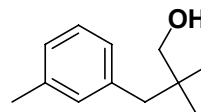


2,2-Dimethyl-3-(3-tolyl)propan-1-ol

CAS N°: 103694-68-4**Empirical formula:** C₁₂H₁₈O

Synonyms: Benzenepropanol, β, β, 3-trimethyl
 2,2-Dimethyl-3-(3-methylphenyl)propanol
 Majantol (commercial name)
 Linlan alcohol (commercial name)

Structure:

History: Initial reviews: July 2008 (43rd Amendment), March 2010
 Current revision date: June 11, 2010
Implementation date: For new submissions*: January 11, 2011
 For existing fragrance compounds*: January 11, 2012
Next review date: March 2015

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

RECOMMENDATION: RESTRICTED / SPECIFICATION

RESTRICTIONS:

Limits in the finished product:				
Category 1	See Note box (1)	0.28%	Category 7	0.8%
Category 2		0.36%	Category 8	2.0%
Category 3		1.5%	Category 9	5.0%
Category 4		4.5%	Category 10	2.5%
Category 5		2.4%	Category 11	See Note box (2)
Category 6	See Note box (1)	7.2%		
Note box: (1) See the IFRA Code of Practice (Appendix 8, Introduction to the IFRA Standards) regarding the Note on Oral Care Products and other products with the potential of ingestion. (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. This Standard replaces the existing one on 2,2-Dimethyl-3-(3-tolyl)propan-1-ol distributed with the 43rd Amendment, which only contained the restrictions based on the QRA.				
Fragrance material specifications: 2,2-Dimethyl-3-(3-tolyl)propan-1-ol should only be used as a fragrance ingredient if traces of organochlorine compounds are restricted. Total chlorine, which can be measured by Atomic Absorption Spectroscopy, must not exceed 25 ppm in the raw material.				

2,2-Dimethyl-3-(3-tolyl)propan-1-ol

Indicative contribution from other sources: None known at the time of the publication of the Standard

Critical effect: Sensitization

RIFM Summaries:

EC3 value from one LLNA (not the mean) (µg/cm ²)	Potency Classification Based on Animal Data ¹	Human Data			WoE NESIL ³ (µg/cm ²)
		NOEL – HRIPT (induction) (µg/cm ²)	NOEL – HMT (induction) (µg/cm ²)	LOEL ² (induction) (µg/cm ²)	
>7500	Weak	9900 ⁴	N/A	N/A	9900

All data in this Table are available from RIFM and are listed in the RIFM Database.

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

¹Based on animal data using classification defined in ECETOC, Technical Report No. 87, 2003.

²Data derived from HRIPT or HMT.

³WoE NESIL limited to two significant figures.

⁴MT-NOEL = Maximum Tested No Effect Level. No sensitization was observed in human predictive studies. Dose reported reflect the highest concentration tested, not necessarily the highest achievable NOEL.

REXPAN Rationale / Conclusion:

The RIFM Expert Panel reviewed the critical effect data for 2,2-Dimethyl-3-(3-tolyl)propan-1-ol and, based on the weight of evidence, established the No Expected Sensitization Induction Level (NESIL) as 9900 µg/cm². They recommend the limits for the 11 different product categories, which are the acceptable use levels of 2,2-Dimethyl-3-(3-tolyl)propan-1-ol 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:

RIFM (Research Institute for Fragrance Materials, Inc.), 2002. Local Lymph Node Assay. Unpublished report from Symrise GmbH & Co. KG, 9 December. Report number 49523 (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2005. Repeated Insult Patch Test. Unpublished report from Symrise GmbH & Co. KG,. Report number 49526 (RIFM, Woodcliff Lake, NJ, USA)

RIFM (Research Institute for Fragrance Materials, Inc.), 2007. Repeated Insult Patch Test. Unpublished report from Symrise GmbH & Co. KG, 26 September. Report number 53799 (RIFM, Woodcliff Lake, NJ, USA).