

## **Justification for the selection of a candidate CoRAP substance**

**Substance Name (Public Name):** Benzophenone

**Chemical Group:** Organic

**EC Number:** 204-337-6

**CAS Number:** 119-61-9

**Submitted by:** Danish Environmental Protection Agency,  
Strandgade 29, 1401 Copenhagen. Denmark

**Published:** 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

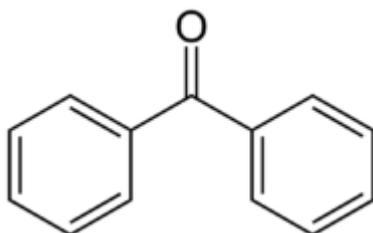
### 1.1 Name and other identifiers of the substance

Table 1: Substance identity

<b>Public Name:</b>	Benzophenone
<b>EC number:</b>	204-337-6
<b>EC name:</b>	Benzophenone
<b>CAS number (in the EC inventory):</b>	119-61-9
<b>CAS number:</b>	119-61-9
<b>CAS name:</b>	-
<b>IUPAC name:</b>	Diphenyl methanone
<b>Index number in Annex VI of the CLP Regulation</b>	Not applicable
<b>Molecular formula:</b>	C <sub>13</sub> H <sub>10</sub> O
<b>Molecular weight or molecular weight range:</b>	182
<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

Not applicable.

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

Not applicable.

### 2.3 Self classification

According to CLP criteria:

STOT Rep. Exp. 2 H373: May cause damage to organs through prolonged or repeated exposure.

Affected organs: liver, kidney.

Route of exposure: Oral.

According to DSD

Xn; R48/22 Harmful: Dangerous to health by prolonged exposure if swallowed.

N; R51/53: Dangerous for the environment, toxic to aquatic organisms, may cause long term effects in the aquatic environment.

The following other self classifications are in addition notified to the Classification and labeling inventory:

Acute Tox. 4; H301: Harmful if swallowed

Skin Irrit. 2; H315: Causes skin irritation

Eye irrit. 2 ; H319 : Causes serious eye irritation

STOT SE 3 ; H335 : May cause respiratory irritation

Aquatic Acute 1 ; H400 : Very toxic to aquatic life

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

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

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

**Human Health** - In a rat and mouse carcinogenicity studies, tumors were observed. The relevance of these tumors to human health should be evaluated. Also, the relevance of the positive finding in the SOS/umu study conducted with human P450s could be further evaluated.

**Exposure** - The scope of the exposure assessment should also be evaluated to ensure that all life cycle stages have been adequately covered. Where RCRs have been calculated, in the majority of cases, these are between 0.5 and 1 for industrial, professional and consumer exposure.

### 3.3 Information on aggregated tonnage and uses

<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 – 1000,000 tpa	<input type="checkbox"/> > 1000,000 tpa		
<input type="checkbox"/> Confidential			
<i>Please provide further details</i>			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System

Industrial Uses:

- Compounding/Formulation
- Industrial end-use/fragrances
- Other industrial uses: Chemical synthesis / Protective group
- Other industrial uses: Photoinitiator in coatings

Professional Uses:

- Professional end-use of fragrances

Consumer Uses:

- Consumer end-use of fragrances

### 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 checked="" type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<p>Benzophenone is included in Annex 1 of Regulation 10/2011 on food contact materials with a specific migration limit of 0.6 mg/kg food. The European Food Safety Authority set a TDI of 0.03mg/kg/day in 2009.</p> <p>Benzophenone is listed in the 1<sup>st</sup> Update of the Inventory of Ingredients Employed in Cosmetic Products Section II: Perfume and Aromatic Raw Materials (2000)</p>	

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

<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 checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Other (provide further details below)	
<p>Request for additional exposure assessments or monitoring data if these are required.</p> <p>Further details of the potential for exposure during various uses to clarify if additional exposure scenarios need to be developed.</p>	

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

<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>Classification and labeling proposal.</p> <p>The registrant may be asked to update the registration dossier with additional exposure scenarios.</p>			