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Draft

COMMISSION DIRECTIVE ../.../EC

of [...]

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 products¹, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Consumer Products,

Whereas:

- (1) 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 substances². 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).
- (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) 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

¹ OJ L 262, 27.9.1976, p. 169.

² OJ L 196, 16.8.1967, p.1.

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%.

- (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 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 formulations at a concentration up to 9.0% does not pose a risk to the health of consumer. Moreover, the committee considers that the use of EGBE as a solvent at a concentration up to 4.0% in oxidative hair dye formulations and up to 2.0% in non-oxidative hair dye formulations 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:

Article 1

Annexes II and III to Directive 76/768/EEC are amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by [Day, Month, Year = 6 months after the publication of the Directive³] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from [Day, Month, Year = 9 months after the publication of the Directive⁴].

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

³ Date to be included.

⁴ Date to be included.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, [...]

For the Commission

[...]

Member of the Commission

ANNEX

Directive 76/768/EEC is amended as follows:

(1) In Annex II, the following reference numbers are added:

Ref. No	Chemical name	CAS No EC No
[...] ⁵	Diethylene glycol (DEG), for traces level see Annex III	CAS No 111-46-6
[...] ⁶	Phytonadione [INCI], phytomenadione [INN]	CAS No 84-80-0; EINECS No 201-564-2

(2) In Part 1 of Annex III, the following reference numbers [...] ⁷ to [...] ⁸ are added:

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
[...] ⁷	Toluene CAS No108-88-3 EU No303-625-9	Nail cosmetic products	25%		Keep out of reach of children
[...] ⁸	Diethylene	Traces in	0.1%		

⁵ Relevant reference number to be included at the time of the publication

⁶ Relevant reference number to be included at the time of the publication

⁷ Relevant reference number to be included at the time of the publication

⁸ Relevant reference number to be included at the time of the publication

	glycol (DEG) CAS No 111-46-6	ingredients			
[...]	Butoxydiglycol CAS No 112-34-5 diethylene glycol monobutyl ether (DEGBE)	Solvent in hair dyes,	9%	Not to be used in sprays	
[...]	Butoxyethanol CAS No 111-76-2 ethylene glycol monobutyl ether (EGBE)	Solvent in oxidative hair dyes Solvent in non-oxidative hair dyes	4.0% 2.0%	Not to be used in sprays Not to be used in sprays	