Opoponax

CAS N°:	8021-36-1 9000-78-6 93384-32-8	**Empirical formula:**	N/A
Synonyms:	Opoponax (absolute, resinoid, oil, gum, tincture) Bisabol-myrrh Sweet myrrh Opoponax chironium (L.) W.D.J. Koch Commiphora erythraea Engler var. glabrescens (Burseraceae)		

History:	Initial reviews:	March 1978, 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:	**RESTRICTED**

RESTRICTIONS:

Limits in the finished product:			
Category 1 See Note box (1)	0.03%	Category 7	0.08%
Category 2	0.04%	Category 8	0.60%
Category 3	0.15%	Category 9	0.60%
Category 4	0.45%	Category 10	0.60%
Category 5	0.24%	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:	Opoponax oil can be obtained from solvent extraction or pyrolysis. Opoponax 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 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 Styrax oil, the total concentration of both of the markers should not exceed 1 ppb in the final product.**

Opoponax

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) ($\mu g/cm^2$)	
4450 – 5625 [2][4]	Weak	NA		NA	1000

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. A default value based on the LLNA data was employed because the material is used a very low volume and there are no HRIPT data.
[4] A range of values and not the weighted mean was provided because three studies were performed on three materials having different compositions – opoponax essential oil, opoponax extract and opoponax pyrogenated. Of these LLNAs, opoponax essential oil and opoponax pyrogenated resulted in a positive response.

REXPAN RATIONALE / CONCLUSION:

The RIFM Expert Panel reviewed the critical effect data for Opoponax (all forms) and, based on the weight of evidence, established the No Expected Sensitization Induction Level (NESIL) as 1000 $\mu g/cm^2$, which is a default value based on the LLNA data. They recommend the limits for the 11 different product categories, which are the acceptable use levels of Opoponax (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 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. Local Lymph Node Assay. Draft RIFM Report number 63817. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2012. Local Lymph Node Assay. Draft RIFM Report number 63818. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2012. Local Lymph Node Assay. Draft RIFM Report number 63819. (RIFM, Woodcliff Lake, NJ, USA).