COMMISSION

THIRTEENTH COMMISSION DIRECTIVE

of 12 March 1991

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

(91/184/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 90/121/EEC [2], and in particular Article 8 (2) thereof,

Whereas, on the basis of the available information, certain provisionally permitted colouring agents, substances and preservatives 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 lidocaine and thiomersal;

Whereas, on the basis of the latest scientific and technical research, the use of magnesium fluoride may be permitted subject to certain restrictions and obligatory inclusion on the label of health warnings;

Whereas, on the basis of the latest scientific and technical research, 7-ethyl bicyclo-oxazolidine may be used as a preservative up to 31 December 1992 and 3,3'-(1.4-phenylene dimethylidyne) *bis* (7,7-dimethyl-2-oxo-bicyclo-(2,2,1) heptane-1-methane sulphonic acid) and its salts may be used as an ultraviolet filter in cosmetic products subject to certain restrictions and conditions;

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. Annex II

(a) No 221, 'in Annexes V and VI, Part 1' is replaced by 'in Annex VI, Part 1';

[1] OJ No L 262, 27. 9. 1976, p. 169.
[2] OJ No L 71, 17. 3. 1990, p. 40.

(b) the following numbers are added :

'395. hydroxy-8-quinoline and its sulphate, except for the uses provided for in No 51 in Annex III, Part 1

396. dithio-2,2'-bispyridine-dioxide 1,1' (additive with trihydrated magnesium sulphate) — (pyrithione disulphide + magnesium sulphate)

397. Colouring agent CI 12075 and its lakes, pigments and salts

398. Colouring agent CI 45170 and CI 45170 :1

399. Lidocaine'

2. In Annex III, Part 1, reference No 56 is added :

a	b	c	d	e	f
'56	Magnesium fluoride	Dental hygiene products	0,15 % calculated as F when mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		Contains magnesium fluoride'

3. Annex III, Part 2

(a) reference Nos 1 and 4 are deleted ;

(b) '31 December 1990' in the column 'Allowed until' is replaced by '31 December 1991' for the following number : 2. 1,1,1-Trichloroethane (methyl chloroform) ;

4. In Annex IV, Part 1, Nos 12075, 15585, 45170 and 45170 :1 are deleted ;

5. In Annex IV, Part 2 :

(a) '31 December 1990' in the column 'Allowed until' is replaced by '31 December 1991' for Nos 26 100 and 73 900 ;

(b) the following colouring agent is added :

'Colour index No or denomination	Colour	Field of application				Other limitations and requirements	Allowed until
		1	2	3	4		
15 585 (3)	Red		×			Maximum 3 % in the products intended to come into contact with mucous membranes	31. 12. 1991

(3) Lakes, pigments or salts of barium, strontium and zirconium insoluble in these colouring agents are also allowed. They must satisfy the insolubility test, which will be determined in accordance with the procedure provided for in Article 8' ;

6. In Annex V, reference Nos 7 and 8 are deleted ;

7. In Annex VI, Part 1, the following reference numbers are added :

a	b	c	d	e
'44	Alkyl (C12-C22) trimethyl ammonium, bromide and chloride (*)	0,1 %		
45	4,4-dimethyl-1,3-oxazolidine	0,1 %	The pH of the finished product must not be lower than 6.'	
46	N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl) urea	0,5 %		