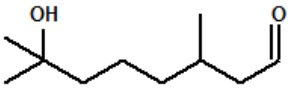
Hydroxycitronellal

CAS N°:	107-75-5	**Empirical formula:**	$C_{10}H_{20}O_2$
		Structure:	
Synonyms:	Citronellalhydrate 3,7-Dimethyl-7-hydroxyoctanal Octanal, 7-hydroxy-3,7-dimethyl- Oxydihydrocitronellal Laurinal, Laurine		

History:	Initial reviews:	March 1987, September 2000, April 2005, May 2007, June 2008	
	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)	0.1 %	Category 7	0.4 %
Category 2	0.2 %	Category 8	1.0 %
Category 3	0.8 %	Category 9	1.0 %
Category 4	1.0 %	Category 10	1.0 %
Category 5	1.0 %	Category 11	See Note box (2)
Category 6	3.6 %		

Note box:

For this material, for pragmatic reasons, restrictive levels allowed by the QRA for certain categories but actually being higher than those already in place before applying the QRA, will temporarily not be implemented until the end of a 5 year monitoring phase. At the end of the 5 years the position will be reevaluated again.
(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:

See **Annex II**

Hydroxycitronellal

CRITICAL EFFECT:	SENSITIZATION

RIFM SUMMARIES:

LLNA weighted mean EC3 values ($\mu g/cm^2$) [no. studies]	Potency Classification Based on Animal Data[1]	Human Data			WoE NESIL[3] ($\mu g/cm^2$)
		NOEL – HRIPT (induction) ($\mu g/cm^2$)	NOEL – HMT (induction) ($\mu g/cm^2$)	LOEL[2] (induction) ($\mu g/cm^2$)	
5612 [9]	Weak	5000[4]	NA	5906	5000

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

[1] Based on animal data using classification defined in ECETOC, Technical Report No. 87, 2003
[2] Data derived from HRIPT or HMT
[3] WoE NESIL limited to three significant figures
[4] MT-NOEL = Maximum Tested No Effect Level. No sensitization was observed in human predictive studies. Doses 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 Hydroxycitronellal and, based on the weight of evidence, established the No Expected Sensitization Induction Level (NESIL) as 5000 µg/cm². They recommend the limits for the 11 different product categories, which are the acceptable use levels of Hydroxycitronellal 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:

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Basketter, D. A., Wright, Z., Warbrick, E. V., Dearman, R. J., Kimber, I., Ryan, C. A.,

Gerberick, G. F., White, I. R., 2001. Comparison of the local lymph node assay with the guinea-pig maximization test for the detection of a range of contact allergens. *Food and Chemical Toxicology*, 30(1), 65-69.

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