

Tea leaf absolute

CAS N°:	84650-60-2	Empirical formula:	N/A
Synonyms:	Camellia sinensis leaf extract Tea, ext. Tea sinensis absolute Thea chinensis ext. Thea sinensis ext.		

History:	Initial reviews:		
	Current revision date:	2006	
	Implementation date:	For new submissions*:	June 11, 2007
		For existing fragrance compounds*:	June 11, 2008
	Next review date	2011	

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

RECOMMENDATION:	RESTRICTED
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RESTRICTIONS:

Limits in the finished product:			
Category 1 See Note box (1)	0.01 %	Category 7	0.04 %
Category 2	0.02 %	Category 8	0.5 %
Category 3	0.07 %	Category 9	2.4 %
Category 4	0.2 %	Category 10	2.5 %
Category 5	0.1 %	Category 11	See Note Box (2)
Category 6	0.3 %		
Note box:			
<p>(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.iofi.org/).</p> <p>(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.</p>			
Fragrance material specifications:		N/A	

CONTRIBUTION FROM OTHER SOURCES:

N/A

CRITICAL EFFECT:	SENSITIZATION
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RIFM SUMMARIES:

Tea Leaf Absolute - Sensitization Potency Estimation Based on Weight of Evidence

LLNA weighted mean EC3 values ($\mu\text{g}/\text{cm}^2$) [no. studies]	Potency Classification Based on Animal Data ²	Human Data			WoE NESIL ³ ($\mu\text{g}/\text{cm}^2$)
		NOEL – HRIPT (induction) ($\mu\text{g}/\text{cm}^2$)	NOEL – HMT (induction) ($\mu\text{g}/\text{cm}^2$)	LOEL ¹ (induction) ($\mu\text{g}/\text{cm}^2$)	
>1250[1] ⁴	Moderate	480	NA	NA	480

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 Irritation was observed at higher concentrations; EC3 value not calculable

REXPAN RATIONALE / CONCLUSION:

The RIFM Expert Panel reviewed the critical effect data for tea leaf absolute and based on the weight of evidence established the No Expected Sensitization Induction Level (NESIL) as 480 $\mu\text{g}/\text{cm}^2$. They recommend the limits for the 11 different product categories, which are the acceptable use levels of tea leaf 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 QRA Expert Group Technical Dossier of March 15, 2006.

REFERENCES:

Gerberick, GF. et. al. (2001) Contact allergenic potency: Correlation of human and local lymph node assay data. American Journal of Contact Dermatitis, 12(3), 156-161.

QRA Expert Group* (AM Api, DA Basketter, PA Cadby, M-F Cano, G Ellis, GF Gerberick, P Griem, PM McNamee, CA Ryan and R Safford), Dermal Sensitization Quantitative Risk Assessment (QRA) for Fragrance Ingredients, Technical Dossier, March 15, 2006, <http://www.rifm.org/pub/publications.asp>.

Research Institute for Fragrance Materials, Inc (1990). Delayed contact hypersensitivity study of tea leaf absolute in guinea pigs. RIFM report number 12409 (RIFM, Woodcliff Lake, NJ USA).

Research Institute for Fragrance Materials, Inc (2004). Repeated insult patch test of tea leaf absolute in human subjects. Unpublished report from Robertet Incorporated, Report number 44878 (RIFM, Woodcliff Lake, NJ USA).

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