

Labeling of Allergenic Fragrances in Cosmetic Products

Cosmetic products commonly contain fragrance as ingredients. However, certain substances have been identified as an important cause of contact-allergy reactions in fragrance-sensitive consumers. Currently, some of the fragrances, nitro & poly-musk have been governed by the regulation in the EU.



26 chemicals commonly presented in fragrance are highly related to allergenic reactions, and subsequently being included in Annex III of 76/768/EEC. In order to minimize the exposure of fragrance-sensitive consumer to these allergens, it is compulsory to **indicate their presence on the product label** when exceeding certain level according to 76/768/EEC, amended with 2003/15/EC in 2003 (Table 1, page 2 & 3).

The regulatory limit of the allergens is 0.001% in leave-on products (e.g. body lotion) & 0.01% in rinse-off products (e.g. shampoo)

In 2008/42/EC, there are updates on the restriction of the 26 allergenic fragrances. The maximum authorized concentration of Hydroxycitronellal

and Isoeugenol are limited to 1.0% and 0.02% for cosmetics except oral products, respectively. When Methyl 2-octynoate present in combination with methyl octine carbonate, their combined level must not exceed 0.01% and methyl octine carbonate should not exceed 0.002%. This directive came into force on 4 October 2008.

Substances functions as masking or perfuming (e.g. nitro & poly musk) are also being regulated by 76/768/EEC and corresponding regulations (Table 2, page 4).

If you ever doubt whether your cosmetic products contain the potential allergens, SGS can help to provide you an answer.

Contact us now!

Table 1 Allergenic fragrances being listed in 2003/15/EC

Substance	CAS No.	Limitation and Requirement
Amyl cinnamal	122-40-7	<p>The presence of the substance must be indicated in the list of ingredients on the label when its concentration exceeds:</p> <p>⇒ 0.001% in leave-on products</p> <p>⇒ 0.01% in rinse-off products</p>
Benzyl alcohol	100-51-6	
Cinnamyl alcohol	104-54-1	
Citral	5392-40-5	
Eugenol	97-53-0	
Amylcinnamyl alcohol	101-85-9	
Benzyl salicylate	118-58-1	
Cinnamal	104-55-2	
Coumarin	91-64-5	
Geraniol	106-24-1	
Hydroxymethylpentyl-cyclohexenecarboxaldehyde	31906-04-4	
Anisyl alcohol	105-13-5	
Benzyl cinnamate	103-41-3	
Farnesol	4602-84-0	
2-(4-tert-Butylbenzyl)propionaldehyde	80-54-6	
Linalool	78-70-6	
Benzyl benzoate	120-51-4	
Citronellol	106-22-9	
Hexyl cinnamaldehyde	101-86-0	
d-Limonene	5989-27-5	
3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5	
Oak moss extract	90028-68-5	
Treemoss extract	90028-67-4	

(To be continued)

Table 1 Allergenic fragrances being listed in 2003/15/EC (Continued)

Substance	CAS No.	Limitation and Requirement
Hydroxycitronellal	107-75-5	<p>The presence of the substance must be indicated in the list of ingredients on the label when its concentration exceeds:</p> <ul style="list-style-type: none"> ⇒ 0.001% in leave-on products ⇒ 0.01% in rinse-off products <p><i>The maximum authorized concentration in the finished cosmetic product is 1.0% except oral product.</i></p>
Isoeugenol	97-54-1	<p>The presence of the substance must be indicated in the list of ingredients on the label when its concentration exceeds:</p> <ul style="list-style-type: none"> ⇒ 0.001% in leave-on products ⇒ 0.01% in rinse-off products <p><i>The maximum authorized concentration in the finished cosmetic product is 0.02% except oral product.</i></p>
Methyl 2-octynoate	111-12-6	<p>The presence of the substance must be indicated in the list of ingredients on the label when its concentration exceeds:</p> <ul style="list-style-type: none"> ⇒ 0.001% in leave-on products ⇒ 0.01% in rinse-off products <p><i>The maximum authorized concentration in the finished cosmetic product is 0.01% except oral product. When present in combination with methyl octine carbonate, their combined level must not exceed 0.01% and methyl octine carbonate should not exceed 0.002%</i></p>



Table 2 Regulation of nitro or poly musk substances in 76/768/EEC & 2004/88/EC

Substance	CAS No.	Limitation and Requirement
Musk ambrette	83-66-9	Prohibited to be used in cosmetic.
Musk tibetene	145-39-1	
Musk moskene	116-66-5	
Musk ketone	81-14-1	<p>The maximum authorized concentration in the finished cosmetic product except oral product:</p> <ul style="list-style-type: none"> ⇒ 1.4% in fine fragrance ⇒ 0.56% in eau de toilette ⇒ 0.042% in other products <p><i>(According to Norwegian Product Regulation, it is prohibited to produce, import, export or sell consumer products that contain 0.05 % of musk ketone by weight.)</i></p>
Musk xylene	81-15-2	<p>The maximum authorized concentration in the finished cosmetic product except oral product:</p> <ul style="list-style-type: none"> ⇒ 1.0% in fine fragrance ⇒ 0.4% in eau de toilette ⇒ 0.03% in other products <p><i>(According to Norwegian Product Regulation, it is prohibited to produce, import, export or sell consumer products that contain 0.05 % of musk xylene by weight.)</i></p>
Tonalide, AHTN	1506-02-1	<p>The maximum authorized concentration in the finished cosmetic product except oral product:</p> <ul style="list-style-type: none"> ⇒ 0.1% in leave-on products, except: <ul style="list-style-type: none"> • 1% in hydroalcoholic products • 2.5% in fine fragrance • 0.5% in fragrance cream ⇒ 0.2% in rinse-off products
Phantolide, AHMI	15323-35-0	<p>The maximum authorized concentration in the finished cosmetic product:</p> <ul style="list-style-type: none"> 2% in leave-on products

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