

Citrus oils and other furocoumarins containing essential oils

History:	Initial reviews:	December 1996	
	Current revision date:	2015	
	Implementation date:	For new submissions*:	Not applicable
		For existing fragrance compounds*:	Not applicable
	Next review date	2020	

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

RECOMMENDATION:	RESTRICTED
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RESTRICTIONS:

Limits in the finished product:			
<u>Skin contact products:</u>			
Leave-on products:	15 ppm 5-MOP	Rinse-off products:	No Restriction
		<i>Including household cleaning products</i>	
<u>Non skin contact products:</u>	No Restriction		
Note box:			
<p>The Standard is set due to the phototoxic effects of the material. The limit only applies to applications on skin exposed to sunshine, excluding rinse-off products (please refer to Table 4 of the QRA booklet for more detailed information).</p> <p>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.</p> <p>Note: See remark on phototoxic ingredients in the Introduction to the IFRA Standards (Appendix 8 to the IFRA Code of Practice).</p>			
Fragrance material specifications:		<p>Where the bergapten (5-methoxypsoralen) content of all relevant oils present in a compound has been determined, it is recommended that for applications on areas of skin exposed to sunshine, excluding bath preparations, soaps and other products which are washed off the skin, the total level of bergapten in the consumer products should not exceed 0.0015% (15 ppm). This is equivalent to 0.0075% (75 ppm) in a fragrance compound used at 20% in the consumer product.</p> <p>Where the level of bergapten has not been determined by appropriate methods, the limits specified in the guidelines on individual oils should apply.</p> <p>In those cases, where such oils are used in combination with other phototoxic ingredients, the additive effect has to be taken into consideration and 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.</p> <p>Restrictions for furocoumarin containing essential oils have been recommended for:</p> <p style="text-align: center;">Angelica root oil, Bergamot oil expressed, Bitter orange oil expressed, Cumin oil, Grapefruit oil expressed, Lemon oil cold pressed, Lime oil expressed, Rue oil.</p> <p>The following essential oils contain small amounts of phototoxic furocoumarins. These levels are not high enough to require special</p>	

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	<p>restrictions if used alone, but if used in combination with one or the other phototoxic essential oil, attention should be paid that the total level of bergapten (5-MOP) in the consumer product does not exceed 15 ppm. It is the responsibility of fragrance manufacturers to ensure that the level is observed.</p> <p>Typical levels of 5-MOP are the following: Petitgrain Mandarin oil - 50 ppm, Tangerine oil cold pressed - 50 ppm, Mandarin oil cold pressed - 250 ppm, Parsley leaf oil - 20 ppm.</p>
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CRITICAL EFFECT:	PHOTOTOXICITY
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REFERENCES:

These recommendations are based on the published phototoxic effects of bergapten and the established dose-effect relationships (Young at al., J. Photochem. Photobiol. B,7, 231 (1990); Dubertret et al. *ibid* 7, 251 (1990), *idem, ibid*, 7, 362 (1990).