Styrax

CAS N°:	8046-19-3 8024-01-9 94891-27-7 94981-28-8	**Empirical formula:**	N/A
Synonyms:	**For the crude materials banned:** Styrax crude gums **For the distillates specified:** Stryax resin Styrax oil Styrax oil, rectified Styrax officinalis		

History:	Initial reviews:	November 1977, July 1994	
	Current revision date:	June 2013	
	Implementation date:	For new submissions*:	January 10, 2014
		For existing fragrance compounds*:	January 10, 2015
	Next review date	2018	

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

RECOMMENDATION:	**PROHIBITED / RESTRICTED**

RESTRICTIONS:

Limits in the finished product:			
Category 1 See Note box (1)	0.04 %	Category 7	0.11 %
Category 2	0.05 %	Category 8	0.60 %
Category 3	0.23 %	Category 9	0.60 %
Category 4	0.60 %	Category 10	0.60 %
Category 5	0.36 %	Category 11	See Note box (2)
Category 6	0.60 %		

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.

Fragrance material specifications:	**Crude gums of *Liquidambar styraficula* L. var. macrophylla or *Liquidambar orientalis* Mill. should not be used as fragrance ingredients**: Only extracts or distillates (resinoids, absolutes and oils), prepared from exudations of *Liquidambar styraciflua* L. var. macrophylla or *Liquidambar orientalis* Mill., can be used.This recommendation is made in order to promote good manufacturing practice (GMP) for the use of styrax derivatives as fragrance ingredients. It is based on a wide variety of RIFM test data with gums, resinoids, absolutes and oils of American and Asian styrax (private communication to IFRA). In addition, Styrax oil can be obtained from solvent extraction or pyrolysis. Styrax oil obtained through pyrolysis shall be rectified according to Good Manufacturing Practices and the content of **polynuclear aromatic hydrocarbons (PAH)** resulting from their use shall respect the following

Styrax

	requirement: **Benzopyrene and 1,2-Benzanthracene are to be used as markers for PAH. If used alone or in combination with rectified Cade oil, rectified Birch tar oils or rectified Opoponax oil, the total concentration of both of the markers should not exceed 1 ppb in the final product.**

CONTRIBUTION FROM OTHER SOURCES:

N/A

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) ($\mu g/cm^2$)	
> 1525 [1][4,5]	Moderate	1500[5]	NA	NA	1500

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]Study conducted on a well-characterized sample of Styrax oil – pyrogenated. The same sample was evaluated in both the LLNA and
HRIPT reported within the Standard.

REXPAN RATIONALE / CONCLUSION:

The RIFM Expert Panel reviewed the critical effect data for Styrax (all forms) and, based on the weight of evidence, established the No Expected Sensitization Induction Level (NESIL) as 1500 $\mu g/cm^2$. They recommend the limits for the 11 different product categories, which are the acceptable use levels of Styrax (all forms) 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.), 2012. Local Lymph Node Assay on Styrax Oil - Pyrogenated. Draft RIFM Report number 64109. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2012. Human Repeated Insult Patch Test on Styrax Oil - Pyrogenated. Draft RIFM Report number 64110. (RIFM, Woodcliff Lake, NJ, USA