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: New Standard

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.

STANDARD: **RESTRICTED**

RESTRICTIONS:

Limits in the finished product:
For a description of the categories, refer to the QRA Informational Booklet.

Category 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 (1)
Category 6	0.3 %		

Note box:

(1) Category 11 includes all non-skin contact or incidental skin contact products. Due to negligible skin contact the concentration of a fragrance ingredient should not exceed the usual concentration of the fragrance compound in the finished product.

For example, hypothetically if the usual concentration of a fragrance compound in the final product, for example a candle, is at 5%, then any individual fragrance ingredient (in this case tea leaf absolute) must not exceed 5% in the candle.

(2) Prior to the introduction of this Standard, this material was listed under the so-called 'other materials' due to insufficient data supporting its use.

Fragrance material specification: Not applicable

TEA LEAF ABSOLUTE

Contribution from other sources: Not applicable

Critical effect: **Sensitization**

RIFM Summaries:

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

LLNA weighted mean EC3 values (μg/cm^2) [no. studies]	Human Data			Potency Classification[2]	WOE NESIL[3] (μg/cm^2)
	NOEL – HRIPT (induction) (μg/cm^2)	NOEL – MAX (induction) (μg/cm^2)	LOEL[1] (induction) (μg/cm^2)		
> 1250 [1][4]	480	NA	NA	Moderate	480

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

[1]Data derived from HRIPT or Human Max tests
[2]Gerberick *et al*., 2001
[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 μg/cm2. 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:

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).

TEA LEAF ABSOLUTE

Research Institute for Fragrance Materials, Inc (2005). Local Lymph Node Assay on tea leaf absolute. Unpublished report from Robertet Incorporated, Report number 47597 (RIFM, Woodcliff Lake, NJ USA).