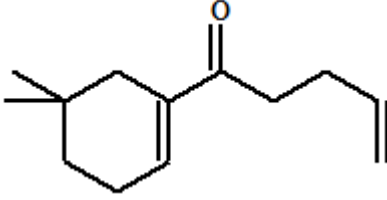


1-(5,5-Dimethyl-1-cyclohexen-1-yl)pent-4-en-1-one

CAS N°:	56973-85-4	Empirical formula:	C ₁₃ H ₂₀ O
Structure:			
Synonyms:	α-Dynascone 4-Penten-1-one, 1-(5,5-dimethyl-1-cyclohexen-1-yl)- Galbascone		

History:	Initial reviews:	New Standard		
	Current revision date:	2009		
	Implementation date:	For new submissions*:	August 7, 2009	
		For existing fragrance compounds*:	August 7, 2011	
	Next review date	2014		

* 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)	0.07 %	Category 7	0.19 %
Category 2	0.09 %	Category 8	2.00 %
Category 3	0.38 %	Category 9	5.00 %
Category 4	1.13 %	Category 10	2.50 %
Category 5	0.60 %	Category 11	See Note Box (2)
Category 6	1.81 %		
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 http://www.iofiorg.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:

None to consider (see also the note on contributions from other sources in the **Introduction to the IFRA Standards**)

CRITICAL EFFECT:
SENSITIZATION

1-(5,5-Dimethyl-1-cyclohexen-1-yl)pent-4-en-1-one

RIFM SUMMARIES:

LLNA weighted mean EC3 values (µg/cm ²) [no. studies]	Potency Classification Based on Animal Data ²	Human Data			WoE NESIL ³ (µg/cm ²)
		NOEL – HRIPT (induction) (µg/cm ²)	NOEL – HMT (induction) (µg/cm ²)	LOEL ¹ (induction) (µg/cm ²)	
745 [1] ^{4,5}	Moderate	2500	NA	NA	2500

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.

¹ Data derived from HRIPT or HMT.

² Based on animal data using classification defined in ECETOC, Technical Report No. 87, 2003.

³ WoE NESIL limited to two significant figures.

⁴ EC3 value from one LLNA, not the mean.

⁵ LLNA used a very wide spacing of doses. Based on the response at each dose the EC3 value would be slightly on the low side. The response in the LLNA was:

- 0.1% SI of 0.9
- 1.0% SI of 0.9
- 10% SI of 10.4
- 100% SI of 17.5

REXPAN RATIONALE / CONCLUSION:

The RIFM Expert Panel reviewed the critical effect data for 1-(5,5-Dimethyl-1-cyclohexen-1-yl)pent-4-en-1-one and, based on the weight of evidence, established the No Expected Sensitization Induction Level (NESIL) as 2500 mg/cm². They recommend the limits for the 11 different product categories, which are the acceptable use levels of 1-(5,5-Dimethyl-1-cyclohexen-1-yl)pent-4-en-1-one 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.), 1999. Human repeated insult patch test. Unpublished study from Firmenich Inc., 29a June. Report number 42138. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2001a. Local Lymph Node Assay. Unpublished study from Givaudan, 16 May. Report number 42073. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2001b. Human repeated insult patch test. Unpublished study from IFF Inc., 29 October. Report number 51118. (RIFM, Woodcliff Lake, NJ, USA).