Verbena absolute (Lippia citriodora Kunth.)

CAS N°:	8024-12-2 85116-63-8	**Empirical formula:** **Strucutre:**	N/A
Synonyms:	Lippia citriodora absolute Verbena absolute Aloysia triphylla absolute Lippia triphylla absolute Verbena triphylla absolute Zappania citrodora absolute		

History:	Initial reviews:	November 1987	
	Current revision date:	June 11, 2010	
	Implementation date:	For new submissions*:	August 11, 2010
		For existing fragrance compounds*:	August 11, 2011
	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**

RESTRICTIONS:

Limits in the finished product:			
Category 1 See Note box (1)	0.05%	Category 7	0.12%
Category 2	0.06%	Category 8	0.2%
Category 3	0.2%	Category 9	0.2%
Category 4	0.2%	Category 10	0.2%
Category 5	0.2%	Category 11	See Note Box (2)
Category 6	1.2%		

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) 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.

Fragrance material specifications:	N/A

CONTRIBUTION FROM OTHER SOURCES:

N/A

CRITICAL EFFECT:	**SENSITIZATION**

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RIFM SUMMARIES:

LLNA weighted mean EC3 values (µg/cm^2) [no. studies]	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)	
4500 [1][4]	Weak	1600	1380	8280[5]	1600

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]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 two significant figures.
[4]EC3 value from one LLNA, not the mean.
[5]LOEL from human maximization test, not a human repeated insult patch test.

REXPAN RATIONALE / CONCLUSION:

The RIFM Expert Panel reviewed the critical effect data for verbena absolute and, based on the weight of evidence, established the No Expected Sensitization Induction Level (NESIL) as 1600 µg/cm^2. They recommend the limits for the 11 different product categories, which are the acceptable use levels of verbena absolute 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 GF, 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.), 1979. Maximization study with verbena absolute. RIFM report number 1697, October 24a. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2009. Cutaneous tolerance and sensitizing potential of verbena. Unpublished study from Robertet, September 23. Report number 58178. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2009. Local Lymph Node Assay. Unpublished study from Robertet, January 23. Report number 54268. (RIFM, Woodcliff Lake, NJ, USA).