

OPINION OF THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD
PRODUCTS INTENDED FOR CONSUMERS

CONCERNING

AN INITIAL LIST OF PERFUMERY MATERIALS
WHICH MUST NOT FORM PART OF COSMETIC PRODUCTS
EXCEPT SUBJECT TO THE RESTRICTIONS AND CONDITIONS LAID DOWN

adopted by the SCCNFP during the 18th Plenary meeting
of 25 September 2001

1. Terms of Reference

Opinion concerning a review on the safety of perfumery materials

In recent years there has been concern on the safety of fragrance (perfumery) materials. Dermatologists have highlighted the frequency of allergic contact dermatitis from perfumes.

Under current legislation, fragrance materials do not fall under all the requirements of Directive 76/768/EEC on cosmetic products. The 6th Amendment (93/35/EEC) provides for the labelling of ingredients on cosmetic products. However, it is not a requirement to label fragrance constituents on the packaging of cosmetic products, current legislation requires only the word *parfum*.

In response to growing concern over this issue, the Commission was asked for positive actions with respect to legislative measures on fragrance materials.

2. Mandate

The SCCNFP has been asked to respond to the following questions :

1. Does the SCCNFP agree to the inclusion of all IFRA restricted materials in the Annex III (List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down)? Are the permitted levels recommended by IFRA suitable for use in the Cosmetics Directive 76/768/EEC ?
2. Does the SCCNFP agree that all materials that IFRA recommend should not be used as fragrance compounds are included in Annex II (List of substances which must not form part of the composition of cosmetic products)?
3. It is proposed that all known fragrance allergens are labelled on cosmetics if used in the products. Does the SCCNFP agree to this proposal? If so :
 - Which chemicals fall under this classification ?
 - Is there a maximum concentration of each chemical permissible without the requirement for labelling ?
4. Restrictions are proposed for the 3 most common fragrance allergens (cinnamic aldehyde, isoeugenol, hydroxycitronellal). Does the SCCNFP agree to restriction on the use of common fragrance allergens (Annex III listing)? If so :
 - Which fragrance materials should be subject to restrictions?
 - What are the conditions for restrictions (maximum concentration, fields of applications, etc) ?

Obviously, in response to each of the questions listed above, a scientific justification will be necessary.

3. Strategy of the SCCNFP

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The SCCNFP has considered that this mandate can be usefully divided into two sections (Interim position on Fragrance allergy, document n° SCCNF/0202/99 adopted by the SCCNFP during the 8th Plenary meeting of 23 June 99) :

1. Identification of those fragrance ingredients, which are of concern as allergens for the consumer. Recommendations on informing the consumer of the presence of important allergens to permit the consumer with a known fragrance allergy a means to avoid contact with an allergen. An opinion as to whether such identification can be related to concentrations present in a product when elicitation levels are known.
2. An opinion on the adoption of industry prohibited substances into Annex 2 and adoption of industry restricted substances into Annex 3. Considerations as to whether the concentration limits or other restrictions suggested by industry can be supported or need to be changed if there is such inclusion in Annex 3. Whether there are additional substances which should be subject to inclusion in an Annex.

An opinion concerning fragrance allergy was adopted by the SCCNFP during the 10th Plenary meeting of 8 December 1999 (doc. n° SCCNFP/0017/98 final). During its 12th plenary meeting of 3 May 2000, the SCCNFP adopted an opinion on an initial list of perfumery materials which must not form part of fragrance compounds used in cosmetic products (doc. n° SCCNFP/0320/00 final).

The current opinion consists of the adoption of an initial list of perfumery materials to be included in Annex III - List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down - to Directive 76/768/EEC.

The opinion is based on information submitted as ‘monographs’ (synopses) on behalf of industry.

4. Opinion

On the basis of the available information and assessment of the cutaneous toxicity of the substances tabulated, it is the recommendation of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) that these substances may be used as ingredients in cosmetic products only under the conditions and restrictions specified in the attached table.

Additional substances will be discussed for possible inclusion at a later date.

Table 1 : List of perfumery materials which must not form part of cosmetic products except subject to the restrictions and conditions laid down

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N°	Substance name	Restriction and condition
1	<p><i>Abies alba oil from cones (Abies Alba Mill.)</i> CAS n° : 8021-27-0</p> <p><i>Abies alba oil from needles (Abies Alba Mill.)</i> CAS n° : 8021-27-0</p> <p><i>Abies sachalinensis oil</i> CAS n° : Unknown</p> <p><i>Fir balsam (Abies balsamea (L.) Mill)</i> CAS n° : 8021-28-1</p> <p><i>Fir needle oil (Abies sibirica)</i> CAS n° : 8021-29-2</p> <p><i>Fir needle oil, Canadian (Abies balsamea)</i> CAS n° : 8021-28-1</p> <p><i>Pine needle, dwarf, oil (Pinus mugo turra var. pumilio (Haenke) Zenari)</i> CAS n° : 8000-26-8</p> <p><i>Pine needle oil (Abies spp.)</i> CAS n° : 8021-29-2</p> <p><i>Pine scotch oil (Pinus sylvestris L.)</i> CAS n° : 8023-99-2</p> <p><i>Pinus nigra oil</i> CAS n° : 90082-74-9</p> <p><i>Turpentine gum (Pinus spp.)</i> CAS n° : 9005-90-7</p> <p><i>Turpentine oil</i> CAS n° : 8006-64-2</p> <p><i>Turpentine oil rectified</i> CAS n° : 8006-64-2</p> <p><i>Turpentine, steam distilled (Pinus spp.)</i> CAS n° : 8006-64-2</p>	Essential oils and isolates derived from the Pinaceae family, including <i>Pinus</i> and <i>Abies</i> genera, should only be used when the level of peroxides is kept to the lowest practicable level, for instance by adding antioxidants at the time of production. Such products should have a peroxide value of less than 10 millimoles peroxide per liter. Based on the published literature mentioning sensitising properties when containing peroxides (Food and Chemical Toxicology 11,1053(1973); 16,843(1978); 16,853(1978)).
2	Acetyl hexamethyl indan CAS n° : 15323-35-0	For applications on areas of skin exposed to sun, excluding bath preparations, soaps and other rinse-off products, limit use to 2% in the finished cosmetic product. Based on the phototoxic potential showing no effects at 10% in human photo-toxicity tests (IFRA guidelines).

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N°	Substance name	Restriction and condition
3	<i>Allyl butyrate</i> CAS n° : 2051-78-7 <i>Allyl cinnamate</i> CAS n° : 1866-31-5 <i>Allyl cyclohexaneacetate</i> CAS n° : 4728-82-9 <i>Allyl cyclohexanepropionate</i> CAS n° : 2705-87-5 <i>Allyl heptanoate</i> CAS n° : 142-19-8 <i>Allyl hexanoate</i> CAS n° : 123-68-2 <i>Allyl isovalerate</i> CAS n° : 2835-39-4 <i>Allyl octanoate</i> CAS n° : 4230-97-1 <i>Allyl phenoxyacetate</i> CAS n° : 7493-74-5 <i>Allyl phenylacetate</i> CAS n° : 1797-74-6 <i>Allyl 3,5,5-trimethylhexanoate</i> CAS n° : 71500-37-3	Use only when the level of free allyl alcohol in the ester is less than 0.1%. Based on the delayed irritant potential of allyl alcohol (Food and Chemical Toxicology 15,611(1977)).
4	<i>Allyl heptine carbonate</i> CAS n° : 73157-43-4	Should not be used such that the level in the finished cosmetic products exceeds 0.002 %. Based on test results showing the absence of sensitising reactions for allyl heptine carbonate at low concentrations in a test on humans. This material should not be used in combination with any other 2-alkynoic acid ester (e.g. methyl heptine carbonate). (IFRA guidelines).
5	<i>Amylcyclopentenone</i> CAS n° : 25564-22-1	Should not be used such that the level in the finished cosmetic product exceeds 0.1 %. Based on test results showing sensitisation at 10% and no sensitisation at 1 %. (IFRA guidelines).

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N°	Substance name	Restriction and condition
6	<p><i>Angelica root oil (Angelica archangelica L.)</i> CAS n° : 8015-64-3</p> <p><i>Bergamot oil</i> CAS n° : 8007-75-8</p> <p><i>Grapefruit oil, expressed (Citrus paradisi Macf.)</i> CAS n° : 8016-20-4</p> <p><i>Lemon oil</i> CAS n° : 8008-56-8</p> <p><i>Lemon oil, cold pressed, California type</i> CAS n° : 8008-56-8</p> <p><i>Lemon oil, cold pressed, desert type</i> CAS n° : 8008-56-8</p> <p><i>Lime oil, cold pressed, Mexican</i> CAS n° : 8008-26-2</p> <p><i>Lime oil, expressed</i> CAS n° : 8008-26-2</p> <p><i>Lime oil expressed rectified</i> CAS n° : 8008-26-2</p> <p><i>Orange peel oil, bitter (Citrus aurantium L.)</i> CAS n° : 68916-04-1</p> <p><i>Rue oil (Ruta graveolens L.)</i> CAS n° : 8014-29-7</p>	May be used in cosmetic products, provided that the total concentration of furocoumarin-like substances in the finished cosmetic product do not exceed 1ppm.
7	<p><i>Balsam oil, Peru (Myroxylon pereirae Klotzsch)</i> CAS n° : 8007-00-9</p> <p><i>Balsam absolute, Peru</i> CAS n° : 8007-00-9</p> <p><i>Balsam anhydrol, Peru</i> CAS n° : 8007-00-9</p>	Extracts and distillates of Peru balsam (the exudation from Myroxylon pereirae (Royle) Klotzsch) should not be used such that the total level exceeds 0.4% in cosmetic products. Based on a wide variety of test results on the sensitising potential of Peru balsam and its derivatives.
8	<p><i>p-tert-Butyldihydro-cinnamaldehyde</i> CAS n° : 18127-01-0</p>	Should not be used such that the level in the finished cosmetic product exceeds 0.6%. Based on test results showing sensitising potential and no sensitisation reactions when tested at 6%. (IFRA guidelines).

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N°	Substance name	Restriction and condition
9	Cinnamal CAS n° : 104-55-2 <i>Cinnamic aldehyde-methyl anthranilate (Schiff base)</i> CAS n° : 94386-48-8	The concentration of Cinnamic aldehyde in the finished cosmetic product should not exceed 0.1%.
10	<i>Cassia oil</i> CAS n° : 8007-80-5 <i>Cinnamon bark oil</i> CAS n° : 8015-91-6	The prime allergen is Cinnamic aldehyde. The concentration of Cinnamic aldehyde in the finished cosmetic product should not exceed 0.1%.
11	Cinnamyl alcohol CAS n° : 104-54-1	Should not be used such that the level in finished cosmetic products exceeds 0.8%. Based on test results showing sensitising potential. (IFRA guidelines).
12	<i>Cumin oil</i> CAS n° : 8014-13-9	For applications on areas of skin exposed to sun, excluding bath preparations, soaps and other wash-off products, limit cumin oil to 0.4% in the finished cosmetic product. Based on the photo-toxicity of cumin oil, the observed no-effect level of 25% on the skin of the hairless mouse and on the no-effect level of 5% in tests with humans.
13	<i>cis-.alpha.-Damascone</i> CAS n° : 23726-94-5 <i>trans-. beta.-Damascone</i> CAS n° : 23726-91-2 <i>Isodamascone</i> CAS n° : 39872-57-6 <i>1-(2,6,6-Trimethylcyclohexa-1,3-dienyl)-2-buten-1-one</i> CAS n° : 23698-85-7 <i>1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one</i> CAS n° : 57378-68-4 <i>1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one</i> CAS n° : 23726-92-3 <i>1-(2,6,6-Trimethyl-2-cydohexen-1-yl)-2-buten-1-one</i> CAS n° : 43052-87-5	Should not be used as fragrance ingredients such that the total level in finished cosmetic products exceeds 0.02%, individually or in combination. Based on test data showing sensitising potential for these materials and on evidence of cross-reactivity. (IFRA guidelines)
14	<i>trans-Hexen-2-al</i> CAS n° : 6728-26-3	Should not be used such that the level in finished cosmetic products exceeds 0.002%. Based on test results of RIFM showing sensitisation reactions at 0.2% and no sensitisation reactions when tested at 0.02% (IFRA guidelines).

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N°	Substance name	Restriction and condition
15	Hydroxycitronellal CAS n° : 107-75-5	Should not be used such that the level in finished cosmetic products exceeds 1.0%. Based on a review of a large number of animal and human test data (IFRA guidelines).
16	Isoeugenol CAS n° : 97-54-1	Should not be used such that the level in finished cosmetic products exceeds 0.02%. Based on test results showing sensitising potential (IFRA guidelines).
17	<i>d</i> -Limonene CAS n° : 5989-27-5 <i>l</i> -Limonene CAS n° : 5989-54-8 dl-Limonene (racemic) CAS n° : 138-86-3	Limonene and natural products containing substantial amounts of it, should only be used when the level of peroxides is kept to the lowest practical level, for instance by adding antioxidants at the time of production. Such products should have a peroxide value of less than 20 millimoles peroxide per liter. (IFRA guidelines).
18	<i>p</i> -Mentha-1,8-dien-7-al CAS n° : 2111-75-3	Should not be used such that the level in finished cosmetic products exceeds 0.1%. Based on test results showing sensitisation (IFRA guidelines).
19	Menthadiene-7-methyl formate CAS n° : 68683-20-5	Should not be used such that the level in finished cosmetic products exceeds 0.1 %. Based on tests showing sensitisation (IFRA guidelines).
20	<i>Methoxy dicyclopentadiene carboxaldehyde</i> CAS n° : 86803-90-9	Should not be used such that the level in finished cosmetic products exceeds 0.5%. Based on test results showing sensitisation potential (IFRA guidelines).
21	<i>Methyl N-methylantranilate</i> CAS n° : 85-91-6	For applications on areas of the skin exposed to sunlight, excluding bath preparations, soaps and other wash-off products, limit to 10% in the finished cosmetic product. Based on the phototoxic potential and on the observed no-effect level of approximately 2 mg/cm ² of the hairless mouse (Food and Chemical Toxicology 17, 273 (1979)).
22	<i>3-Methyl-2(3)-nonenenitrile</i> CAS n° : 53153-66-5	Should not be used such that the level in finished cosmetic products exceeds 0.2%. Based on test results showing sensitisation (Food Chemical Toxicology 20, 757 (1982)).
23	<i>Methyl octine carbonate</i> CAS n° : 111-80-8 <i>Methyl heptine carbonate</i> CAS n° : 111-12-6	Should not be used such that the level in finished cosmetic products exceeds 0.002%. When used alone level in the finished cosmetic products should not exceed 0.01%. When present in combination, the combined level in the finished product should not exceed 0.01% of which methyl heptine carbonate should not be more than 0.002%

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N°	Substance name	Restriction and condition
24	<i>Oakmoss absolute (Evernia spp.)</i> CAS n° : 9000-50-4 <i>Oakmoss resinoid (Evernia spp.)</i> CAS n° : 9000-50-4 <i>Treemoss absolute (Usnea spp.)</i> CAS n° : 68648-41-9 <i>Treemoss concrete (Usnea spp.)</i> CAS n° : 68648-41-9 <i>Treemoss resinold (Usnea spp.)</i> CAS n° : 868648-41-9	<p>Should not be used such that the level in finished cosmetic products exceeds 0.1%. The maximum concentration of Oakmoss and Treemoss in combination in the finished cosmetic product should not exceed 0.1%.</p> <p>The allergenic fractions in these species have not been fully elucidated nor has the relative contribution of the allergenic fractions between the species. Information needs to be obtained on the nature and the importance of the respective allergenic fractions at which time a review of the acceptance of the restriction in levels and relative proportions of the species will be undertaken.</p>
25	<i>1-Octen-3-yl acetate</i> CAS n° : 2442-10-6	Should not be used such that the level in finished cosmetic products exceeds 0.3%. Based on test results showing sensitising potential (IFRA guidelines).
26	<i>3-Propylenephthalide</i> CAS n° : 17369-59-4	Should not be used such that the level in finished cosmetic products exceeds 0.01 %. Based on test results showing sensitisation potential (IFRA guidelines).
27	<i>2,4,6-Trimethyl-3-cyclohexene-1-methanol</i> CAS n° : 68527-77-5	Should not be used such that the level in finished cosmetic products exceeds 0.5%. Based on test results showing sensitisation potential (IFRA guidelines).
28	<i>Verbena absolute</i> CAS n° : 8024-12-2	Verbena absolute obtained from Lippia citriodora Kunth should not be used such that the level in finished cosmetic products exceeds 0.2%. Based on test results showing sensitisation (IFRA guidelines).