

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

OPINION

CONCERNING

AN UPDATE OF THE 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 26th Plenary meeting
of 9 December 2003

Opinion concerning a review on the safety of perfumery materials

1. Terms of Reference

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.

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3. Strategy of the SCCNFP

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.

4. Opinion

During the 18th Plenary meeting of 25 September 2001, the SCCNFP adopted an opinion on 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 (doc. n° SCCNFP/0392/00 final).

The current opinion consists of an update of this list.

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.

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

N°	Substance name	Restriction and condition
1	2-Hexylidene cyclopentanone CAS n° : 17373-89-6	Should not exceed a level of 0.06% in consumer products when used as such or present in other fragrance materials. This is equivalent to 0.3% in a fragrance compound used at 20% in the consumer product. For use in consumer products for which no skin contact is foreseeable under normal conditions of use, e.g. closed system air fresheners, toilet blocks but not rinse off products and household cleaning products, the level in the consumer product should not exceed 0.6%. Based on test results showing sensitization reactions at 1% and greater and no sensitization reaction when tested at 0.6% (IFRA guidelines).
2	6-Methyl-3,5-heptadien-2-one (Methyl heptadienone) CAS n° : 1604-28-0	Should not be used such that the level in consumer products exceeds 0.002%. This is equivalent to 0.01% in a fragrance compound used at 20% in the consumer product. Based on the sensitising potential of the material tested at 2%. The powerful olfactive properties of the material allow its use at very low concentrations. It is predicted that testing at such low levels would not reveal any sensitising potential (IFRA guidelines).