II

(Acts whose publication is not obligatory)

COMMISSION

ELEVENTH COMMISSION DIRECTIVE

of 21 February 1989

adapting to technical progress Annexes II, III, IV, V, VI and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

(89/174/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic 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 (1), as last amended by Directive 88/667/EEC (2), and in particular Article 8 (2) thereof,

Whereas, on the basis of the available information, certain provisionally permitted colouring agents, substances, preservatives and ultraviolet filters may be definitively permitted, while others must be definitively prohibited or be permitted for a further specified period;

Whereas, in order to protect public health, it is necessary to prohibit the use of Padimate A (INN) used as an ultraviolet filter, benzoyl peroxide, all oestrogen hormones in cosmetic products and certain substances used as hair dyes;

Whereas, on the basis of the available information, the field of application of quinolin-8-ol and bis (8-hydroxyquinolinium) sulphate should be extended;

Whereas, on the basis of the latest scientific and technical research, the use of glutaraldehyde as a preservative and of 2,4,6-Trianilino-(p-carbo-2'-ethylhexyl-1'-oxi)-1,3,5-triazine as an ultraviolet filter may be permitted in cosmetic products subject to certain limitations and requirements;

Whereas, in order to protect public health, it is advisable to reduce the concentration of a mixture of 5-chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate used as a preservative in cosmetic products;

(1) OJ No L 262, 27. 9. 1976, p. 169.
(2) OJ No L 382, 31. 12. 1988, p. 46.

Whereas the measures provided for in this Directive are in accordance with the opinion of the Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 76/768/EEC is hereby amended as follows:

1. in Annex II:
   - in No 260, 'with the exception of those listed in Annex V' is deleted,
   - the following numbers are added:
     381. Amyl 4-dimethylaminobenzoate, mixed isomers (Padimate A (INN))
     382. Benzoyl peroxide
     383. 2-Amino-4-nitrophenol
     384. 2-Amino-5-nitrophenol;
2. in Part 1 of Annex III in the French version, points (a) and (b):
   (a) under reference No 1, boric aid, 'Mouth-care products' in column c (b) is replaced by 'Oral hygiene products';
   (b) under reference No 12, hydrogen peroxide, 'Skin-care preparations' in column c (b) is replaced by 'Skin-hygiene preparations';
   (c) under reference No 53, etidronic acid, the words in column f are deleted;
3. in Part 2 of Annex III:
   the words in the column 'Other limitations and requirements' are deleted from reference Nos 12 700, 15 800, 20 470, 42 170, 45 190 and 47 000;
4. in Part 1 of Annex IV a reference No 1 is added:

a	b	c	d	e	f	g
'1	Quinolin-8-ol and bis (8-hydroxy-quinolium) sulphate	(a) Preparations for skin hygiene not rinsed off after use	0,02 % calculated as base		(a) (b) (c) Contains quinolin-8-ol	31. 12. 1990'
		(b) Foot hygiene preparations not rinsed off after use	0,04 % calculated as base			
		(c) Mouth hygiene products	0,01 % calculated as base			

5. in Part 2 of Annex IV:

(a) the numbers 15 800, 19 120, 20 470, 21 115, 42 170, 45 190, 47 000, 73 905 and 75 660 are deleted;

(b) '31. 12. 1988' in the column 'Allowed until' is replaced by '31. 12. 1989' for the following numbers: 13 065, 21 110, 26 100, 42 045, 42 535, 44 045, 61 554, 73 900 and 74 180;

(c) for the colouring agent CI 42 535 'solely in hair preparations at a maximum concentration of 100 ppm' is added to the 'other limits and requirements column';

6. in Annex V, item (a) of reference No 3, oestrone, oestradiol and its esters, oestriol and its esters, is deleted;

7. in Annex VI, Part 1:

(a) in the French version:

under reference No 5, formaldehyde and paraformaldehyde, the words in column c are replaced by the following:

'0,2 % (except for oral hygiene)
0,1 % (for oral hygiene)
concentrations expressed as free formaldehyde';

(b) the maximum authorized concentration in column c for reference No 39, 5-chloro-2-methyl-isothiazol-3(2H)one and 2-methyl-isothiazol-3(2H)-one with magnesium chloride and magnesium nitrate, is replaced by 0,0015 %;

(c) under reference No 20, bromo-5-nitro-5-dioxane, 1,3, 'see Annex VI, Part 2, reference No 7' in column d is deleted;

8. in Part 2 of Annex VI:

(a) the following reference number is added:

a	b	c	d	e	f
'26	Glutaraldehyde	0,1 %	Prohibited in aerosols (sprays)	Contains glutaraldehyde where the glutaraldehyde concentration in the finished product exceeds 0,05 %	31. 12. 1991'

(b) the following reference numbers are deleted:

— 1. Boric acid (+)
— 3. Dibromopropamidine (INN) and its salts (including isethionate)
— 5. 3-Heptyl-2-(3-heptyl-4-methyl-4-thiazolin-2-ylidene methyl)-4-methyl-thiazolinium iodide
— 19. 4-Hydroxybenzoic acid benzyl ester
— 25. 1,3,5-Tris(2-hydroxyethyl)hexahydro-1,3,5-triasine,

(c) '31. 12. 1988' in column f is replaced by '31. 12. 1989' for the following reference numbers:

— 4. Alkyl(C12-C22) trimethyl-ammonium bromide and chloride (including Cetrimonium bromide (INN) (+))
— 15. Benzethonium chloride (INN) (+)
— 16. Benzalkonium chloride (INN), bromide and saccharinate (+)
— 20. Hexamidine (INN) and its salts (including isethionate and 4-hydroxybenzoate) (+);

9. in Part 2 of Annex VII the following reference numbers are deleted:

— 3. Padimate A (INN)
— 7. 3,3,5-Trimethylcyclohexyl-2-acetamidobenzoate
— 8. Potassium cinnamate
— 9. 4-Methoxycinnamic acid salts (potassium, sodium and diethanolamine salts)
— 10. Propyl 4-methoxycinnamate
— 11. Salicylic acid salts (potassium, sodium and triethanolamine salts)
— 14. Cinoxate (INN)
— 15. 3,4-Dihydroxy-5-(trihydroxybenzoyloxy) benzoic acid, trioleate
— 18. 2-Ethylhexyl 2-(4-phenylbenzoyl)-benzoate
— 19. 5-Methyl-2-phenylbenzoxazole
— 20. Sodium 3,4-dimethoxyphenylglyoxylate
— 21. 1,3-bis(4-methoxyphenyl) propane-1,3-dione
— 22. 5-(3,3-Dimethyl-8,9,10-trinorborn-2-ylidene) pent-3-en-2-one