Bitter orange peel oil expressed

CAS N°:	68916-04-1 72968-50-4	**Empirical formula:** **Structure :**	N/A N/A
Synonyms:	Orange Peel Oil, Bitter (*Citrus aurantium* L. subsp amara L.) Bitter orange oil (*Citrus aurantium* L. subsp. amara L.) Citrus aurantium peel oil Curacao peel oil (*Citrus aurantium* L.) Daidai peel oil (*Citrus aurantium* L.)		

History:	Initial reviews:	October 1975, June 1992, July 2002	
	Current revision date:	2015	
	Implementation date:	For new submissions*:	Not applicable
		For existing fragrance compounds*:	Not applicable
	Next review date	2020	

* 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:			
Skin contact products:			
Leave on products:	1.25%	Rinse-off products:	No Restriction
		Including household cleaning products	
Non skin contact products:	No Restriction		
Note box:			
The Standard is set due to the phototoxic effects of the material. The limit only applies to applications on skin exposed to sunshine, excluding rinse-off products (please refer to Table 4 of the QRA booklet for more detailed information). If combinations of phototoxic fragrance ingredients are used, the use levels have to be reduced accordingly. The sum of the concentrations of all phototoxic fragrance ingredients, expressed in % of their recommended maximum level in the consumer product, shall not exceed 100. Note: See remark on phototoxic ingredients in the **Introduction to the IFRA Standards (Appendix 8 to the IFRA Code of Practice)** and the **Standard on Citrus oil and other furocoumarins-containing essential oils**.			
Fragrance material specifications:	N/A		

CONTRIBUTION FROM OTHER SOURCES:

None to consider (see also the note on the contributions from other sources in the **Introduction to the IFRA Standards**).

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CRITICAL EFFECT:	PHOTOTOXICITY

RIFM SUMMARIES:

Human Studies: The material was tested for phototoxic potential in human volunteers (Kaidbey and Kligman, 1980). Five µL/cm² of 100% bitter orange oil was applied to 2 cm² under occlusive tape. One cm circular sites were exposed to visible light or 20 J/ cm² UVA.

Reactions were read at 24 and 48 hours. All 8 subjects reacted.

Animal studies: The NOEL was based on studies conducted with pooled samples of bitter orange oil in one miniature swine and hairless mice, which showed NOEL of 6.25%.

LLNA weighted mean EC3 values (µg/cm²) [no. studies]	Potency Classification Based on Animal Data[2]	Human Data			WoE NESIL[3] (µg/cm²)
		NOEL – HRIPT (induction) (µg/cm²)	NOEL – HMT (induction) (µg/cm²)	LOEL[1] (induction) (µg/cm²)	
N/A	N/A	N/A	N/A	N/A	N/A

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]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 orange peel oil, bitter, and recommended that the skin contact level should change to 1.25%, incorporating a 5 fold uncertainty factor.

REFERENCES:

P.D. Forbes, F. Urbach and R.E. Davies (1977). Phototoxicity testing of fragrance raw materials. Food and Cosmetics Toxicology, 15, 55-60. Report number 1422.

Kaidbey, K.H. and Kligman, A.M. (1980). Identification of contact photosensitizers by human assay. Current Concepts in Cutaneous Toxicity, 55-68. Academic Press, NY. Report number 1995.

Research Institute for Fragrance Materials, Inc. (1972). Phototoxicity and irritation studies of fragrance materials in hairless mice and miniature swine. RIFM report number 2034, May 26.

Research Institute for Fragrance Materials, Inc. (1978). Phototoxicity and irritation studies of mice and pigs with fragrance materials. RIFM report number 2042, April 14.