

Bitter orange peel oil expressed

CAS-No.:	68916-04-1 72968-50-4 The scope of this Standard includes, but is not limited to the CAS number(s) indicated above; any other CAS number(s) used to identify this fragrance ingredient should be considered in scope as well.	Molecular 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:	Publication date:	2020 (Amendment 49)	Previous Publications:	1975 1992 2002 2015
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Implementation dates:	For new submissions*:	February 10, 2021
	For existing fragrance compounds*:	February 10, 2022
*These dates apply to the supply of fragrance mixtures (formulas) only, not to the finished consumer products in the marketplace.		

RECOMMENDATION:	RESTRICTION
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RESTRICTION LIMITS IN THE FINISHED PRODUCT (%):			
Category 1	1.25 %	Category 7A	No Restriction
Category 2	1.25 %	Category 7B	1.25 %
Category 3	1.25 %	Category 8	1.25 %
Category 4	1.25 %	Category 9	No Restriction
Category 5A	1.25 %	Category 10A	No Restriction

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Category 5B	1.25 %	Category 10B	1.25 %
Category 5C	1.25 %	Category 11A	No Restriction
Category 5D	1.25 %	Category 11B	1.25 %
Category 6	1.25 %	Category 12	No Restriction

Fragrance ingredient restriction - Note box

The Standard is set due to the phototoxic effects of Bitter orange peel oil expressed. For more detailed information on the application of this Standard, please refer to the note on phototoxic ingredients in chapter 1 of the Guidance for the use of IFRA Standards.

If the level of furocoumarins is unknown, the restriction level specified in this IFRA Standard applies.

Combination effects of phototoxic ingredients are only taken into consideration for the furocoumarin-containing fragrance ingredients (extracts) listed in the IFRA Standard of Citrus oils and other furocoumarins containing essential oils.

If combinations of furocoumarin-containing phototoxic fragrance ingredients (extracts) are used, the use levels must be reduced accordingly. The sum of the concentrations of all furocoumarin-containing phototoxic fragrance ingredients (extracts), expressed in % of their recommended upper concentration level in the consumer product shall not exceed 100.

For qualities of the expressed oil in which the less volatile components have been concentrated by partial or total removal of the terpene fraction, this limit should be reduced in proportion to the degree of concentration.

FLAVOR REQUIREMENTS:	Due to the possible ingestion of small amounts of fragrance ingredients from their use in products in Categories 1 and 6, materials must not only comply with IFRA Standards but must also be recognized as safe as a flavoring ingredient as defined by the IOFI Code of Practice (www.iofi.org). For more details see chapter 1 of the Guidance for the use of IFRA Standards.
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CONTRIBUTIONS FROM OTHER SOURCES:	NONE TO CONSIDER (SEE ALSO THE SECTION ON CONTRIBUTIONS FROM OTHER SOURCES IN CHAPTER 1 OF THE GUIDANCE FOR THE USE OF IFRA STANDARDS)
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Bitter orange peel oil expressed**INTRINSIC PROPERTY DRIVING RISK PHOTOTOXICITY
MANAGEMENT:****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 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%.

The Expert Panel for Fragrance Safety recommended that the skin contact level should be 1.25%, incorporating a 5 fold uncertainty factor.

EXPERT PANEL FOR FRAGRANCE SAFETY RATIONALE / CONCLUSION:

The Expert Panel for Fragrance Safety reviewed all the available data for Bitter orange peel oil expressed and recommends the limits for the 12 different product categories, which are the acceptable use levels of Bitter orange peel oil expressed in the various product categories.

REFERENCES:

The IFRA Standard on Bitter orange peel oil expressed is based on at least one of the following publications:

- 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.
- IFRA Standard on Citrus oils and other furocoumarins containing essential oils.

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Additional information on the application of IFRA Standards is available in the Guidance for the use of IFRA Standards, publicly available at www.ifrafragrance.org.