

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

**Substance Name (Public Name):** Benzyl alcohol

**Chemical Group:**

**EC Number:** 202-859-9

**CAS Number:** 100-51-6

**Submitted by:** Germany

**Date:** 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

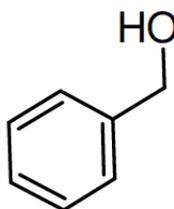
### 1.1 Other identifiers of the substance

Table 1: Substance identity

<b>EC name:</b>	benzyl alcohol
<b>IUPAC name:</b>	phenylmethanol
<b>Index number in Annex VI of the CLP Regulation</b>	603-057-00-5
<b>Molecular formula:</b>	C <sub>7</sub> H <sub>8</sub> O
<b>Molecular weight or molecular weight range:</b>	108.14 g·mol <sup>-1</sup>
<b>Synonyms/Trade names:</b>	Phenylcarbinol

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

**Structural formula:**



## 2 CLASSIFICATION AND LABELLING

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

**Table 2: Harmonised classification**

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
603-057-00-5	Benzyl alcohol	202-859-9	100-51-6	Acute Tox. Cat.4	H302		
				Acute Tox. Cat.4	H332		

### 2.2 Self classification

- In the registration

Acute Tox. Cat.4; H302: Harmful if swallowed.

Acute Tox. Cat.4; H332: Harmful if inhaled

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

Acute Tox. 4; H312: Harmful in contact with skin

Eye Dam. Cat.1; H318: Causes serious eye damage

Eye Irrit. Cat.2; H319: Causes serious eye irritation

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

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

There is currently no proposal for harmonised classification registered or under consideration for this substance.

### 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 type="checkbox"/> 1000 – 10,000 tpa	<input checked="" 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 checked="" type="checkbox"/> Closed System
<p>Due to its good solvent properties and low toxicity, benzyl alcohol is widely used for many different industrial and professional applications. It is used as a solvent, in coating materials, in paint strippers. It is also used in inks and as an auxiliary in textile industry. It is an intermediate for synthesis of pharmaceuticals, fragrances and cosmetics. In the EU benzyl alcohol is approved as a food additive (E 1519) and is used for in flavorings.</p> <p>The professional use include applications of benzyl alcohol e.g. for mixing/loading, charging/discharging operations, roller application, brushing, spraying or dipping.</p> <p>The industrial and professional uses can be characterized by the following process categories: 1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 11, 12, 13, 14, 15, 18, 19, 23, 24, 25.</p>			

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

<input type="checkbox"/> Compliance check, Final decision	<input checked="" type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input checked="" 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) (MemberState 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 type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input checked="" 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 type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input checked="" type="checkbox"/> High RCR	<input 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

Several sensitization tests in different animal systems yielded both positive and negative results. Thus no firm conclusion on the sensitizing potential of benzyl alcohol in animals could be reached. Further testing with volunteers indicates rather low sensitizing potential for benzyl alcohol in humans. A weight of evidence approach should be used for overall evaluation of the available studies in both animals and humans.

The DNELs given in the registration dossiers seem not to be derived in accordance with the procedure laid down in the REACH guidance document which gives rise to the concern of higher resulting RCRs than those described by the registrants.

Due to the high tonnage (>1000 t) and wide dispersive use a high potential of exposure is anticipated.

#### 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)

It has to be checked whether further studies on the effects of benzyl alcohol on skin sensitisation are necessary. In addition, the submitted data for the endpoint Reproductive Toxicity seems not sufficient to cover the standard information requirements for Annex X substances: for example, there is no two generation reproductive toxicity study available in the registration dossier, and the usability and outcome of the provided developmental toxicity studies has to be evaluated.

If the Substance Evaluation indicates that risks for workers arise further information on exposure might be necessary.

#### 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)
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Depending on the outcome of the substance evaluation a harmonized classification for sensitization and/or reproductive toxicity might be necessary. It is unclear if a risk for workers arises and further risk management measures need to be implemented.