

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-hydroxy-quinolinium) 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-Triamino-(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;

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 acid, '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:

⁽¹⁾ OJ No L 262, 27. 9. 1976, p. 169.

⁽²⁾ OJ No L 382, 31. 12. 1988, p. 46.

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 (b) Foot hygiene preparations not rinsed off after use (c) Mouth hygiene products	0,02 % calculated as base 0,04 % calculated as base 0,01 % calculated as base		(a) (b) (c) Contains quinolin-8-ol	31.12.1990'

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 ;

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-triazine,
- (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 :

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 :

- 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

- 23. alpha'-(2-Oxoborn-3-ylidene)-p-xylene-2-sulphonic acid
- 27. alpha-cyano-4-methoxy cinnamic acid and its hexyl ester
- 30. Cyclohexyl 4-methoxycinnamate ;

10. Part 2 of Annex VII is replaced by the text in the Annex to this Directive.

Article 2

1. Without prejudice to the allowed dates referred to in Article 1 (4), (5), (8) and (10), Member States shall take the necessary measures to ensure that, with effect from 1 January 1990 for substances referred to in Article 1 (1) and with effect from 1 January 1991 for substances referred to in Article 1 (2), (4), (5), (7), (8) and (10), neither manufacturers nor importers established in the Community place on the market products which do not meet the requirements of this Directive.

2. Member States shall take the necessary measures to ensure that the products referred to in paragraph 1 may not be sold or disposed of to the final consumer after 31 December 1990 when they contain the substances

referred to in Article 1 (1) and after 31 December 1992 when they contain the substances referred to in Article 1 (2), (4), (5), (7), (8) and (10).

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1989. They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the text of such provisions of national law as they adopt in the field governed by this Directive.

Article 4

This Directive is addressed to the Member States

Done at Brussels, 21 February 1989.

For the Commission

Karel VAN MIERT

Member of the Commission

ANNEX

ANNEX VII

PART 2

LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MAY PROVISIONALLY CONTAIN

Reference number	Substances	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label	Allowed until
a	b	c	d	e	f
1	N-Propoxylated ethyl-4-aminobenzoate (mixed isomers)	5 %			31. 12. 1991
2	Ethoxylated ethyl-4-aminobenzoate	10 %			31. 12. 1991
4	Glycerol 1-(4-aminobenzoate)	5 %	Free from benzocaine (INN)		31. 12. 1991
5	2-Ethylhexyl 4-dimethylaminobenzoate	8 %			31. 12. 1991
6	2-Ethylhexyl salicylate	5 %			31. 12. 1991
12	Isopentyl-4-methoxycinnamate (mixed isomers)	10 %			31. 12. 1991
13	2-Ethylhexyl 4-methoxycinnamate	10 %			31. 12. 1991
16	2-Hydroxy-4-methoxy-4'-methylbenzophenone (mexenone)	4 %		Contains mexenone (!)	31. 12. 1991
17	2-Hydroxy-4-methoxybenzophenone-5 sulphonic acid and sodium salt (Sulisobenzone and Sulisobenzone sodium)	5 % (expressed as acid)			31. 12. 1991
24	alpha-(2-Oxoborn-3-ylidene) toluene-4-sulphonic acid and its salts	6 % (expressed as acid)			31. 12. 1991
25	3-(4'-Methylbenzylidene)-d-1-camphor	6 %			31. 12. 1991
26	3-Benzylidene camphor	6 %			31. 12. 1991
28	4-Isopropyl-dibenzoylmethane	5 %			31. 12. 1991
29	4-Isopropylbenzyl salicylate	4 %			31. 12. 1991
31	1-(4-tert-Butylphenyl)-3-(4-methoxyphenyl)propane-1,3-dione	5 %			31. 12. 1991
32	2,4,6-Trianiino-(p-carbo-2'-ethylhexyl-1'-oxi)-1,3,5-triazine	5 %			31. 12. 1991

(!) Not required if concentration is 0,5 % or less and when it is used only for product protection purposes.