

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

OPINION

CONCERNING

CHEMICAL INGREDIENTS IN COSMETIC PRODUCTS CLASSIFIED AS
CARCINOGENIC, MUTAGENIC OR TOXIC TO REPRODUCTION ACCORDING
TO THE CHEMICALS DIRECTIVE 67/548/EEC

Adopted by the SCCNFP during the 28th Plenary meeting
of 25 May 2004

1. Term of References

1.1. Background

In its opinion of September 2001 on "Chemical ingredients in cosmetic products classified as carcinogenic, mutagenic or toxic to reproduction according to the chemical directive 67/548/EEC", doc n° SCCNFP/0474/01, the SCCNFP considered that:

"The presence of carcinogens, mutagens, or substances toxic to reproduction in cosmetic products is of concern to the health of the consumer. Substances classified according to Council Directive 67/548/EEC as carcinogens category 1 or 2 (except substances only carcinogenic by inhalation), mutagens category 1 and 2, or toxic to reproduction category 1 or 2 and substances with similar potentials, must not be intentionally added to cosmetic products.

Substances classified according to Council Directive 67/548/EEC as carcinogens category 3, mutagens category 3, or toxic to reproduction category 3 and substances with similar potentials, must not be intentionally added to cosmetic products unless it can be demonstrated that their levels do not pose a threat to the health of the consumer.

If a carcinogen, mutagen, or a substance toxic to reproduction is present in a cosmetic product from its presence in a natural ingredient, as an impurity, or because it is formed during the manufacture, it must be demonstrated that the product does not pose a threat to the health of the consumer."

Based on this opinion, the Council and the European Parliament adopted on the 27th February 2003 Directive 2003/15/EC¹ that introduce in Directive 76/768/EEC a new provision namely Article 4b. This article stipulates that:

"The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC shall be prohibited. To that end the Commission shall adopt the necessary measures in accordance with the procedure referred to in Article 10(2). A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products."

In order to implement that provision, the Commission, in accordance with Article 8, paragraph 2, of Directive 76/768/EEC, has to consult the SCCNFP.

Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances², as last amended by Commission Directive 2001/59/EC of 6 August 2001³, in

¹ OJ L 66, 11.03.2003, p. 26. See recital (12).

(12) "The SCCNFP stated in its opinion of 25 September 2001 that substances classified pursuant to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances 1 as carcinogenic (except substances only carcinogenic by inhalation), mutagenic or toxic for reproduction, of category 1 or 2, and substances with similar potential, must not be intentionally added to cosmetic products, and that substances classified pursuant to Directive 67/548/EEC as carcinogenic, mutagenic or toxic for reproduction, of category 3, and substances with similar potential, must not be intentionally added to cosmetic products unless it can be demonstrated that their levels do not pose a threat to the health of the consumer."

² OJ L 196, 16.08.1967, p. 0001

³ OJ L 225, 21.08.2001, p. 1.

Substances classified as carcinogenic, mutagenic, or toxic for reproduction

accordance with its provision, classifies in its Annex I certain substances as CMR category 1, 2 and 3.

The above-mentioned Article 4b prohibits the use in cosmetic products of the substances CMR category 1, 2 and 3 as classified in the Annex I of the Council Directive 67/548/EEC. Some of these substances are already included in Annex II of Directive 76/768/EEC.

Currently five mandates on substances CMR category 3 have been submitted for risk assessment to the SCCNFP:

- * Acetaldehyde, CAS number 75-07-0
- * 4-Aminophenol, CAS number 123-30-8
- * Furfural, CAS number 98-01-01
- * Glyoxal, CAS number 107-22-2
- * Octamethyltetrasiloxane (D4), CAS number 556-67-2 (INCI name: Cyclomethicone D4)

1.2. Request to the SCCNFP

The SCCNFP was asked to whether there are new elements that would lead it to amend its opinion on CMR substances of 25 September 2001 and, if so, to revise it accordingly.

2. Opinion of the SCCNFP

The SCCNFP is of the opinion that there are no new elements that would lead it to amend its opinion on CMR substances of 25 September 2001 (doc. n° SCCNFP/0474/01).

3. Other considerations

Not applicable

4. Minority opinions

Not applicable