

Commission Directive 2009/6/EC of 4 February 2009 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and III thereto to technical progress (Text with EEA relevance)

COMMISSION DIRECTIVE 2009/6/EC

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amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and III thereto to technical progress

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products<sup>(1)</sup>, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Consumer Products,

Whereas:

- (1) Following restrictive measures taken by one Member State on the basis of Article 12 of Directive 76/768/EEC regarding the use of diethylene glycol (DEG) in cosmetic products, the SCCP was consulted. Considering that this scientific committee is of the opinion that DEG should not be used as an ingredient in cosmetic products, but that a maximum concentration of up to 0,1 % of DEG from impurities in the finished cosmetic products can be considered to be safe, this substance should be banned for use in cosmetic products and its traces limit should be fixed at 0,1 %.
- (2) Following restrictive measures taken by one Member State on the basis of Article 12 of Directive 76/768/EEC regarding the use of phytonadione in cosmetic products, the SCCP was consulted. The scientific committee is of the opinion that use of phytonadione in cosmetic products is not safe, since it may cause cutaneous allergy and individuals so affected may be denied an important therapeutic agent. Therefore the substance should be banned.
- (3) Directive 76/768/EEC prohibits the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction (hereinafter, CMR substances), of category 1, 2 and 3, under Annex I 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<sup>(2)</sup>. However, the use of substances classified in category 3 pursuant to Directive 67/548/EEC may be allowed subject to evaluation and approval by the Scientific Committee on Consumer Products (SCCP).
- (4) The SCCP considers that toluene, a substance classified as a CMR substance of category 3 under Annex I to Directive 67/548/EEC, is safe from the general toxicological point

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of view when present up to 25 % in nail products; however its inhalation by children should be avoided.

- (5) Following restrictive measures decided by one Member State on the basis of Article 12 of Directive 76/768/EEC regarding the use of diethylene glycol monobutyl ether (DEGBE) and ethylene glycol monobutyl ether (EGBE) in cosmetic products, the SCCP was consulted. This scientific committee is of the opinion that the use of DEGBE as a solvent in hair dye products at a concentration up to 9,0 % does not pose a risk to the health of consumer. Moreover, the committee considers that the use EGBE as a solvent at a concentration up to 4,0 % in oxidative hair dye products and up to 2,0 % in non-oxidative hair dye products does not pose a risk to the health of the consumer. However, the SCCP did not consider the use of these substances safe when the product is presented in aerosol/spray; this potential use should therefore be banned.
- (6) Directive 76/768/EEC should therefore be amended accordingly.
- (7) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS DIRECTIVE:

- (1) OJ L 262, 27.9.1976, p. 169.
- (2) OJ 196, 16.8.1967, p. 1.