

BITTER ORANGE PEEL OIL EXPRESSED

CAS N°: 68916-04-1
72968-50-4

Empirical formula: Not applicable

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

Current revision date: July 2002

Implementation date: for new submissions*: July 3, 2002

for existing fragrance compounds*: July 3, 2003

Next review date: July 2007

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

STANDARD: RESTRICTED

Limits in the finished product:

Skin contact products:	Non skin contact products: No restriction
Leave-on products*: 1.25 %	Purity: not applicable
Rinse-off products: No restriction <i>including household cleaning products</i>	Others: not applicable

Note box: *Applications on skin areas exposed to sunshine.

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.

For Bitter orange peel oil expressed the general Standard on "Citrus oils and other furocoumarin containing essential oils" also needs to be taken into account.

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Contribution from other sources: None known

Critical effect: **Photoirritation**

RIFM summaries:

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

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:

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.

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.

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