

II

(Acts whose publication is not obligatory)

COMMISSION

FIFTEENTH COMMISSION DIRECTIVE 92/86/EEC

of 21 October 1992

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

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 Commission Directive 92/8/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, whilst 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 1,2-epoxybutane, CI 15585, strontium lactate, strontium nitrate, strontium polycarboxylate, pramocaine, 4-ethoxy-m-phenylenediamine and its salts, 2,4-diaminophenylethanol and its salts, catechol, pyrogallol, nitrosamines and dialkanolamines;

Whereas, on the basis of the latest scientific and technical research, the use of strontium chloride, strontium acetate, fatty acid dialkanolamides, monoalkanolamines, trialkanolamines and hydrated magnesium silicate may be permitted subject to certain restrictions and conditions and the obligatory inclusion of health warnings on the label;

Whereas, on the basis of the latest scientific and technical research, 3-iodo-2-propynylbutyl carbamate and sodium hydroxymethylaminoacetate may be used as preservatives in cosmetic products up to 30 June 1993 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,

⁽¹⁾ OJ No L 262, 27. 9. 1976, p. 169.

⁽²⁾ OJ No L 70, 17. 3. 1992, p. 23.

HAS ADOPTED THIS DIRECTIVE :

Article 1

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

1. the following numbers are added to Annex II :

- '400. 1,2-epoxybutane
- 401. Colouring agent CI 15585
- 402. Strontium lactate
- 403. Strontium nitrate
- 404. Strontium polycarboxylate
- 405. Pramocaine
- 406. 4-ethoxy-m-phenylenediamine and its salts
- 407. 2,4-diaminophenylethanol and its salts
- 408. Catechol
- 409. Pyrogallol
- 410. Nitrosamines
- 411. Secondary dialkanolamines';

2. in Annex III, Part 1 :

(a) the following reference numbers are added :

a	b	c	d	e	f
'57	Strontium chloride hexahydrate	Toothpaste	3,5 %, calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3,5 %		Contains strontium chloride. Frequent use by children is not advisable
58	Strontium acetate hemihydrate	Toothpaste	3,5 % calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3,5 %		Contains strontium acetate. Frequent use by children is not advisable
59	Talc : Hydrated magnesium silicate				Powder products : Keep powder away from baby's nose and mouth
60	Fatty acid dialkanolamides		Maximum dialkanolamine content : 0,5 %	<ul style="list-style-type: none"> — Do not use with nitrosating systems — Maximum dialkanolamine content : 5 % (concerns raw materials) — Maximum N-nitroso-dialkanolamine content : 50 µg/kg — Keep in nitrite-free containers 	

a	b	c	d	e	f
61	Monoalkanolamines		Maximum dialkanolamine content: 0,5 %	<ul style="list-style-type: none"> — Do not use with nitrosating systems — Minimum purity: 99 % — Maximum secondary alkanolamine content: 0,5 % (concerns raw materials) — Maximum N-nitrosodialkanolamine content: 50 µg/kg — Keep in nitrite-free containers 	
62	Trialkanolamines	(a) non-rinse-off products (b) other products	(a) 2,5 %	(a) (b): <ul style="list-style-type: none"> — Do not use with nitrosating systems — Minimum purity: 99 % — Maximum secondary alkanolamine content: 0,5 % (concerns raw materials) — maximum N-nitrosodialkanolamine content: 50 µg/kg — Keep in nitrate-free containers 	

(b) reference number 20 is deleted;

(c) 'sensitivity test advisable before use' in column f (a) and (b) in reference numbers 8, 9 and 10 is deleted;

(d) reference number 12 is replaced by the following number:

a	b	c	d	e	f
12	Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	(a) Hair-care preparations (b) Skin-care preparations (c) Nail hardening preparations (d) Oral hygiene products	12 % of H ₂ O ₂ (40 volumes), present or released 4 % of H ₂ O ₂ , present or released 2 % of H ₂ O ₂ , present or released 0,1 % of H ₂ O ₂ , present or released		(a) (b) (c): Contains hydrogen peroxide. Avoid contact with eyes. Rinse immediately if product comes into contact with them.

3. in Annex III, Part 2, reference number 2 is deleted;

4. in Annex IV, Part 1:

(a) the following number is added;

Colour index number or denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
'26100	Red			×		Purity criteria : aniline $\leq 0,2\%$ 2-naphtol $\leq 0,2\%$ 4-aminoazobenzene $\leq 0,1\%$ 1-(phenylazo)-2-naphtol $\leq 3\%$ 1-[2-(phenylazo)phenylazo]-2-naphthalenol $\leq 2\%$;

(b) 'see Annex IV, Part 2' in the column 'other limitations and requirements' is deleted in numbers CI 73900 and CI 74180 ;

5. in Annex IV, Part 2, colouring agents CI 26100, CI 73900, CI 74180, CI 15585 and Solvent Yellow 98 are deleted ;

6. in Annex V, reference number 5 is replaced by the following :

'5. Strontium and its compounds, with the exception of strontium lactate, strontium nitrate and strontium polycarboxylate listed in Annex II, strontium sulphide, strontium chloride and strontium acetate, under the conditions laid down in Annex III, Part 1, and of strontium lakes, pigments and salts of the colouring agents listed with reference (3) in Annex IV, Part 1.' ;

7. in Annex VI, Part 1 :

(a) the limitation 'not to be used in cosmetic sunscreen products' in reference number 36 is replaced by 'not to be used in cosmetic sunscreen products at a concentration exceeding 0,025 %' ;

(b) the following substance is added :

a	b	c	d	e
'47	1,6-Di (4-amidinophenoxy)-n-hexane (Hexamidine) and its salts (including isethionate and p-hydroxybenzoate) (+)	0,1 % ;		

8. in, Annex VI, Part 2 :

(a) '30. 6. 1992' in reference numbers 2, 21, 26, 27 is replaced by '30. 6. 1993' ;

(b) '31. 12. 1992' in reference number 28 is replaced by '30. 6. 1993' ;

(c) reference number 20 is deleted ;

(d) reference number 15 is replaced by the following :

a	b	c	d	e	f
'15	Diisobutyl-phenoxy-ethoxy-ethyl dimethyl benzyl ammonium chloride (Benzethonium chloride)	0,1 %	Only for deodorants, hair care products and after-shave products. Not permitted in products intended to come into contact with mucous membranes		30. 6. 1993' ;

(e) reference number 16 is replaced by the following :

a	b	c	d	e	f
'16	Alkyl (C8-C18) dimethyl benzyl ammonium chloride bromide and saccharinate (+) (Benzalkonium chloride, bromide and saccharinate)	0,1 %			30. 6. 1993';

(f) the following reference numbers are added :

a	b	c	d	e	f
'29	3-Iodo-2-propynyl-butyl carbamate	0,1 %			30. 6. 1993
30	Sodium hydroxymethyl aminoacetate	0,1 %			30. 6. 1993';

9. in Annex VII, Part 2 :

- (a) the following reference numbers are deleted : 1, 4 and 16 ;
 (b) '30. 6. 1992' is replaced by '30. 6. 1993' for the following reference numbers : 2, 5, 6, 12, 13, 17, 24, 25, 26, 28, 29, 31 and 32.

Article 2

- Notwithstanding the dates referred to in Article 1, Member States shall take all the necessary measures to ensure that as from 1 July 1993 for the substances referred to in Article 1, neither manufacturers nor importers established in the Community shall place on the market products which do not comply with the requirements of this Directive.
- Member States shall take the necessary measures to ensure that the products referred to in paragraph 1 containing the substances referred to in Article 1 shall not be sold or otherwise disposed of to the final consumer as from 1 July 1994 if they do not comply with the requirements of this Directive.

Article 3

- Member States shall bring into force the laws, regulations and administrative provisions needed to comply with this Directive no later than 30 June 1993. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 21 October 1992.

For the Commission

Karel VAN MIERT

Member of the Commission