

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

<b>Substance Name (Public Name):</b>	propyl 4-hydroxybenzoate
<b>Chemical Group:</b>	Parabens
<b>EC Number:</b>	202-307-7
<b>CAS Number:</b>	94-13-3
<b>Submitted by:</b>	BE CA
<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>	propyl 4-hydroxybenzoate
<b>IUPAC name:</b>	propyl 4-hydroxybenzoate
<b>Index number in Annex VI of the CLP Regulation</b>	NA
<b>Molecular formula:</b>	C <sub>10</sub> H <sub>12</sub> O <sub>3</sub>
<b>Molecular weight or molecular weight range:</b>	180.2 g/mol
<b>Synonyms/Trade names:</b>	Propylparaben

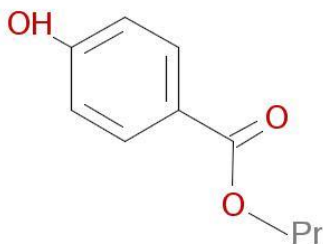
**Type of substance**

Mono-constituent

Multi-constituent

UVCB

**Structural formula:**



### 1.2 Similar substances/grouping possibilities

parabens

## 2 CLASSIFICATION AND LABELLING

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

NA

### 2.2 Self classification

- In the registration

NA

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

Skin Irrit. 2 ; H315: Causes skin irritation

Eye Irrit. 2; H319: Causes serious eye irritation

STOT SE 3; H335: May cause respiratory irritation

Eye Dam. 1; H318: Causes serious eye damage

Skin Sens. 1; H317: May cause an allergic skin reaction

STOT SE 3; H336: May cause drowsiness or dizziness (central nervous...)

Aquatic Chronic 4; H413: May cause long lasting harmful effects to aquatic life

Aquatic Acute 1; H400: Very toxic to aquatic life

Aquatic Acute 2; H411: Toxic to aquatic life with long lasting effects

Resp. Sens. 1; H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled

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

NA

## 3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<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 - 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 type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
Consumer use in: Cosmetics and personal care products; Pharmaceuticals			

#### 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 checked="" type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<p>« Parabens » are currently authorized as preservatives in cosmetics (entry 12 of annex VI of the Cosmetic Directive). This entry is currently under discussion for amendment.</p> <p>Information on other completed/ongoing regulatory processes was not found.</p>	

#### 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

<b>Hazard based concerns</b>		
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 checked="" 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)
<b>Exposure/risk based concerns</b>		
<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 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 substance shows endocrine mode(s) of action. However, evaluation of adversity is challenging. Indeed, most of the available <i>in vivo</i> assays are not designed to give information on adversity. Moreover, the reported findings appear sometimes conflicting.</p> <p>There is direct human exposure. The wide dispersive indoor use can lead to substantial environmental exposure.</p>		

### 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 checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

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

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>Depending on the outcome of the evaluation, any of the above mentioned risk management measures could be initiated if warranted.</p>			

<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