

II

(Acts whose publication is not obligatory)

COMMISSION

TENTH COMMISSION DIRECTIVE

of 2 March 1988

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

(88/233/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 87/137/EEC⁽²⁾, and in particular Article 8 (2) thereof,

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

Whereas, with a view to the protection of public health, it is necessary to prohibit the use of 3,4',5-tribromosalicylanilide, *Phytolacca* spp. and their preparations, retinoic acid and certain hair-dyeing substances;

Whereas, with a view to the protection of public health, it is necessary to adopt provisions concerning the instruction for use and the compulsory label warnings of cosmetic products containing thioglycollic acid, its salts and esters;

Whereas, on the basis of the information available, it is necessary to extend the field of application of quinolin-8-ol and bis (8-hydroxyquinolium) sulphate:

Whereas, in the light of the results of the most recent scientific and technical research, the use of etidronic acid and its salts for hair care and in specific soaps may be authorized under certain conditions;

Whereas it is necessary to prohibit the other uses of the preservative chlorphenesin;

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

1. In Annex II:

- delete 'except as impurities of tribromosalicylanilide in accordance with the criteria laid down in Annex IV (Part 1)' in 350 and 351;
- delete 'except as an impurity of hexachlorophene under the conditions provided for in Annex VI, Part 1, point 6' in 367;

⁽¹⁾ OJ No L 262, 27. 9. 1976, p. 169.

⁽²⁾ OJ No L 56, 26. 2. 1987, p. 20.

— add the following numbers :

- '373. 3,4',5-Tribromosalicylanide (tribromsalan)
- 374. *Phytolacca spp.* and their preparations
- 375. Tretinoin* (retinoic acid and its salts)
- 376. 1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole — CI 76050)
- 377. 1-Methoxy-2,5-diaminobenzene (2,5-diaminoanisole)
- 378. Colouring agent CI 12140
- 379. Colouring agent CI 26105
- 380. Colouring agent CI 42555
- Colouring agent CI 42555-1
- Colouring agent CI 42555-2'

2. In Annex III, Part 1 :

— replace Nos 2 and 51 by :

a	b	c	d	e	f
'2a	Thioglycollic acid and its salts	(a) Hair waving or straightening products : — general use — professional use (b) Depilatories (c) Other hair-care products which are removed after application	— 8 % ready for use pH 7 to 9,5 — 11 % ready for use pH 7 to 9,5 — 5 % ready for use pH 7 to 12,7 — 2 % ready for use pH to 9,5 The abovementioned percentages are calculated as thioglycollic acid	(a) (b) (c) : The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences : — Avoid contact with eyes — In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice — Wear suitable gloves (a) and (c) only	(a) : — Contains thioglycolate — Follow the instructions — Keep out of reach of children — For professional use only (b) and (c) : — Contains thioglycolate — Follow the instructions — Keep out of reach of children
2b	Thioglycollic acid esters	Hair waving or straightening products : — general use — professional use	— 8 % ready for use pH 6 to 9,5 — 11 % ready for use pH 6 to 9,5 The abovementioned percentages are calculated as thioglycollic acid	The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences : — May cause sensitization in the event of skin contact — Avoid contact with eyes — In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice — Wear suitable gloves	— Contains thioglycolate — Follow the instructions — Keep out of reach of children — For professional use only'
'51	Quinolin-8-ol and bis (8-hydroxyquinolium) sulphate	Stabilizer for hydrogen peroxide in rinse-off hair-care preparations Stabilizer for hydrogen peroxide in non-rinse-off hair-care preparations	0,3 % calculated as base 0,03 % calculated as base'		

— add Nos 53 and 54 :

a	b	c	d	e	f	
'53	Etidronic acid and its salts (1-hydroxyethylidene-di-phosphonic acid and its salts)	(a) Hair-care (b) Soap	1,5 % 0,2 %	} expressed as etidronic acid		Contains etidronic acid
54	1-Phenoxypropan-2-ol	— Rinse-off products only — Prohibited in oral hygiene products	2 %		As a preservative, see Annex VI, Part 1, No 43'	

3. In Annex III, Part 2 :

(a) add the colouring agent Acid Red 195, together with :

- colour : red,
- field of application : 3 ;

(b) delete 13065

4. Annex IV, Part 1 is hereby amended as follows :

(a) replace '31. 12. 1987' by '31. 12. 1989' in column (g) for the following numbers :

- No 2, 1,1,1-trichloroethane,
- No 4, 2,2'-dithiobis (pyridine 1-oxide), addition product with magnesium sulphate trihydrate ;

(b) delete Nos 3 and 5 — 3,4',5-tribromosalicylanilide and 1-phenoxypropan-2-ol

5. In Annex IV, Part 2 :

(a) delete Nos 12700, 44025, 73312 and Acid Red 195 ;

(b) replace '31. 12. 1987' by '31. 12. 1988' in the 'Authorization valid until' column in the case of Nos 13065, 21110, 42535, 44045, 61554 and 73900 ;

(c) delete the wording in the 'Other limitations and requirements' column in the case of No 13065 ;

6. In Annex VI — Part One :

(a) add the following numbers :

a	b	c	d	e
'41	2-Chloroacetamide	0,3 %		Contains chloroacetamide
42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+)	0,3 % expressed as chlorhexidine		
43	1-Phenoxypropan-2-ol	1,0	Only for rinse-off products'	

(b) delete the wording in column (d) in the case of substance No 19 ;

7. In Annex VI, Part 2 :

(a) delete the following numbers :

- 7. 5-Bromo-5-nitro-1,3-dioxane,
- 8. Undec-10-enoic acid : esters, the amide, the mono- and bis (2-hydroxyethyl) amides and their sulphosuccinates (+),
- 10. 2-Chloro-N(hydroxymethyl) acetamide,
- 11. Pyrithione aluminium camsilate (INN),
- 14. 1-Phenoxypropan-2-ol,

18. Hexetidine (INN) (+),
 22. 2-Chloroacetamide,
 23. 1-Dodecylguanidinium acetate (dodine — ISO) (+),
 24. Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+);
- (b) in the case of No 2, chlorphenesin, delete the symbol (+) in column (b), replace 0,5 % by 0,3 % for the concentration value in column (c) and replace '31. 12. 1987' by '31. 12. 1989' in column (f);
- (c) replace '31. 12. 1987' by '31. 12. 1988' in column (f) in the case of the following number :
16. Benzalkonium chloride (INN), bromide and saccharinate (+);
- (d) replace '31. 12. 1987' by '31. 12. 1989' in column (f) in the case of No 17, 1-[1,3-bis (hydroxymethyl)2,5-dioximidazolidin-1-yl]-1,3-bis (hydroxymethyl) urea ;
- (e) in the case of No 21, benzylformal, replace the name in column (b) by Benzylhemiformal and replace '31. 12. 1987' by '31. 12. 1989' in column (f).

Article 2

1. Without prejudice to the authorization dates referred to in Article 1 (4), (5) and (7), Member States shall take the necessary measures to ensure that, from 1 January 1989 in the case of the substances referred to in Article 1 (1), and from 1 January 1990 in the case of the substances referred to in Article 1 (2), (3), (6) and (7), neither manufacturers nor importers established in the Community place on the market products which do not satisfy the requirements of this Directive.
2. 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 (1) and the substances referred to in Article 1 (2), (3), (6) and (7) can no longer be sold or disposed of to the final consumer after 31 December 1989 and 31 December 1991, respectively.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the provisions of this Directive not later than 30 September 1988. They shall forthwith inform the Commission thereof.
2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by its Directive.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 2 March 1988.

For the Commission

Grigoris VARFIS

Member of the Commission
