

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON BENZYL ALCOHOL

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Substance name: Benzyl alcohol

CAS number: 100-51-6

EC number: 202-859-9

Dossier submitter: Germany

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France		MemberState	1
Comment received				
The minimum purity of test item used to perform physicochemical properties tests should have been reported.				
A typo error has occurred in the SMILES notation of the substance (OCc1ccccc1)				
Dossier Submitter's Response				
RAC's response				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Lanxess Deutschland GmbH	Company-Manufacturer	2
Comment received				
Please refer to the attachment for further information				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment LetterBzOH_ECHA_HarmonisedClassification_final 171220_Redacted.pdf				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Benzylalkohol_Med_Stellungnahme_08092019.pdf				
Dossier Submitter's Response				
RAC's response				

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Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United States	Household & Commercial Products Association	Industry or trade association	3
Comment received				
<p>HCPA appreciates the opportunity to offer these comments. Accurate and scientifically supported classifications are necessary to avoid unintended consequences on manufacturers and marketers of formulated products that utilize benzyl alcohol as a component and their ability to innovate new products with this substance.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment HCPA Comments on Proposal for Harmonized Classification and Labelling on Benzyl Alcohol NC.pdf</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment HCPA Comments on Proposal for Harmonized Classification and Labelling on Benzyl Alcohol.pdf</p>				
Dossier Submitter’s Response				
RAC’s response				

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	Germany	IVDK - Information Network of Departments of Dermatology, Institute at the University Medical Center Göttingen	Academic institution	4
Comment received				
<p>We do not agree to the “Conclusion on classification and labelling for skin sensitisation” (section 9.7.6, page 33 of the CLH report). Considering the fact that benzyl alcohol is an extremely rare contact sensitizer, despite its very widespread use, categorizing benzyl alcohol as skin sensitizer 1B and labelling it with H 317 is not justified from the dermatological point of view.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment IVDK Comment on Benzyl alcohol.zip</p>				
Dossier Submitter’s Response				
RAC’s response				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France		MemberState	5
Comment received				

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<p>Acute Toxicity by oral route: FR agrees with the proposal as Acute Tox 4 based on the available dataset. However, it has to be noted that the level of details prevents clear assessment of the data (only summary available or reliability not assignable). In this context, the generic ATE of 500 mg/kg bw can be more appropriate considering the uncertainties of the results instead of the proposed ATE of 1570 mg/kg bw/day.</p> <p>Acute Toxicity by dermal route: FR agrees that benzyl alcohol should not be classified based on the data available.</p> <p>Acute toxicity by inhalation: According to CLP guidance : "Differentiation between vapour and mist will be made on the basis of the saturated vapour concentration (SVC) for a volatile substance, which can be estimated as follows: SVC [mg/l] = 0.0412 x MW x vapour pressure (vapour pressure in hPa at 20°C). An LC50 well below the SVC will be considered for classification according to the criteria for vapours; whereas an LC50 close to or above the SVC will be considered for classification according to the criteria for mists"</p> <p>According to the calculation based on the equation above, the LC50 > 3 mg/L should be compared to the classification thresholds for mist in the case of benzyl alcohol. In this context, since nearly all the LC50 are about 5 mg/L, the substance should not be classified for acute toxicity by inhalation. However, it has to be noted that the quality of the overall dataset is quite limited (old studies, only summary available or reliability not assignable) that may raise a doubt when deleting a current classification.</p>
Dossier Submitter's Response
RAC's response

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United States	Household & Commercial Products Association	Industry or trade association	6

Comment received
N/A
ECHA note – An attachment was submitted with the comment above. Refer to public attachment HCPA Comments on Proposal for Harmonized Classification and Labelling on Benzyl Alcohol NC.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment HCPA Comments on Proposal for Harmonized Classification and Labelling on Benzyl Alcohol.pdf
Dossier Submitter's Response
RAC's response

Date	Country	Organisation	Type of Organisation	Comment number
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18.12.2020	Belgium		MemberState	7
Comment received				
<p>ORAL</p> <p>BECA supports the DS proposal for classification as Acute tox. 4; H302. Indeed, the most reliable and recent studies (1978 and 1980) based on similar guidelines to OECD TG 401 both concluded on comparable LD50 of 1620 and 1570 mg/kg bw for the rat.</p> <p>Less reliable studies (poorly reported) mentioned LD50 < 2000 mg/kg bw in the rat and the mouse, which is consistent with the above mentioned LD50 and are therefore considered as supportive information. In the guinea pig, the LD50 was determined to be between 1040 and 2600 mg/kg bw.</p> <p>Therefore, a LD50 < 2000 mg/kg bw warranting a classification as Acute Tox. 4 is supported by BECA. Furthermore, an ATE of 1570 mg/kg bw (the most sensitive LD50, from one the most reliable studies, probably combined for both sexes) is supported. However, it should be stressed that no purity was stated and the reliability of this study is considered to bare several restrictions.</p> <p>DERMAL</p> <p>Three poorly reported studies are available for the following species: Guinea pig, cat and rabbit. All the mentioned LD50 are above 2000 mg/kg bw, not warranting a classification according to the CLP guidance for criteria. However, no data on either the rat, nor the mouse are available. Furthermore, the LD50 for the guinea pig is mentioned to be lower than 5000 mg/kg bw. It is not excluded that this LD50 could be under 2000 mg/kg bw.</p> <p>In conclusion, BECA is of the opinion that there is not enough data to correctly assess this endpoint and therefore considers that there is not enough data to conclude. However, BE CA notes that benzyl alcohol is currently classified Acute Tox 4* (H332, dermal) according to the former Directive on chemicals. BE CA would therefore kindly ask the Dossier Submitter to detail the grounds of the actual Acute Tox 4* (H332) classification and to ensure that all available information is detailed in the CLH dossier, including the studies used to justify this classification according to the former Directive.</p> <p>INHALATION</p> <p>Five studies are available for this endpoint. Two studies, with more reliable data (test design similar to OECD 403 and GLP-compliance), exposed rats to an aerosol of benzyl alcohol. They concluded on a LC50 > 4.18 and LC50 > 5.4 mg/L for <anonymous> 1990 and <anonymous> 1993, respectively. BECA agrees that the studies conducted with aerosol do not seem to warrant any classification for benzyl alcohol since the LC50 of 4.18 induced only transient effects (no more details) and it could be expected that death would have occurred at a much higher concentration.</p> <p>However, other studies conducted with vapours of benzyl alcohol concluded on a LC50 that could warrant a classification as acute tox. 4 (<anonymous> 1951 and <anonymous> 1949). These findings are very poorly reported and analytical concentrations were not monitored. Concerning the remaining study, the DS highlighted that the LC50 value proposed by <anonymous> (1982) was questionable.</p> <p>The relevant guidance values for classification as Acute Tox. are:</p> <ul style="list-style-type: none"> - For aerosol: 1.0 < ATE < 5.0 (Acute Tox. cat.4) - For vapours: 2.0 < ATE < 10.0 mg/L (Acute Tox. cat.3) and 10.0 < ATE < 20.0 mg/L (cat. 4) <p>All in all, it looks like benzyl alcohol behaves differently depending of its form and may induce toxic effects when the animals are exposed to vapours of the test substance, but</p>				

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not to aerosol. Since the reliability of the studies is quite low considering the poor amount of available information, and the previous owned classification of benzyl alcohol as Acute Tox. 4; H332, BECA is of the opinion to consider the available data as inconclusive.
Dossier Submitter's Response
RAC's response

OTHER HAZARDS AND ENDPOINTS – Eye Hazard

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France		MemberState	8
Comment received				
Eye irritation: FR agrees with the classification as Eye Irrit 2 based on the in vivo data on rabbit.				
Dossier Submitter's Response				
RAC's response				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United States	Household & Commercial Products Association	Industry or trade association	9
Comment received				
N/A				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment HCPA Comments on Proposal for Harmonized Classification and Labelling on Benzyl Alcohol NC.pdf				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment HCPA Comments on Proposal for Harmonized Classification and Labelling on Benzyl Alcohol.pdf				
Dossier Submitter's Response				
RAC's response				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium		MemberState	10
Comment received				
In line with the current classification, BECA supports the classification proposed for benzyl alcohol as Eye Irrit. Cat. 2 (H319 – causes serious eye irritation), based on two different studies showing consistent results, including corneal opacity ≥ 1 and for conjunctival				

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redness ≥ 2 for all three animals in each study. The effects were however fully reversible within 21 days.
Dossier Submitter's Response
RAC's response

OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	Johnson & Johnson Santé Beauté France	Company-Downstream user	11

Comment received
<p>Johnson & Johnson Consumer Health welcomes the opportunity to provide its views on the proposed classification of Benzyl Alcohol (CAS: 100-51-6, EC: 202-859-9) under Regulation (EC) n°1272/2008 on classification, labelling and packaging of substances and mixtures.</p> <p>While Johnson & Johnson Consumer Health supports efforts to harmonize classification and ensure high protection of workers, consumers and environment, Johnson & Johnson Consumer Health believes the proposed classification of benzyl alcohol as Skin Sens. 1B appears to be overly conservative given the extensive safety data, both from external professional dermatology literature as well as our pre-market safety evaluations.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Benzyl Alcohol public consultation JJ non confidential.pdf</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Benzyl Alcohol public consultation JJ confidential.pdf</p>
Dossier Submitter's Response
RAC's response

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United States	Household & Commercial Products Association	Industry or trade association	12

Comment received
<p>HCPA does not believe the data supports the proposed classification as it is inconsistent and the conclusions presented are not aligned with the reports from RIFM (pages 1-2).</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment HCPA Comments on Proposal for Harmonized Classification and Labelling on Benzyl Alcohol NC.pdf</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment HCPA Comments on Proposal for Harmonized Classification and Labelling on Benzyl Alcohol.pdf</p>
Dossier Submitter's Response
RAC's response

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Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	United Kingdom		Individual	13
Comment received				
Please see attachment				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Benzyl Alcohol. Animal and in vitro data. 10th December 2020.pdf				
Dossier Submitter’s Response				
RAC’s response				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Netherlands	Valtris AO Maastricht BV	Company-Manufacturer	14
Comment received				
<p>As a manufacturer of benzyl alcohol for multiple decades, Valtris AO Maastricht BV is highly committed to the safety of the products we manufacture. The well-being and health of our employees and customers is one of our top priorities.</p> <p>During all these years of manufacturing benzyl alcohol by Valtris and its predecessors, no cases of skin sensitization due to the aforementioned product were reported by our employees. This is confirmed by the attached statement issued by our health and safety provider DPSO Arbozorg. Moreover, whilst supplying this product to a multitude of different markets, including to the personal care industry, no issues about skin sensitization by benzyl alcohol have been notified to us by our customers.</p> <p>We understand that the above-mentioned examples have limited scientific value. However, for the scientific arguments with regard to our position, we refer to the comments submitted by Lanxess Germany GmbH on behalf of the consortium for the registrants of benzyl alcohol under REACH. Valtris fully supports the points raised by Lanxess and believes these comments clearly indicate that the currently available human and animal data are inconsistent and do not clearly demonstrate that benzyl alcohol can be classified as a skin sensitizer.</p> <p>We therefore strongly recommend the Committee to take into account the arguments submitted on behalf of the consortium in order to avoid an overly conservative classification of benzyl alcohol as skin sensitizer.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachments Valtris AO Maastricht BV on skin sensitization proposal benzyl alcohol.zip</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Confidential attachments Valtris AO Maastricht BV on skin sensitization proposal benzyl alcohol.zip</p>				
Dossier Submitter’s Response				

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RAC's response

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	Germany	Working Group Epoxy Resins	National NGO	15

Comment received

Benzyl alcohol is a common ingredient of epoxy resin products. Due to the extremely low sensitisation reaction and taking into account the very wide distribution of benzyl alcohol in different products, the working group does not consider this substance to be an allergen.

For substances whose sensitising property is not clear, chapter 3.4.2.2. of Regulation (EC) No 1272/2008 must be applied. According to this regulation, small numbers of cases may lead to classification. However, an evaluation of over 70,000 cases, carried out by the IVDK shows very few and then only weak, often ambiguous reactions to benzyl alcohol (personal communication from Prof. <confidential>, IVDK, publication in preparation). According to chapter 3.4.2.2. of Regulation (EC) No 1272/2008, these aspects must be considered.

The consequences of labelling benzyl alcohol with H317 would have a serious impact on the necessary substitution check for users of products containing benzyl alcohol, which is required according to the risk assessment. The procedure is described in the TRGS 600.

The substitution check stipulates that benzyl alcohol, as a substance classified as skin-sensitising (high risk), must be replaced by corrosive or eye-damaging substances (medium risk). In this specific case, this leads to an increase of risk.

Products that are already labeled with H317 and contain very potent allergens can thus be used because they are equivalent. This applies e.g. for epoxy resins, which have excellent technical properties, but can lead to severe and recurring allergic skin diseases after just a few contacts.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Statement_WG_ER_benzyl_alcohol_2020_Redacted.pdf

Dossier Submitter's Response

RAC's response

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Lanxess Deutschland GmbH	Company-Manufacturer	16

Comment received

Please refer to the attachment for further information

ECHA note – An attachment was submitted with the comment above. Refer to public attachment LetterBzOH_ECHA_HarmonisedClassification_final_171220_Redacted.pdf

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ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Benzylalkohol_Med_Stellungnahme_08092019.pdf
Dossier Submitter’s Response
RAC’s response

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium		MemberState	17

Comment received

Available animal dataset indicates heterogenous results for benzyl alcohol skin sensitisation potential : one LLNA (RFIM, 2005a), two GPMT (<anonymous>, 1981; <anonymous> 1977), three Draize test (<anonymous>, 1981; <anonymous> 1977; <anonymous>, 1978) and two epicutaneous test (<anonymous>, 1979; <anonymous>, 1986) were concluded negative ; benzyl alcohol was concluded as a weak sensitizer in one FCA test (<anonymous>, 1991) and one delayed contact hypersensitivity test (<anonymous>, 1993) and showed clear positive results in three FCA test (<anonymous>, 1981; <anonymous>, 1977, <anonymous>, 1992), two epicutaneous test (<anonymous>, 1981; <anonymous>, 1977) and one GPMT (<anonymous>, 1986). All studies are considered of limited reliability.

Furthermore, there are several evidences of skin sensitisation in human exposed to benzyl alcohol. A human repeated insult patch tests with doses ranging from 3 543 µg/cm² to 23 622 µg/cm² showed dose-dependent increase in numbers of sensitised subjects (0 – 11%) above 7.5% benzyl alcohol (RIFM). Due to the large presence of this compound in cosmetic products, it could not be excluded that the volunteers were already sensitised to benzyl alcohol. In contrast, a HMT on 25 volunteers showed negative results for 10% benzyl alcohol (RFIM). We however note that this study is older that the RIFM and of limited reliability. BE CA is of the view that the HMT study is not sufficient to discard positive results in other studies.

In addition, several human patch tests are described in the CLH proposal. Sensitisation rates ranged 0.1-2.3 % with a concentration of 1% benzyl alcohol and were comprised between 0.21-1.1 % with a concentration of 10% benzyl alcohol. The studies in which the concentration of benzyl alcohol used is not specified were up to 2% positives. Further human patch studies were also described in a review from 2012 (<anonymous>). The studies described were performed with concentrations ranging from 0.2 to 20 % benzyl alcohol. The observed frequency of skin reactions ranged from 0 to 20 %. Considering studies with > 100 patients only, the sensitisation rates range from 0 up to 7.8 % (14 studies < 1 % and 9 studies > 1 %), whereas 12 of the studies did not show any positive reactions.

Finally, various case reports were also available in the CLH proposal, showing evidences of skin sensitisation after exposure to 0.1-9.5 % benzyl alcohol, indicating that benzyl alcohol has the potential to cause skin sensitisation in humans with a relatively low frequency of occurrence.

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Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France		MemberState	18
Comment received				
<p>Skin sensitisation:</p> <p>No classification can be reached based on the experimental studies: contradictory results were obtained from under-reported studies that prevent independent interpretation.</p> <p>Positive results from HRIPT and Maximisation assays seem questionable since dermal reactions are already observed during the induction phase. No additional reactions are observed after challenge (and sometimes less reactions after rechallenge). Thus, discrimination of sensitizing versus irritation effects should be further discussed for adequate interpretation of these studies.</p> <p>Regarding patch test diagnostic studies in table 15, it is not clear in most of the described studies if the patients included are selected or unselected. From these studies, sensitisation rates > 1% were reported in 3 studies but only consist in 1 to 5 positive cases among the patients tested. This suggests a very low frequency of dermal sensitisation. From table 16, studies report sensitisation rates: from 0% to 20% (19/95 cases), however, it is difficult to explain these different values by the vehicle and the concentrations used.</p> <p>Overall, the dataset is not very consistent with a wide range of responses based on in vitro assays, in vivo experimental studies and human data. However, considering the low frequency of reactions associated with a high exposure in humans in regards to CLP criteria, FR agrees with the proposal Skin Sens. 1B.</p>				
Dossier Submitter's Response				
RAC's response				

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	Germany	IVDK - Information Network of Departments of Dermatology, Institute at the University Medical Center Göttingen	Academic institution	19
Comment received				
<p>Section 9.7 "Skin sensitisation" (p. 16-33), in particular sections 9.7.2 and 9.7.6.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment IVDK Comment on Benzyl alcohol.zip</p>				
Dossier Submitter's Response				
RAC's response				

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Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	United States	Emerald Kalama Chemical B.V.	Company-Manufacturer	20
Comment received				
<p>Emerald Kalama Chemical B.V. disagrees with the proposed classification of benzyl alcohol as Skin Sens. 1B. We base our conclusion on the same data set referenced in the CLH report, and have provided detailed comments on key elements. We would specifically like to direct attention to the 2018 MAK Value Review for benzyl alcohol. As a general point, Emerald feels that both the animal and human data on skin sensitisation potentially caused by benzyl alcohol are inconsistent, and do not support the proposed classification. Please see our detailed comments attached.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Benzyl Alcohol CLH Consultation - EKC BV Comments - 16 Dec 2020_Redacted.pdf</p>				
Dossier Submitter's Response				
RAC's response				

PUBLIC ATTACHMENTS

1. Benzyl Alcohol public consultation JJ non confidential.pdf [Please refer to comment No. 11]
2. HCPA Comments on Proposal for Harmonized Classification and Labelling on Benzyl Alcohol NC.pdf [Please refer to comment No. 3, 6, 9, 12]
3. LetterBzOH_ECHA_HarmonisedClassification_final 171220_Redacted.pdf [Please refer to comment No. 2, 16]
4. Benzyl Alcohol CLH Consultation - EKC BV Comments - 16 Dec 2020_Redacted.pdf [Please refer to comment No. 20]
5. Public attachments Valtris AO Maastricht BV on skin sensitization proposal benzyl alcohol.zip [Please refer to comment No. 14]
6. Statement_WG_ER_benzyl_alcohol_2020_Redacted.pdf [Please refer to comment No. 15]
7. IVDK Comment on Benzyl alcohol.zip [Please refer to comment No. 4, 19]

CONFIDENTIAL ATTACHMENTS

1. Benzyl Alcohol public consultation JJ confidential.pdf [Please refer to comment No. 11]
2. HCPA Comments on Proposal for Harmonized Classification and Labelling on Benzyl Alcohol.pdf [Please refer to comment No. 3, 6, 9, 12]
3. Benzylalkohol_Med_Stellungnahme_08092019.pdf [Please refer to comment No. 2, 16]
4. Confidential attachments Valtris AO Maastricht BV on skin sensitization proposal benzyl alcohol.zip [Please refer to comment No. 14]
5. Benzyl Alcohol. Animal and in vitro data. 10th December 2020.pdf [Please refer to comment No. 13]