

Categorizing Attar-type Fragrance Products for QRA

An exposure assessment, in support of the proposal to categorize these products in the framework of the RIFM/IFRA QRA for skin sensitizers.

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Safe usage and enjoyment of fragranced products by the consumer is enabled by a voluntarily regulated industry network of regional associations under the global remit of the International Fragrance Association (IFRA). IFRA works with the independent research organization, the Research Institute for Fragrance Materials (RIFM), to determine, implement and update the IFRA Standards, which, as one form, set maximum usage levels of restricted materials in different product types.

Since 2006, RIFM has used the quantitative risk assessment (QRA) method to determine which category of use a given product should be placed in, and therefore define the usage restrictions which should apply to that product to ensure consumer safety.¹⁻³ This method quantifies the degree to which the consumer is exposed via normal and foreseeable usage of the product by determining sensitization assessment factors (SAF) and the consumer exposure level (CEL) relating to the product use, and using these data to allocate the product to one of 11 product-type categories. **T-1** shows examples of products and their categorization under the QRA method, with examples taken from categories 1 to 5. Consideration of the available categories shows a lack of a suitable grouping for attars and attar-type products.

An Introduction to Attars

Attars are defined as neat oils that are alcohol-free and applied directly to the skin.^{4,5} This is a traditional, culturally significant fragrance product popular in the Middle East and India, a regional market of increasing importance for the fragrance industry. There is also a demand for this type of product in areas such as the United States, particularly in regions where a significant proportion of the population is of African, Indian, Middle Eastern or Latino origin.

The typical traditional attar is a neat mixture of essential oils, produced via steam-distillation into a base oil.⁶ The product may be sold decanted into small bottles at the point of purchase, or in prepackaged bottles of varying sizes, often of elaborate design. In the Middle East these may also be referred to as mukhallats, while in the United States the common term is “100% body oils.” The term “attar-type fragrances” is used here to refer to any alcohol-free fragrance oil applied to the skin as a neat fragrance.

A defining characteristic of attar-type products is that they are alcohol-free. The product categories used for eau de toilette and eau de parfum products (category 3 for male use, category 4 for



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female use; see **T-1**) are therefore not suitable, as they specify hydroalcoholic products. IFRA and RIFM have made provisions for the future addition of product types not considered in the initial QRA category list.⁷

Following the protocol defined by the RIFM QRA Expert Group, a study was designed to acquire reliable exposure data for this product in order to formally propose its addition to the QRA list of product categories.⁷

Methods

Information on typical product usage (method of application, areas of the body exposed, frequency of use) was acquired from local knowledge and personal experience of the author during trips to the United Arab Emirates (Dubai and Sharjah) and the United States (New York and New Jersey).

At a Glance

The list of product categories defined by the quantitative risk assessment (QRA) methodology in the International Fragrance Association (IFRA) Standards does not currently contain a suitable category for attars, neat oils applied directly to the skin. Using the recommended procedure for the addition of a new product type, exposure data and usage information was acquired to support the proposal for QRA categorization of attars and attar-type fragrances.

SAFs were defined based on section 3.2.3 and Table 2 of the QRA Expert Group's Dermal Sensitization Quantitative Risk Assessment for Fragrance Ingredients, Technical Dossier.²

Surface area of exposed skin was calculated using the body area measurements defined by Bremmer et al.⁸ Frequency of use was conservatively estimated based on personal observation.

Average amounts used per application were measured locally using volunteer consumers in typical fragrance stores in Dubai, New York and New Jersey.

The consumer exposure level (CEL) was calculated using the surface area, frequency of use and average amount per application, using methodology defined by Api et al. and the QRA Expert Group.^{1,2}

Results

T-2 shows the SAF for this product type, defined using the methodology outlined in section 3.2.3 and Table 2 of the QRA Expert Group's Dermal Sensitization Quantitative Risk Assessment for Fragrance Ingredients, Technical Dossier.²

T-1. Examples of IFRA categories and classes (categories 1–5)*

	Product type (QRA)	Class for IFRA certificate
Category 1	Lip products of all types (solid and liquid lipsticks, balms, clear or colored, etc.)	Class 1.A
	Waxes for mechanical hair removal	Class 1.B
Category 2	Deodorant and antiperspirant products of all types (pump spray, aerosol spray, stick, roll-on, under-arm and body, etc.)	Class 2
Category 3	Hydroalcoholic products applied to recently shaved skin (EDT)	Class 3.A
	Hydroalcoholic products applied to recently shaved skin (fine fragrance)	Class 3.B
	Eye products of all types (eye shadow, mascara, eyeliner, eye make-up, eye masks, eye pillows, etc.)	Class 3.C
	Men's facial creams and balms	Class 3.C
Category 4	Hydroalcoholic products applied to unshaved skin (4A includes body mists (aqueous based, alcoholic based and hydroalcoholic)) (EDT)	Class 4.A
	Hydroalcoholic products applied to unshaved skin (4A includes body mists (aqueous based, alcoholic based and hydroalcoholic)) (fine fragrance)	Class 4.B
	Body creams, oils, lotions of all types (except baby creams, lotions, oils)	Class 4.C
	Fragrancing cream	Class 4.D
Category 5	Women's facial creams/facial make-up Hand cream Facial masks	Class 5

*Taken from Table 4 of RIFM Expert Panel's QRA Information Booklet Version 6.0⁹

T-2. Sensitization assessment factors (SAF) for attar-type fragrances

Product type	Inter-individual SAF	Matrix SAF	Matrix SAF rationale (experimental vs. real life exposure)	Use SAF	Use SAF rationale	SAF
Attar-type fragrance	10	3.16*	Matrix for the product not the same as the experimental** conditions	3.16*	The area is the neck, wrists, palms, antecubital fossa that may have increased permeability	100

*Half log of 10

**Experimental in this context is defined in QRA Expert Group's Dermal Sensitization Quantitative Risk Assessment for Fragrance Ingredients, Technical Dossier, Section 3.2.2.1²

T-3 shows the average amounts used per application, as measured locally using volunteer consumers. For a conservative approach, the highest figure (27.3 mg) was used for further calculations.

Typical surface areas for perfume use are taken from Bremmer et al.⁸ **T-4** shows the surface areas exposed during a typical use.

T-5 shows the calculation of the CEL, derived from the surface area (605 cm²), amount per application (27.3 mg) and

applications per day (two). The calculated CEL for attar-type fragrances is therefore 0.09 mg/cm²/day.

As consumer exposure data was acquired in a retail store setting, the typical amount used (mg/application) can be doubled to account for the fact that an individual may use a greater amount in a home setting. This conservative estimate gives a CEL of 0.18 mg/cm²/day.

T-6 shows how this CEL and the SAF value of 100 compares to CEL and SAF values of existing product categories.

T-3. Average usage levels, mg/application

Consumers		Average mg/application
UAE: Male	n = 33	27.3 mg*
Female	n = 18	25.0 mg
Combined	n = 51	26.5 mg
United States: Male	n = 29	22.1 mg
Female	n = 27	20.7 mg
Combined	n = 56	21.4 mg
Male, all locations	n = 62	24.8 mg
Female, all locations	n = 45	22.4 mg
Total combined average	n = 107	23.8 mg

*Highest average usage level

T-4. Surface areas* exposed during typical use of an attar-type fragrance

Body part exposed	Surface area, cm ²
Palms (1/2 hands)	430
Wrists, left and right	25 x 2
Antecubital fossas, left and right	25 x 2
Area of the neck behind each ear	25 x 2
Suprasternal notch	25
Total	605

*Taken from Bremmer et al., 2006⁸

T-5. Consumer exposure level (CEL), attar-type fragrances

Product type	Surface area, cm ²	Surface area reference	Retention factor	mg/application	Applications/day	CEL, mg/cm ² /day
Attar-type fragrance	605*	Bremmer et al. (2006) ⁸ , perfume (wrists, palms, neck, antecubital fossa)	1	27.3 mg**	1-2	0.09***

*7 x 25 cm² + 430 cm² = 605 cm²

**Highest average figure calculated from UAE and US consumers

***Calculated from two applications/day

T-6. Comparison of established SAF and CEL category values* with the values derived for attar-type fragrances

IFRA QRA category	Example product type	SAF	CEL, mg/cm ² /day
Category 1	Lip products	300	11.7
Category 2	Deodorants/antiperspirants	300	9.1
Category 3	Hydroalcohols for shaved skin	300	2.2
Category 4	Hydroalcohols for unshaved skin	100	2.2
Category 5	Hand cream	100	4.2
Category 6	Mouthwash	100	1.4
Category 7	Intimate wipes	300	4.4
Category 8	Hair styling aids	100	1.0
Category 9	Rinse-off hair conditioners	100	0.2
Category 10	Hard surface cleaners	100	0.1
Category 11	Candles	10	0.00033
Attar-type fragrances	—	100	0.18

*Taken from Table 1 of RIFM Expert Panel's QRA Information Booklet Version 6.0⁹

SAFs and CELs for existing product categories are taken from Table 1 of the RIFM Expert Panel's QRA Information Booklet Version 6.0.⁹

The author therefore proposes that the product “attar-type fragrances” be added to the list of product categories used by IFRA/RIFM. From the results above, the data acquired match closely with those for category 9, suggesting that this would be a suitable category. The full description of the product type can be as suggested below:

“Attar-type fragrance products applied to the skin (non-alcoholic neat fragrance oil; includes attars, mukhallats and 100% body oils).”

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Competing Interests

The author is employed by CPL Aromas Ltd., a global fragrance manufacturer with headquarters based in the United Kingdom. All expenses incurred in the acquisition of exposure data and usage information were funded by CPL Aromas Ltd.

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