

Tagetes oil and absolute

CAS-No.:	<p>Prohibition of <i>Tagetes erecta</i>: 90131-43-4 8016-84-0</p> <p>Restriction and Specification of <i>Tagetes patula</i> and <i>Tagetes minuta</i>: 91722-29-1 8016-84-0 91770-75-1</p> <p>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 these fragrance ingredients should be considered in scope as well.</p>
Synonyms:	<p>Prohibition of <i>Tagetes erecta</i>:</p> <p><i>Tagetes erecta</i> L.</p> <p>Restriction and Specification of <i>Tagetes patula</i> and <i>Tagetes minuta</i>:</p> <p><i>Tagetes absolute</i> (<i>Tagetes patula</i> L.) <i>Tagetes patula absolute</i> <i>Tagetes patula, ext.</i> <i>Tagetes minuta absolute</i> <i>Tagetes oil</i></p>

History:	Publication date:	2020 (Amendment 49)	Previous Publications:	1986 2001 2015
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Implementation dates:	For new creation*:	February 10, 2021
	For existing creation*:	February 10, 2022
	*These dates apply to the supply of fragrance mixtures (formulas) only, not to the finished consumer products in the marketplace.	

RECOMMENDATION:	PROHIBITION / RESTRICTION / SPECIFICATION
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FRAGRANCE INGREDIENT PROHIBITION:	<p><i>Tagetes erecta</i> should not be used as a fragrance ingredient in any finished product application. Only <i>Tagetes patula</i> and <i>Tagetes minuta</i> should be used as fragrance ingredients according to the Restriction and Specification set in this Standard.</p>
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MAXIMUM ACCEPTABLE CONCENTRATIONS IN THE FINISHED PRODUCT (%):			
Category 1	0.010 %	Category 7A	0.10 %

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Category 2	0.010 %	Category 7B	0.010 %
Category 3	0.010 %	Category 8	0.010 %
Category 4	0.010 %	Category 9	0.10 %
Category 5A	0.010 %	Category 10A	0.10 %
Category 5B	0.010 %	Category 10B	0.010 %
Category 5C	0.010 %	Category 11A	No Restriction
Category 5D	0.010 %	Category 11B	0.010 %
Category 6	0.10 %	Category 12	No Restriction

Fragrance ingredient restriction - Note box
 The Standard is set due to the phototoxic effects of Tagetes oil and absolute. 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.
 The restriction only applies to Tagetes patula and Tagetes minuta.

FRAGRANCE INGREDIENT SPECIFICATION: The content of alpha-Terthienyl (Terthiophene, CAS number 1081-34-1) in Tagetes patula and Tagetes minuta oils and absolutes must not exceed 0.35 %.

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 BEYOND TRACES (SEE ALSO THE SECTION ON CONTRIBUTIONS FROM OTHER SOURCES IN CHAPTER 1 OF THE GUIDANCE FOR THE USE OF IFRA STANDARDS)

INTRINSIC PROPERTY DRIVING RISK MANAGEMENT: PHOTOTOXICITY

RIFM SUMMARIES:

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Tagetes oils and absolutes obtained from *Tagetes minuta* L. (syn. *Tagetes glandulifera* Schrank and *Tagetes patula* L.) were evaluated by RIFM (Letizia and Api, 2000).

A no effect level for phototoxicity of 0.05% was determined on humans using Egyptian *Tagetes minuta* (RIFM, 1986a).

The following studies have also been considered:

- At 0.003% in guinea pigs, no observable effects, 0/10 (RIFM, 1985a).
- At 0.01% in guinea pigs, phototoxicity observed, 8/10 (RIFM, 1985b).
- At 100% in mice, phototoxicity was observed, 6/6 (RIFM, 1986b).
- At 1% in mice, phototoxicity was observed, 6/6 (RIFM, 1986c).
- At 0.1% in mice, phototoxicity was observed, 6/6 (RIFM, 1986c).
- At 0.01% in mice, phototoxicity was observed, 2/6 (RIFM, 1986c).

EXPERT PANEL FOR FRAGRANCE SAFETY RATIONALE / CONCLUSION:

The Restriction and Specification of this Standard is based on the recommendations from the Scientific Committee on Consumer Safety (SCCS) Opinions on the fragrance ingredients *Tagetes minuta* and *Tagetes patula* extracts and essential oils (phototoxicity only) (SCCS/1551/15) (https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_172.pdf).

The Expert Panel for Fragrance Safety reviewed the SCCS Opinion SCCS/1551/15 for *Tagetes minuta* and *Tagetes Patula* and recommends the limits for the 12 different product categories, which are the acceptable use levels of *Tagetes minuta* and *Tagetes Patula* in the various product categories.

In addition, they recommend to use *Tagetes minuta* and *Tagetes Patula* according to the its specification above mentioned.

The Prohibition of this Standard is based on the Scientific Committee on Consumer Products (SCCP) Opinion on *Tagetes erecta*, *T. minuta* and *T. patula* Extracts and Oils (phototoxicity only) (SCCP/0869/05) (https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_025d.pdf).

The Expert Panel for Fragrance Safety recommends not to use *Tagetes erecta* in any finished product application.

REFERENCES:

The IFRA Standard *Tagetes* oil and absolute is based on at least one of the following publications:

- The RIFM Safety Assessment on *Tagetes* oil and absolute is available at the RIFM Safety Assessment Sheet Database: <http://fragrancematerialsafetyresource.elsevier.com/>.
- Api A.M., Belsito D., Bruze M., Cadby P., Calow P., Dagli M. L., Dekant W., Dent M., Ellis G., Fryer A. D., Fukayama M., Griem P., Hickey C., Kromidas L., Lalko J., Liebler D.C., Miyachi Y., Politano V.T., Renskers K., Ritacco G., Salvito D., Schultz T.W., Sipes I. G., Smith B., Vitale D., Wilcox D.K. (2015). Criteria for the Research Institute for Fragrance Materials, Inc. (RIFM) safety evaluation process for fragrance ingredients. *Food Chem Toxicol.* 2015 Aug;82 Suppl:S1-S19 (doi: 10.1016/j.fct.2014.11.014). (http://fragrancematerialsafetyresource.elsevier.com/sites/default/files/Criteria_Document_Final.pdf).
- IDEA project (International Dialogue for the Evaluation of Allergens) Final Report on the QRA2: Skin Sensitisation Quantitative Risk Assessment for Fragrance Ingredients, September 30, 2016 (<http://www.ideaproject.info/uploads/Modules/Documents/qra2-dossier-final--september-2016.pdf>).
- Salvito D.T., Senna R. J., Federle T.W. (2002). A framework for prioritizing fragrance materials for aquatic risk assessment. *Environ Toxicol Chem.* 2002;21:1301-1308.

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(<https://www.ncbi.nlm.nih.gov/pubmed/12069318>).

- Letizia C.S. and Api A.M (2000). A dermal safety evaluation of extracts from Tagetes plants used in fragrances. *The Toxicologist*, 54(1), 397.
- Research Institute for Fragrance Materials, Inc. (1985a). Guinea Pig Phototoxicity Test. Unpublished report from Givaudan. Report number 3361, 17 December.
- Research Institute for Fragrance Materials, Inc. (1985b). Guinea Pig Phototoxicity Test. Unpublished report from Givaudan. Report number 3362, 17 December.
- Research Institute for Fragrance Materials, Inc. (1986a). Human Photosensitization Test. RIFM report number 1690, 21 November.
- Research Institute for Fragrance Materials, Inc. (1986b). Mouse Phototoxicity Test. RIFM report number 3828, 25 June.
- Research Institute for Fragrance Materials, Inc. (1986c). Mouse Phototoxicity Test. RIFM report number 4343, 31 July.
- Scientific Committee on Consumer Safety (SCCS) Opinions on the fragrance ingredients *Tagetes minuta* and *Tagetes patula* extracts and essential oils (phototoxicity only) (SCCS/1551/15) (https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_172.pdf).
- Scientific Committee on Consumer Products (SCCP) Opinion on *Tagetes erecta*, *T. minuta* and *T. patula* Extracts and Oils (phototoxicity only) (SCCP/0869/05) (https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_025d.pdf).

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.