

Commission Directive 2005/42/EC of 20 June 2005 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexes II, IV and VI thereto to technical progress (Text with EEA relevance)

COMMISSION DIRECTIVE 2005/42/EC

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amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexes II, IV and VI 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 Cosmetic Products and Non-Food Products intended for Consumers,

Whereas:

- (1) On the basis of the assessment of the cutaneous toxicities of costus root oil (*Saussurea lappa Clarke*), 7-Ethoxy-4-methylcoumarin, hexahydrocoumarin and peru balsam (*Myroxylon pereirae*), the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) is of the opinion that those substances should not be used as fragrance ingredients in cosmetic products. They should therefore be included in Annex II to Directive 76/768/EEC.
- (2) Azo-dyes CI 12150, CI 20170 and CI 27290 are included in Part 1 of Annex IV to Directive 76/768/EEC as colouring agents which are allowed for use in cosmetic products. The safety of those colorants has been questioned on the ground that they may form carcinogenic amines during metabolism. The SCCNFP is of the opinion, based on the available information, that the use of the colorants CI 12150, CI 20170 and CI 27290 poses a risk to the health of the consumer as they may release one or more carcinogenic aromatic amines. Those colorants should therefore be excluded from Part 1 of Annex IV to Directive 76/768/EEC.
- (3) Benzethonium chloride is included as reference number 53 in Part 1 of Annex VI to Directive 76/768/EEC as a preservative which may be employed in rinse-off cosmetic products up to a concentration of 0,1 %. It is the opinion of the SCCNFP that Benzethonium chloride should also be allowed to be employed in leave-on cosmetic products other than for oral care use up to a concentration of 0,1 %. The entry under the reference number 53 in Part 1 of Annex VI to Directive 76/768/EEC should therefore be amended accordingly.

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IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.*

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- (4) The SCCNFP is of the opinion that Methylisothiazolinone does not pose a risk to the health of consumers if employed in finished cosmetic products as a preservative up to a concentration of 0,01 %. Methylisothiazolinone should therefore be included in Part 1 of Annex VI to Directive 76/768/EEC as reference number 57.
- (5) Directive 76/768/EEC should therefore be amended accordingly.
- (6) 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](#). Directive as last amended by Commission Directive 2005/9/EC ([OJ L 27, 29.1.2005, p. 46](#)).