

alpha-Bisabolol

CAS-No.:	515-69-5 23089-26-1 23178-88-3 78148-59-1 76738-75-5 72691-24-8 The scope of this Standard includes, but is not limited to the CAS number(s) indicated above; any other CAS number(s) used to identify this fragrance ingredient should be considered in scope as well.
Synonyms:	$(R^*,R^*)\text{-}\alpha.,4\text{-Dimethyl-}.\alpha.\text{-}(4\text{-methyl-}3\text{-pentenyl})\text{cyclohex-}3\text{-ene-}1\text{-methanol}\\ 3\text{-Cyclohexene-}1\text{-methanol},\ .\alpha.,4\text{-dimethyl-}\alpha.\text{-}(4\text{-methyl-}3\text{-pentenyl})\text{-},\ (R^*,R^*)\text{-}\\ 6\text{-Methyl-}2\text{-}(4\text{-methyl-}3\text{-cyclohexen-}1\text{-yl})\text{-}5\text{-hepten-}2\text{-ol}\\ 3\text{-Cyclohexene-}1\text{-methanol},\ \alpha,4\text{-dimethyl-}\alpha\text{-}(4\text{-methyl-}3\text{-penten-}1\text{-yl})\text{-},\ (\alpha S,1S)\text{-}\\ 3\text{-Cyclohexene-}1\text{-methanol},\ \alpha,4\text{-dimethyl-}\alpha\text{-}(4\text{-methyl-}3\text{-penten-}1\text{-yl})\text{-},\ (\alpha R,1R)\text{-}\\ 3\text{-Cyclohexene-}1\text{-methanol},\ \alpha,4\text{-dimethyl-}\alpha\text{-}(4\text{-methyl-}3\text{-penten-}1\text{-yl})\text{-},\ (\alpha R,1S)\text{-}\\ 3\text{-Cyclohexene-}1\text{-methanol},\ \alpha,4\text{-dimethyl-}\alpha\text{-}(4\text{-methyl-}3\text{-penten-}1\text{-yl})\text{-},\ (\alpha S,1R)\text{-}\\ alpha-Bisabolol\\ Bisabolol\\ Bisabolol\ nat.\ roh\ (Candela-Öl)\ (Commercial\ name)\\ Dragosantol\ (Commercial\ name)$

History:	Publication date:	2020 (Amendment 49)	Previous Publications:	Not applicable.

Implementation	For new creation*:	February 10, 2021	
dates:	For existing creation*:	February 10, 2022	
	*These dates apply to the supply of fragrance mixtu	res (formulas) only, not to the	
	finished consumer products in the marketplace.		

RECOMMENDATION:	RESTRICTION

MAXIMUM ACCEPTABLE CONCENTRATIONS IN THE FINISHED PRODUCT (%):				
Category 1	0.42 %	Category 7A	3.0 %	
Category 2	0.13 %	Category 7B	3.0 %	
Category 3	2.5 %	Category 8	0.20 %	
Category 4	2.4 %	Category 9	4.6 %	



al	pha-	Bisal	bolol	
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Category 5A	0.60 %	Category 10A	4.6 %
Category 5B	0.60 %	Category 10B	17 %
Category 5C	0.60 %	Category 11A	0.20 %
Category 5D	0.20 %	Category 11B	0.20 %
Category 6	1.4 %	Category 12	No Restriction

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Due to the possible ingestion of small amounts of fragrance ingredients from their use in products in Categories 1 and 6, materials must not only comply with IFRA Standards but must also be recognized as safe as a flavoring ingredient as defined by the IOFI Code of Practice (www.iofi.org). For more details see chapter 1 of the Guidance for the use of IFRA Standards.

CONTRIBUTIONS FROM OTHER SOURCES:

SEE ANNEX ON CONTRIBUTIONS FROM OTHER SOURCES

INTRINSIC PROPERTY MANAGEMENT:

DRIVING RISK

DERMAL SENSITIZATION AND SYSTEMIC TOXICITY

RIFM SUMMARIES:

Maximum acceptable concentrations are based on a comprehensive safety assessment, considering various endpoints. Depending on the outcome of the safety assessment, it might be one or more endpoint(s) that will drive the derivation of the concentration levels. If more than one endpoint is of relevance, the maximum acceptable concentrations for each product category are derived from comparing maximum permitted level per endpoint consideration (e.g. dermal sensitization and/or systemic toxicity). Such maximum acceptable concentrations correspond to the lowest level obtained per category.

Additional information is available in the RIFM safety assessment for alpha-Bisabolol, which can be downloaded from the RIFM Fragrance Material Safety Assessment Center: http://fragrancematerialsafetyresource.elsevier.com/.

EXPERT PANEL FOR FRAGRANCE SAFETY RATIONALE / CONCLUSION:

The Expert Panel for Fragrance Safety reviewed all the available data for alpha-Bisabolol and recommends the concentrations for the 12 different product categories, which are the maximum acceptable concentrations of alpha-Bisabolol in the various product categories.

REFERENCES:

The IFRA Standard on alpha-Bisabolol is based on at least one of the following publications:



alpha-Bisabolol

- The RIFM Safety Assessment on alpha-Bisabolol if available at the RIFM Fragrance Material Safety Assessment Center: http://fragrancematerialsafetyresource.elsevier.com
- Api A.M., Belsito D., Bruze M., Cadby P., Calow P., Dagli M. L., Dekant W., Dent M., Ellis G., Fryer A. D., Fukayama M., Griem P., Hickey C., Kromidas L., Lalko J., Liebler D.C., Miyachi Y., Politano V.T., Renskers K., Ritacco G., Salvito D., Schultz T.W., Sipes I. G., Smith B., Vitale D., Wilcox D.K. (2015). Criteria for the Research Institute for Fragrance Materials, Inc. (RIFM) safety evaluation process for fragrance ingredients. Food Chem Toxicol. 2015 Aug;82 Suppl:S1-S19 (http://fragrancematerialsafetyresource.elsevier.com/sites/default/files/Criteria_Document_Final.pdf).
- Salvito D.T., Senna R. J., Federle T.W. (2002). A framework for prioritizing fragrance materials for aquatic risk assessment. Environ Toxicol Chem. 2002;21:1301-1308 (https://www.ncbi.nlm.nih.gov/pubmed/12069318).

Additional information on the application of IFRA Standards is available in the Guidance for the use of IFRA Standards, publicly available at www.ifrafragrance.org.