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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, ..2006
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Draft

COMMISSION DIRECTIVE ../.../EC

of [...]

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

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(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) Annex VI to Directive 76/768/EEC establishes a list of preservatives allowed in cosmetic products. The substances listed in Annex VI marked with the symbol (*) may be used in concentrations other than those fixed in that Annex for non-preservative purposes, if the specific purpose is apparent from the presentation of the product. The substances listed in Annex VI without the symbol (*) may not be used in concentrations other than those listed in that Annex and the restrictions set out therein apply when those substances are used for other specific purposes.
- (2) The Scientific Committee on Consumer Products, hereinafter “the SCCP”, has issued an opinion stating that the restrictions for usage level and warnings in Annex VI should also apply if the preservatives marked with the symbol (*) are used for other specific purposes.
- (3) The Commission therefore called upon the industry to submit safety files for substances listed with the symbol (*) when used in higher concentrations for other specific purposes.
- (4) On the basis of those safety-files the SCCP concluded that the use of several of the preservative substances in Annex VI for other specific purposes in higher concentrations is safe.

¹ OJ L 262, 27.9.1976, p. 169. Directive as last amended by [\[to be included at the time of publication\]](#).

- (5) The safe concentration limits for those preservative substances when used for other specific purposes should be included in Annex III to Directive 76/768/EEC. For the sake of clarity, it should be indicated for the relevant entries in Annex III that the same substance is listed in Annex VI to that Directive.
- (6) Substances that were not considered to be safe by the SCCP when used in concentrations other than those laid down in Annex VI for other specific purposes should be subject to the restrictions laid down in that Annex for use as preservatives. The symbol (*) should therefore be deleted from those substances in Annex VI.
- (7) Moreover, the SCCP considered it safe to increase the maximum concentration of benzoic acid and sodium salt in rinse-off products and oral-care products and to increase the maximum concentration of zinc pyrithione in rinse-off hair products for preservative use. It is therefore appropriate to amend reference numbers 1 and 8 of Annex VI to Directive 76/768/EEC accordingly.
- (8) The SCCP is also of the opinion that methyldibromo glutaronitrile should not be present in any cosmetic products, as no safe use-levels in cosmetic leave-on and rinse-off products have been established. It is therefore necessary to delete that substance from reference number 36 of Annex VI to Directive 76/768/EEC.
- (9) Following the opinions of the SCCP issued on the basis of scientific studies, the Commission together with Member States and stakeholders agreed on an overall strategy to regulate hair dye substances according to which the industry was required to submit the files with scientific data on hair dye substances to be evaluated by the SCCP.
- (10) The substances for which no explicit interest was expressed during the public consultation in defence of their use in hair dyes and for which no updated safety files were submitted to allow an adequate risk assessment should be included in Annex II.
- (11) The substance 4-amino-3-fluorophenol has until now been considered to be covered by the general entry, reference number 22, concerning aniline, its salts and its halogenated and sulphonated derivatives. However, as it is not obvious that 4-amino-3-fluorophenol belongs to that aniline family a specific entry for that substance should be included in Annex II.
- (12) For the sake of clarity, the substance epoxinazole should be moved from the separate reference number 1182 to reference number 663 in Annex II to Directive 76/768/EEC.
- (13) As no new further scientific data were submitted to the SCCP before 31 July 2006 for the evaluation of N,N'-dihexadecyl-N,N'-bis(2-hydroxyethyl)propanediamide, that substance should be included in Annex II.
- (14) Directive 76/768/EEC should therefore be amended accordingly.

- (15) 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, III and VI to Directive 76/768/EEC are amended in accordance with the Annex to this Directive.

Article 2

Member States shall ensure that with effect from [Day, Month, Year = Twelve months after the entry into force of the Directive], cosmetic products which fail to comply with this Directive are not sold or disposed of to the final consumer.

Article 3

1. Member States shall adopt and publish, by [Day, Month, Year = Six months after the entry into force of the Directive] 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 = nine months after the entry into force of the Directive...].

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.

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 4

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

Article 5

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) Annex II is amended as follows:

(a) The following reference numbers [X]² to [Y]³ are added:

Ref. No	Chemical name/INCI name	CAS No
[X] ⁴	PEG-3,2',2'-di-p-Phenylenediamine	144644-13-3
	6-Nitro-o-Toluidine	570-24-1
	HC Yellow no.11	73388-54-2
	HC Orange no. 3	81612-54-6
	HC Green no. 1	52136-25-1
	HC Red no. 8 and its salts	97404-14-3, 13556-29-1
	Tetrahydro-6-nitroquinoxaline and its salts	158006-54-3, 41959-35-7
	Disperse Red 15, except as impurity in Disperse Violet 1	116-85-8
	4-amino-3-fluorophenol	399-95-1
[Y] ⁵	N,N'-dihexadecyl-N,N'-bis(2-hydroxyethyl)propanediamide Bishydroxyethyl Biscetyl Malonamide	149591-38-8 ⁶

(b) The entry under reference number 1182 is deleted;

(c) Reference number 663 is replaced by the following: “(2*RS*,3*RS*)-3-(2-Chlorophenyl)-2-(4-fluorophenyl)-[1*H*-1,2,4-triazol-1-yl)methyl]oxirane; epoxiconazole (CAS No 133855-98-8)”.

2. Annex III, part 1, is amended as follows:

a) Reference numbers [X]⁶ to [Y]⁷ are added as indicated below:

Reference No	Substance	Restrictions			Conditions of use and warnings which must be printed
		Field of application and/or use	Maximum authorised concentration in the	Other limitation and requirements	

² the relevant reference numbers will be introduced at the time of the publication
³ the relevant reference numbers will be introduced at the time of the publication
⁴ the relevant reference numbers will be introduced at the time of the publication
⁵ the relevant reference numbers will be introduced at the time of the publication
⁶ the relevant reference numbers will be introduced at the time of the publication
⁷ the relevant reference numbers will be introduced at the time of the publication

			finished cosmetic product		on the label
a	B	C	D	E	F
“[X] ⁸ ”	Salicylic acid ¹ (CAS No 69-72-7)	a) Rinse-off hair products b) Other products	a) 3.0% b) 2.0%	Not to be used in preparations for children under three years of age, except for shampoos. For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	Not to be used for children under three years of age. (Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin).
[...]	Inorganic sulfites and bisulfites ²	a) Oxidative hair dye products b) Hair straightening products c) Self tanning products for the face d) Other self tanning products	a) 0.67% expressed as free SO ₂ b) 6.7% expressed as free SO ₂ c) 0.45% expressed as free SO ₂ d) 0.40% expressed as free SO ₂	For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	
[...]	Triclocarban ³	Rinse-off products	1.5%	Purity criteria:	

⁸ the relevant reference numbers will be introduced at the time of the publication

	(CAS No 101-20-2)			3,3',4,4'-Tetrachloroazobenzene <1 ppm 3,3',4,4'-Tetrachloroazoxybenzene <1 ppm For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	
[Y] ⁹	Zinc pyrithione ⁴ (CAS No 13463-41-7)	Leave-on hair products	0.1%	For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	

¹ As a preservative, see Annex VI, Part 1 No. 3.

² As a preservative, see Annex VI, Part 1 No. 9.

³ As a preservative, See Annex VI, Part 1 No. 23.

⁴ As a preservative, see Annex VI, Part 1 No. 8.”.

3. Annex VI, part 1, is amended as follows:

a) In column b, the symbol “(*)” is deleted for the reference numbers 1, 2, 4, 7, 12, 14, 18, 19, 21, 22, 24, 25, 26, 27, 28, 29, 30, 32, 33, 35, 37, 42, 44 and 47.

b) Reference number 1 is replaced by the following:

Reference	Substance	Maximum authorised concentration	Limitation and requirements	Conditions of use and
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⁹ the relevant reference numbers will be introduced at the time of the publication

No				warnings which must be printed on the label
a	B	C	D	E
“1	Benzoic acid (CAS No 65-85-0) and its sodium salt (CAS No 532-32-1)	Rinse-off products, except oral care products: 2.5% (acid) Oral care products: 1.7% (acid) Leave-on products: 0.5% (acid)		
1a	Benzoic acid (CAS No 65-85-0), its salts and esters	0.5% (acid)”		

c) Reference number 8 is replaced by the following:

Reference No	Substance	Maximum authorised concentration	Limitation and requirements	Conditions of use and warnings which must be printed on the label
a	B	C	d	E
“8	Zinc pyrithione (*) (CAS No 13463-41-7)	Hair products: 1.0 % Other products: 0.5%	Rinse-off products only. No use in products for oral hygiene.”	

d) Reference number 36 is deleted.