ANGELICA ROOT OIL

CAS N°: 8015-64-3 **Empirical formula:** Not applicable

Synonyms: **Angelica archangelica oil**
Angelica archangelica root oil
Angelica root oil (Angelica archangelica L.)

History: Initial reviews: June 1975, October 1978

Current revision date: September 2001

Implementation date: for new submissions*: Not applicable
for existing fragrance compounds*: Not applicable

Next review date: 2006

* 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:

Skin-contact products:

Leave-on products: 0.8% 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, excluding rinse-off products.

If combinations of phototoxic fragrance ingredients are used, the use levels have to be reduced accordingly. The sum of the concentrations of all phototoxic ingredients, expressed in % of their recommended maximum level in the consumer product shall not exceed 100.

Fragrance material specification: Not applicable

Contribution from other sources: None known

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Critical effect: **Phototoxicity**

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. Twenty-three 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).

- 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).

Rexpan Rationale / Conclusion:

The RIFM Expert Panel reviewed the critical effect data for angelica root oil and has no concerns with the current limit of 0.8% (September 2001).

References:

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

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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.