

**Committee for Risk Assessment**  
**RAC**

Annex 2  
**Response to comments document (RCOM)**  
to the Opinion proposing harmonised classification and  
labelling at EU level of

**Benzyl salicylate**

**EC Number: 204-262-9**  
**CAS Number: 118-58-1**

CLH-O-0000001412-86-267/F

**Adopted**  
**15 March 2019**

## ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON BENZYL SALICYLATE

### COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public 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 public 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 public 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.

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**Substance name: benzyl salicylate**

**EC number: 204-262-9**

**CAS number: 118-58-1**

**Dossier submitter: Germany**

### OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
19.09.2018	Finland		MemberState	1
Comment received				
<p>The FI CA supports the proposal to classify benzyl salicylate as Skin Sens. Category 1B (H317 - May cause an allergic skin reaction).</p> <p>For your information two additional information sources:</p> <p>The Scientific Committee on Consumer Safety (SCCS) opinion on fragrance allergens from 2012 contains assessment of available information on benzyl salicylate as well as other fragrance allergens up to year 2011 (SCCS 2012). The SCCS considered a number of surveys on the presence and content of certain fragrances in consumer products, based mostly on labelling information. Benzyl salicylate was found present in 9.6 – 38.9 % of the products covered. Benzyl salicylate was reported to be one of the most frequently reported and well-recognised consumer allergens.</p> <p>The International Fragrance Association (IFRA) has established maximum recommended limits of benzyl salicylate in specific product categories based on a quantitative risk assessment approach (IFRA 2007). The maximum limits of benzyl salicylate in leave-on cosmetic products are between 0.5-8.0% depending on the specific product category. The recommended limits for rinse-off cosmetic products are between 5.0-12.8% and 2.5 % for non-cosmetic products with direct skin contact. If IFRA recommendations have been implemented most products appear to contain low concentrations of benzyl salicylate today.</p> <p>As benzyl salicylate is widely used in many different types of consumer products, repeated exposure every day seems very likely. Today, skin exposure can be considered to be relatively high. Historical exposure levels that have induced the sensitisation in the positive patch tests is not known but as concluded in CLH report these probably were relatively high.</p> <p>SCCS, 2012. SCCS (Scientific Committee on Consumer Safety), opinion on fragrance allergens in cosmetic</p>				

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<p>products, 26-27 June 2012.</p> <p>IFRA, 2007: IFRA Standard Benzyl salicylate. 42nd amendment to the IFRA code of practice, International Fragrance Association. <a href="http://www.ifraorg.org/en-us/standards">http://www.ifraorg.org/en-us/standards</a></p>
<b>Dossier Submitter's Response</b>
<p>We thank FI CA for the support to classify benzyl salicylate as Skin Sens. 1B. We also acknowledge the additional comments provided to the CLH Report. We checked the two additional sources suggested by FI CA and we agree that the opinion of the Scientific Committee on Consumer Safety (SCCS) on fragrance allergens should be included in the current CLH Report. More specifically we would like to add the following citation: "Benzyl salicylate was found present in 9.6 – 38.9 % of the products covered. Benzyl salicylate was reported to be one of the most frequently reported and well-recognised consumer allergens." SCCS, 2012. SCCS (Scientific Committee on Consumer Safety), opinion on fragrance allergens in cosmetic products, 26-27 June 2012.</p>
<b>RAC's response</b>
<p>Thank you for your comment and for the additional references. RAC agrees with the proposed classification as Skin Sens. 1B.</p>

Date	Country	Organisation	Type of Organisation	Comment number
06.09.2018	France		MemberState	2
<b>Comment received</b>				
<p>Based on animal data, FR agrees the substance should be classified Skin Sens 1B.</p> <p>Based on a human maximisation test, the International Fragrance Association (IFRA) reported a No Expected Sensitisation Induction Level (NESIL) of 17 700 µg/cm<sup>2</sup> and therefore classified benzyl salicylate as a weak sensitiser.</p> <p>Reports from the Scientific Committee on Cosmetic Products and Non-food Products (SCCNFP), 1999 and the Scientific Committee on Consumer Safety (SCCS) list benzyl salicylate as an allergen. Benzyl salicylate is on List A : "Fragrance chemicals, which according to existing knowledge, are most frequently reported and well-recognised consumer allergens" according to SCCS/1459/11 (2012).</p> <p>Benzyl salicylate is listed in the therapeutic Goods (permissible Ingredients) Determination No. 3 of 2017 and if used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> <p>Human data on skin sensitization provide positive and negative results. Due to a high concentration applied to the skin (above 5%), a high frequency of allergic contact dermatitis has been often reported. According to CLP criteria, only a category 1 without subcategorization could be reached based on the large variability in the frequency of skin sensitisation.</p>				
<b>Dossier Submitter's Response</b>				
<p>We thank FR CA for supporting our classification of benzyl salicylate as Skin Sens. 1B. We also acknowledge the additional comments to the CLH Report.</p>				
<b>RAC's response</b>				
<p>Thank you for your comments. RAC agrees with the proposed classification as Skin Sens. 1B.</p>				