

Angelica root oil

CAS-No.:	8015-64-3 84775-41-7 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:	Angelica archangelica oil Angelica archangelica root oil Angelica root oil (Angelica archangelica L.)		

History:	Publication date:	2020 (Amendment 49)	Previous Publications:	1975 1978 2001 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

RESTRICTION LIMITS IN THE FINISHED PRODUCT (%):			
Category 1	0.80 %	Category 7A	No Restriction
Category 2	0.80 %	Category 7B	0.80 %
Category 3	0.80 %	Category 8	0.80 %
Category 4	0.80 %	Category 9	No Restriction
Category 5A	0.80 %	Category 10A	No Restriction
Category 5B	0.80 %	Category 10B	0.80 %

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Category 5C	0.80 %	Category 11A	No Restriction
Category 5D	0.80 %	Category 11B	0.80 %
Category 6	0.80 %	Category 12	No Restriction

Fragrance ingredient restriction - Note box

The Standard is set due to the phototoxic effects of Angelica root oil. 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.

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.

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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INTRINSIC PROPERTY DRIVING RISK PHOTOTOXICITY MANAGEMENT:

RIFM SUMMARIES:

Two human phototoxicity studies were conducted.

In one study, the test material at concentrations of 1% and 5% was applied to the backs of 30 male volunteers for 48 hours, under occlusion. 23 hours after patch removal the sites were irradiated. Observations were made at 72 and 96 hours after application. No phototoxic reactions were observed in any subjects with either 1 or 5% concentrations of the test material (RIFM, 1975a).

In a second study, the test material was applied neat to 13 male and female volunteers. Six hours later, the test sites were exposed to UVA radiation. Positive reactions were observed in 5/13 subjects (Kaidbey and Kligman, 1978, 1980).

Additional studies are:

- 4% on guinea pigs, UVA, photoirritation observed in all animals, 20/20 (Guillot, et al, 1985).
- 100% on hairless mice, UV, photoirritation observed (RIFM, 1974. Forbes, et al, 1977). 0.78, 1.56, 3.125, 6.25, 12.5, 25, 50% on hairless mice. UV. Photoirritation observed at concentrations of 1.56% and higher (RIFM, 1975b).
- 0.375, 0.75, and 1.5% on hairless mice. Photoirritation observed at all concentrations (RIFM, 1987).

EXPERT PANEL FOR FRAGRANCE SAFETY RATIONALE / CONCLUSION:

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

REFERENCES:

The IFRA Standard on Angelica root oil is based on at least one of the following publications:

- Forbes P.D., Urbach F., and Davies R.E. (1977). Phototoxicity testing of fragrance raw materials. Food and Cosmetics Toxicology, 15, 55-60.
- Guillot, J.P., Gonnet, J.F., Loquerie, J.F., Martini, M.C., Convert, P., and Cotte, J. (1985). A new method for the assessment of phototoxic and photoallergic potentials by topical applications in the albino guinea pig. Journal of Toxicology: Cutaneous and Ocular Toxicology, 4(2), 117-133.
- Kaidbey, K.H. and Kligman, A.M. (1978). Identification of topical photosensitizing agents in humans. JID 70(3), 149-151.
- 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.
- Research Institute for Fragrance Materials, Inc. (1974). Phototoxicity and irritation test of

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fragrance materials in the mouse and miniature swine. RIFM report number 2037, 17 July.

- Research Institute for Fragrance Materials, Inc. (1975a). Phototoxicity and irritation test of fragrance materials in the mouse and miniature swine. RIFM report number 2038, 4 February.
- Research Institute for Fragrance materials, Inc. (1975b). Primary skin irritation and phototoxicity evaluation in human subjects with fragrance materials. RIFM report number 15092, December.
- Research Institute for Fragrance Materials, Inc. (1987). Phototoxicity dilution assay of angelica root oil in hairless mice. RIFM report number 5147, 26 May.
- IFRA Standard on Citrus oils and other furocoumarins containing essential oils.

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.