

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name): Oxybenzone

Chemical Group:

EC Number: 205-031-5

CAS Number: 131-57-7

Submitted by: Denmark

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Note

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

Contents

1	IDENTITY OF THE SUBSTANCE.....	3
1.1	Other identifiers of the substance	3
2	CLASSIFICATION AND LABELLING.....	4
2.1	Harmonised Classification in Annex VI of the CLP	4
2.2	Self classification	4
2.3	Proposal for Harmonised Classification in Annex VI of the CLP	4
3	INFORMATION ON AGGREGATED TONNAGE AND USES.....	5
4	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE	5
4.1	Legal basis for the proposal	5
4.2	Selection criteria met (why the substance qualifies for being in CoRAP)	5
4.3	Initial grounds for concern to be clarified under Substance Evaluation	6
4.4	Other completed/ongoing regulatory processes that may affect suitability for substance evaluation	7
4.5	Preliminary indication of information that may need to be requested to clarify the concern	7
4.6	Potential follow-up and link to risk management	7

1 IDENTITY OF THE SUBSTANCE

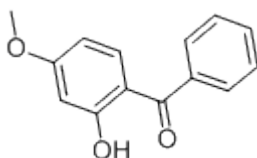
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Oxybenzone
IUPAC name:	(2-hydroxy-4-methoxyphenyl)(phenyl)methanone
Index number in Annex VI of the CLP Regulation	N.a.
Molecular formula:	C ₁₄ H ₁₂ O ₃
Molecular weight or molecular weight range:	228.2433
Synonyms/Trade names:	<i>Benzophenone-3</i> <i>Methanone, (2-hydroxy-4-methoxyphenyl)phenyl-</i> <i>2-hydroxy-4-methoxybenzophenone</i>

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



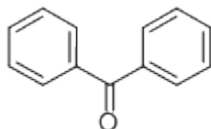
1.2 Similar substances/grouping possibilities

Table 2: Similar substances

Name	CAS No	EC No	Comments
Benzophenone	119-61-9	204-337-6	Registered, SEV by DK in 2013
Benzophenone-1	131-56-6	205-029-4	Not registered
Benzophenone-2	131-55-5	205-028-9	Not registered
Benzophenone-12 (octabenzene)	1843-05-6	217-421-2	Registered, SEV by IT in 2013

Structural formula:

Structural formula for Benzophenone, which constitute the backbone of all benzophenones:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

No entry.

2.2 Self classification

- In the registration dossier:
 - Aquatic Acute 1 (H400)
 - Aquatic Chronic 1 (H410)
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
 - Skin Irrit 2 (H315)
 - Eye Irrit 2 (H319)
 - STOT SE 3 (H335)
 - STOT RE 2 (H373)
 - Aquatic Chronic 2 (H411)
 - Aquatic Chronic 4 (H413)
 - Not Classified

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

No current proposal.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input checked="" type="checkbox"/> 10 – 100 tpa	<input 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	
Decreasing manufacture and import. The total use in the Nordic countries has decreased from approx. 800 tonnes per year in 1999 to approx. 75 tonnes per year in 2010 in less than 200 products registered (cf. SPIN database). Registered in 2013 for the 10-100 tpa range.			
<input type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
According to publicly available information, oxybenzone is used as an UV absorber in cosmetics, personal care products and possibly also in paints, lacquers and varnishes (cf. SPIN database).			

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

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

4.2 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

4.3 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 ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<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 checked="" 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 type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>The registrant has concluded that none of the studies available to him demonstrate that oxybenzone is an endocrine disruptor.</p> <p>However, the potential of the substance for being an endocrine disruptor was evaluated by the Danish Centre for Endocrine Disruptors in 2012 on contract for the Danish EPA. The study concluded that oxybenzone is a potential endocrine disruptor.</p> <p>In addition, new research showing effects of oxybenzone on reproduction and endpoints sensitive to endocrine disruption will be published later in 2014.</p> <p>Various available monitoring data show that oxybenzone can be found in human urine samples as well as in the aquatic environment.</p> <p>If the Substance Evaluation concludes that the substance is an endocrine disruptor, the exposure of and risks to consumers, incl. sensitive populations, workers as well as the environment needs to be further assessed.</p>		

¹ 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

4.4 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)	
<i>Please provide further details when relevant.</i>	

4.5 Preliminary indication of information that may need to be requested to clarify the concern

<input 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 checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
<i>Please provide further details/explanation.</i>	

4.6 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>If the suspicion of oxybenzone being an endocrine disruptor is confirmed, it might qualify for inclusion in the REACH candidate list for eventual inclusion in Annex XIV.</p> <p>If exposure data demonstrates levels exceeding safe levels, a restriction proposal might be required.</p>			