 3.3 Information on aggregated tonnage and uses

<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 - 1000,000 tpa	<input type="checkbox"/> > 1000,000 tpa		
<input type="checkbox"/> Confidential			
-			
<input type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
-			

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

<input type="checkbox"/> Compliance check	<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
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
-	

**3.5 Information to be requested to clarify the suspected risk**

<input 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 type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Other (provide further details below)	
<p>There is a need to evaluate the endpoints persistence as well as bioaccumulation of BPA-DA. As the substance is not easily biodegradable, a water sediment simulation test is required according to Annex IX, which is missing until now. In addition, information on bioaccumulation in aquatic organisms (fish) is required.</p>	

**3.6 Potential follow-up and link to risk management**

<input type="checkbox"/> Restriction	<input type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>Follow-up regulatory action might depend mainly on additional information about persistence and toxicity of the substance. Considering all available and additionally requested information, the PBT properties of BPA-DA need to be evaluated with respect to Annex XIII. Depending on the outcome of this evaluation, an identification as SVHC and additional regulatory action might be appropriate.</p>			