

Benzyl salicylate

CAS N°:	118-58-1	Empirical formula:	C ₁₄ H ₁₂ O ₃
Structure:			
Synonyms:	Benzoic acid, 2-hydroxy-, phenylmethyl ester Benzyl 2-hydroxybenzoate Benzyl o-hydroxybenzoate 2-Hydroxybenzoic acid, benzyl ester Phenylmethyl 2-hydroxybenzoate Salicylic acid, benzyl ester		

History:	Initial reviews:	New Standard	
	Current revision date:	2007	
	Implementation date:	For new submissions*:	June 16, 2007
		For existing fragrance compounds*:	June 16, 2009
Next review date	2012		

* This date applies to the supply of fragrance compounds (formulas) only, not to the finished products in the marketplace.

RECOMMENDATION:	RESTRICTED
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RESTRICTIONS:

Limits in the finished product:			
Category 1 See Note box (1)	0.5 %	Category 7	1.3 %
Category 2	0.7 %	Category 8	2.0 %
Category 3	2.7 %	Category 9	5.0 %
Category 4	8.0 %	Category 10	2.5 %
Category 5	4.2 %	Category 11	See Note box (2)
Category 6	12.8 %		
Note box:			
(1) IFRA would recommend that any material used to impart perfume or flavour in products intended for human ingestion should consist of ingredients that are in compliance with appropriate regulations for foods and food flavourings in the countries of planned distribution and, where these are lacking, with the recommendations laid down in the Code of Practice of IOFI (International Organisation of the Flavor Industry - www.iofi.org.org)			
(2) Category 11 includes all non-skin contact or incidental skin contact products. Due to the negligible skin contact from these types of products there is no justification for a restriction of the concentration of this fragrance ingredient in the finished product.			
Fragrance material specifications:		N/A	

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CONTRIBUTION FROM OTHER SOURCES:

See Annex I

CRITICAL EFFECT:

SENSITIZATION

RIFM SUMMARIES:

LLNA weighted mean EC3 values ($\mu\text{g}/\text{cm}^2$) [no. studies]	Potency Classification Based on Animal Data ²	Human Data			WoE NESIL ³ ($\mu\text{g}/\text{cm}^2$)
		NOEL – HRIPT (induction) ($\mu\text{g}/\text{cm}^2$)	NOEL – HMT (induction) ($\mu\text{g}/\text{cm}^2$)	LOEL ¹ (induction) ($\mu\text{g}/\text{cm}^2$)	
725 [1]	Weak	17717	20690	NA	17700

NOEL = No observed effect level; HRIPT = Human Repeat Insult Patch Test; HMT = Human Maximization Test; LOEL = lowest observed effect level; NA = Not Available.

¹Data derived from HRIPT or HMT.

²Gerberick *et al.*, 2001

³WoE NESIL limited to two significant figures.

REXPAN RATIONALE / CONCLUSION:

The RIFM Expert Panel reviewed the critical effect data for benzyl salicylate and, based on the weight of evidence, established the No Expected Sensitization Induction Level (NESIL) as 17700 $\mu\text{g}/\text{cm}^2$. They recommend the limits for the 11 different product categories, which are the acceptable use levels of benzyl salicylate in the various product categories. These were derived from the application of the exposure-based quantitative risk assessment approach for fragrance ingredients, which is detailed in the QRA Expert Group Technical Dossier of June 22, 2006.

REFERENCES:

Gerberick, GF. et. al. (2001) Contact allergenic potency: Correlation of human and local lymph node assay data. *American Journal of Contact Dermatitis*, 12(3), 156-161

RIFM (Research Institute for Fragrance Materials, Inc.), 1970. Maximization test on Benzyl Salicylate. RIFM report number 1760, October 7. (RIFM, Woodcliff Lake, NJ, USA).

QRA Expert Group (AM Api, DA Basketter, PA Cadby, M-F Cano, G Ellis, GF Gerberick, P Griem, PM McNamee, CA Ryan and R Safford), Dermal Sensitization Quantitative Risk Assessment (QRA) for Fragrance Ingredients, Technical Dossier, March 15, 2006, <http://www.rifm.org/pub/publications.asp>.

RIFM (Research Institute for Fragrance Materials, Inc.), 1975a. Maximization test on Benzyl Salicylate. RIFM report number 1798, March 28. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 1975b. Maximization test on Benzyl Salicylate. RIFM report number 1799, March 27. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2004. Repeated Insult Patch Test on Benzyl Salicylate. RIFM report number 45129, May 3. RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2005. Local Lymph Node Assay on Benzyl Salicylate. RIFM report number 47378, January 20. (RIFM, Woodcliff Lake, NJ, USA)