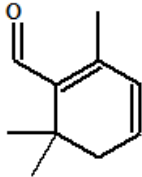


2,6,6-Trimethylcyclohex-1,3-dienyl methanal

CAS N°:	116-26-7	Empirical formula:	C ₁₀ H ₁₄ O
Structure:		Structure:	
Synonyms:	2,6,6-Trimethylcyclohexa-1,3-diene-1-carbaldehyde 2,6,6-Trimethyl-1,3-cyclohexadienal 2,6,6-Trimethyl-1,3-cyclohexadien-1-carboxaldehyde 1,1,3-Trimethyl-2-formylcyclohexa-2,4-diene Dehydro-β-cyclocitral Safranal		

History:	Initial reviews:	December 1998	
	Current revision date:	June 2013	
	Implementation date:	For new submissions*:	August 10, 2013
		For existing fragrance compounds*:	August 10, 2014
	Next review date	2018	

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

RECOMMENDATION:

RESTRICTED

RESTRICTIONS:

Limits in the finished product:			
Category 1 See Note box (1)	0.001 %	Category 7	0.002 %
Category 2	0.001 %	Category 8	0.005 %
Category 3	0.004 %	Category 9	0.005 %
Category 4	0.005 %	Category 10	0.005 %
Category 5	0.005 %	Category 11	See Note box (2)
Category 6	0.02 %		
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)			
(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	

CONTRIBUTION FROM OTHER SOURCES:

See **Annex I**

2,6,6-Trimethylcyclohex-1,3-dienyl methanal
CRITICAL EFFECT:
SENSITIZATION
RIFM SUMMARIES:

LLNA weighted mean EC3 values ($\mu\text{g}/\text{cm}^2$) [no. studies]	Potency Classification Based on Animal Data ¹	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 ² (induction) ($\mu\text{g}/\text{cm}^2$)	
<250 [1]	Strong	29.5	NA	39	29

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.

REXPAN RATIONALE / CONCLUSION:

The RIFM Expert Panel reviewed the critical effect data for 2,6,6-Trimethylcyclohexa-1,3-dienyl methanal and, based on the weight of evidence, established the No Expected Sensitization Induction Level (NESIL) as 29 $\mu\text{g}/\text{cm}^2$. They recommend the limits for the 11 different product categories, which are the acceptable use levels of 2,6,6-Trimethylcyclohexa-1,3-dienyl methanal 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 publication by Api *et al.*, 2008.

REFERENCES:

Api AM, Basketter DA, Cadby PA, Cano M-F, Ellis G, Gerberick G, et al. Dermal Sensitization Quantitative Risk Assessment (QRA) For Fragrance Ingredients. *Regulatory Toxicology and Pharmacology* 2008;52(1): 3-23.

RIFM (Research Institute for Fragrance Materials, Inc.), 2012. Repeat Insult Patch Test. Draft RIFM Report number 63809. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.) 2012. Local Lymph Node Assay. Draft RIFM Report number 63813. (RIFM, Woodcliff Lake, NJ, USA).