

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

CONCERNING

AN UPDATE OF THE INITIAL LIST OF PERFUMERY MATERIALS
WHICH MUST NOT FORM PART OF FRAGRANCE COMPOUNDS USED IN
COSMETIC PRODUCTS

adopted by the SCCNFP during the 26th Plenary meeting
of 9 December 2003

1. Terms of Reference

Opinion concerning a review on the safety of perfumery materials

1.1 Background

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 Pleanry 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.

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| 4. Opinion |
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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 an update of this list.

On the basis of the assessment of the cutaneous toxicities of the substances tabulated, the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) is of the opinion that these substances should not be used as fragrance ingredients in cosmetic products.

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

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Table 1 : List of perfumery materials which must not form part of cosmetic products - update

| N° | Substance Name | IFRA Determination |
|----|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Costus root oil (<i>Saussurea lappa</i> Clarke) CAS n° : 8023-88-9 | Costus oil, absolute and concrete obtained from <i>Saussurea lappa</i> Clarke should not be used as a fragrance ingredient. This recommendation is based on test results of RIFM on the sensitizing potential of several samples (D.L. Opdyke (1974), <i>Fd. Cosmet. Toxicol.</i> 12,867). It is known that certain sesquiterpene lactones with alpha-methylene butyrolactone structure, present in costus root, have a potential for sensitization (J. Foussereau, J.C. Muller and C. Benzeira (1975), <i>Contact Dermatitis</i> , 1, 223-230; J.C. Mitchell and W.L. Epstein (1974), <i>Arch. Dermatol.</i> , 110, 871-872; W.L. Epstein, G.W. Reynolds and E. Rodriguez (1980), <i>Arch. Dermatol.</i> , 116, 59-60; A. Cheminat, C. Benzeira, M.J. Farral and J.M.J. Frechet (1981), <i>Can. J. Chem.</i> , 59, 1405-1414). |
| 2 | 7-Ethoxy-4-methylcoumarin CAS n° : 87-05-8 | Should not be used as a fragrance ingredient. This recommendation is based on the findings of RIFM on the potential for inducing photoallergic reactions of this material. (Private communication to IFRA). |
| 3 | Hexahydrocoumarin CAS n° : 700-82-3 | Should not be used as a fragrance ingredient. The recommendation is based on test results of RIFM on the sensitizing potential of this material (private communication to IFRA). |
| 4 | Peru balsam (<i>Myroxylon pereirae</i> (Royle) Klotzsch) CAS n° : 8007-00-9 | Peru balsam (the exudation from <i>Myroxylon pereirae</i> (Royle) Klotzsch) should not be used as a fragrance ingredient. The recommendation is based on a wide variety of test results on the sensitizing potential of Peru balsam. (D.L. Opdyke (1974), <i>Fd. Cosmet. Toxicol.</i> 12,951 and 953 and private communication to IFRA). |