

SEVENTH COMMISSION DIRECTIVE**of 28 February 1986****adapting to technical progress Annexes II, III, IV and V to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products****(86/179/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 85/391/EEC ⁽²⁾, and in particular Articles 5 and 8 (2) thereof,Whereas, in order to protect public health, it is necessary to prohibit chloroform, 2,3,7,8-tetrachlorodibenzo-*p*-dioxin, 2,6-dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane) and pyri-thione sodium (INNM) in cosmetic products;

Whereas on the basis of the latest findings of scientific and technical research the use of 1,3-bis(hydroxymethyl)imidazolidine-2-thione may be authorized for nail care under certain conditions;

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

Whereas the measures laid down 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, the following numbers are added:

‘366. Chloroform

367. 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin except as an impurity of hexachlorophene, subject to the conditions laid down in Annex VI — Part 1, under No 6

368. 2,6-Dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane)

369. Pyri-thione sodium (INNM)’.

2. Annex III, Part 1 is amended as follows:

⁽¹⁾ OJ No L 262, 27. 9. 1976, p. 169.⁽²⁾ OJ No L 224, 22. 8. 1985, p. 40.

a	b	c	d	e	f
44	1,3-Bis (hydroxymethyl)imidazolidine-2-thione	(a) Hair-care preparations (b) Nail-care preparations	(a) Up to 2 % (b) Up to 2 %	(a) Prohibited in aerosol dispensers (sprays) (b) The pH of the product as applied must be less than 4	Contains 1,3-bis (hydroxymethyl)imidazolidine-2-thione
51	Quinolin-8-ol and bis (8-hydroxyquinolinium) sulphate	Stabilizer for hydrogen peroxide in rinse-off hair-care preparations	0,3 % calculated as base'		

3. Annex III, Part 2, Annex IV, Parts 2 and 3, are replaced by Annexes 1 and 2 to this Directive.

4. Annex V is amended as follows:

- No 10 — Chloroform is deleted,
- In Nos 5 and 6, the footnote reference ⁽⁵⁾ is replaced by ⁽³⁾.

Article 2

1. Member States shall take the necessary measures to ensure that from 1 January 1988 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 can no longer be sold or disposed of to the final consumer after 31 December 1989.

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 31 December 1986. 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 this Directive.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 28 February 1986.

For the Commission
Grigoris VARFIS
Member of the Commission

ANNEX I

ANNEX III

PART 2

LIST OF COLOURING AGENTS ALLOWED FOR USE IN COSMETIC PRODUCTS (1)

Field of application

Column 1 = Colouring agents allowed in all cosmetic products.

Column 2 = Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes, in particular eye make-up and eye-make-up remover.

Column 3 = Colouring agents allowed exclusively in cosmetic products intended not to come into contact with the mucous membranes.

Column 4 = Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

Colour index number or denomination	Colour	Field of application				Other limitations and requirements (2)
		1	2	3	4	
10006	Green				X	
10020	Green			X		
10316 (3)	Yellow		X			
11680	Yellow			X		
11710	Yellow			X		
11725	Orange				X	
11920	Orange	X				
12010	Red			X		
12075 (3)	Orange	X				
12085 (3)	Red	X				3 % maximum concentration in the finished product
12120	Red				X	
12150	Red	X				
12370	Red				X	
12420	Red				X	
12480	Brown				X	
12490	Red	X				
12700	Yellow				X	see Annex IV, Part 2
13015	Yellow	X				E 105
13065	Yellow				X	see Annex IV, Part 2
14270	Orange	X				E 103
14700	Red	X				
14720	Red	X				E 122

Colour index number or denomination	Colour	Field of application				Other limitations and requirements (2)
		1	2	3	4	
14815	Red	X				E 125
15510 ⁽³⁾	Orange		X			
15525	Red	X				
15580	Red	X				
15585 ⁽³⁾	Red		X			
15620	Red				X	
15630 ⁽³⁾	Red	X				3 % maximum concentration in the finished product
15800	Red			X		see Annex IV, Part 2
15850 ⁽³⁾	Red	X				
15865 ⁽³⁾	Red	X				
15880	Red	X				
15980	Orange	X				E 111
15985 ⁽³⁾	Yellow	X				E 110
16035	Red	X				
16185	Red	X				E 123
16230	Orange			X		
16255 ⁽³⁾	Red	X				E 124
16290	Red	X				E 126
17200	Red	X				
18050	Red			X		
18130	Red				X	
18690	Yellow				X	
18736	Red				X	
18820	Yellow				X	
18965	Yellow	X				
19140 ⁽³⁾	Yellow	X				E 102
20040	Yellow				X	maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm
20170	Orange			X		
20470	Black				X	see Annex IV, Part 2
21100	Yellow				X	maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm
21108	Yellow				X	ditto
21230	Yellow			X		
24790	Red				X	
27290 ⁽³⁾	Red				X	
27755	Black	X				E 152
28440	Black	X				E 151
40215	Orange				X	
40800	Orange	X				
40820	Orange	X				E 160 e
40825	Orange	X				E 160 f
40850	Orange	X				E 161 g
42045	Blue				X	see Annex IV, Part 2
42051 ⁽³⁾	Blue	X				E 131
42053	Green	X				
42080	Blue				X	

Colour index number or denomination	Colour	Field of application				Other limitations and requirements (2)
		1	2	3	4	
42090	Blue	X				
42100	Green				X	
42170	Green				X	see Annex IV, Part 2
42510	Violet			X		
42520	Violet				X	5 ppm maximum concentration in the finished product
42640	Violet	X				
42735	Blue			X		
44045	Blue				X	see Annex IV, Part 2
44090	Green	X				E 142
45100	Red				X	
45170 (3)	Red	X				
45170:1			X			
45190	Violet				X	see Annex IV, Part 2
45220	Red				X	
45350	Yellow	X				6 % maximum concentration in the finished product
45370 (3)	Orange	X				not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
45380 (3)	Red	X				ditto
45396	Orange	X				when used in lipstick, the colouring agent is allowed only in free acid form and in a maximum concentration of 1 %
45405	Red		X			not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
45410 (3)	Red	X				ditto
45425	Red	X				not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 3 % 2-(iodo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
45430 (3)	Red	X				E 127, ditto
47000	Yellow			X		see Annex IV, Part 2
47005	Yellow	X				E 104
50325	Violet				X	
50420	Black			X		
51319	Violet				X	
58000	Red	X				
59040	Green			X		
60724	Violet				X	
60725	Violet	X				
60730	Violet			X		
61565	Green	X				
61570	Green	X				
61585	Blue				X	
62045	Blue				X	
69800	Blue	X				E 130
69825	Blue	X				
71105	Orange			X		
73000	Blue	X				
73015	Blue	X				E 132

Colour index number or denomination	Colour	Field of application				Other limitations and requirements (2)
		1	2	3	4	
73360	Red	X				
73385	Violet	X				
73900	Violet				X	see Annex IV, Part 2
73915	Red				X	
74100	Blue				X	
74160	Blue	X				
74180	Blue				X	see Annex IV, Part 2
74260	Green		X			
75100	Yellow	X				
75120	Orange	X				E 160 b
75125	Yellow	X				E 160 d
75130	Orange	X				E 160 a
75135	Yellow	X				E 161 d
75170	White	X				
75300	Yellow	X				E 100
75470	Red	X				E 120
75810	Green	X				E 140 and E 141
77000	White	X				E 173
77002	White	X				
77004	White	X				
77007	Blue	X				
77015	Red	X				
77120	White	X				
77163	White	X				
77220	White	X				E 170
77231	White	X				
77266	Black	X				
77267	Black	X				
77268:1	Black	X				E 153
77346	Green	X				
77400	Brown	X				
77480	Brown	X				E 175
77489	Orange	X				E 172
77491	Red	X				E 172
77492	Yellow	X				E 172
77499	Black	X				E 172
77510	Blue	X				free from cyanide ions
77713	White	X				
77742	Violet	X				
77745	Red	X				
77820	White	X				E 174
77891	White	X				E 171
77947	White	X				
Lactoflavin	Yellow	X				E 101
Caramel	Brown	X				E 150
Capsanthin, capsorubin	Orange	X				E 160 c

Colour index number or denomination	Colour	Field of application				Other limitations and requirements (2)
		1	2	3	4	
Beetroot red	Red	X				E 162
Anthocyanins	Red	X				E 163
Aluminium, zinc, magnesium and calcium stearates	White	X				
Bromothymol blue	Blue				X	
Bromocresol green	Green				X	

- (1) Lakes or salts of these colouring agents using substances not prohibited under Annex II or not excluded under Annex V from the scope of this Directive are equally allowed.
- (2) Colouring agents whose number is preceded by the letter 'E' in accordance with the EEC Directive of 1962 concerning foodstuffs and colouring matters must fulfil the purity requirements laid down in those Directives. They continue to be subject to the general criteria set out in Annex III to the 1962 Directive concerning colouring matters where the letter 'E' has been deleted therefrom.
- (3) The insoluble barium, strontium and zirconium lakes, salts and pigments of these colouring agents shall also be permitted. They must pass the test for insolubility which will be determined by the procedure laid down in Article 8.

ANNEX 2

ANNEX IV

PART 2

LIST OF COLOURING AGENTS PROVISIONALLY ALLOWED FOR USE IN COSMETIC PRODUCTS (1)

Field of application

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Colour index number or denomination	Colour	Field of application				Other limitations and requirements (2)	Authorization valid until
		1	2	3	4		
12700	Yellow			X		see Annex III, Part 2	31. 12. 1987
13065	Yellow			X		see Annex III, Part 2	31. 12. 1987
15800	Red	X				see Annex III, Part 2	31. 12. 1988
19120	Yellow				X		31. 12. 1988
20470	Black			X		see Annex III, Part 2	31. 12. 1988
21110	Orange				X	maximum 3,3'-dichlorobenzidine concentration in the colouring agent: 5 ppm	31. 12. 1987
21115	Orange				X	maximum 3,3'-dichlorobenzidine concentration in the colouring agent: 5 ppm	31. 12. 1988
26100	Red	X					31. 12. 1988
42045	Blue			X		see Annex III, Part 2	31. 12. 1988
42170	Green			X		see Annex III, Part 2	31. 12. 1988
42535	Violet			X			31. 12. 1987
44025	Green				X		31. 12. 1987
44045	Blue			X		see Annex III, Part 2	31. 12. 1987
45190	Violet			X		see Annex III, Part 2	31. 12. 1988
47000	Yellow	X				see Annex III, Part 2	31. 12. 1988

Colour index number or denomination	Colour	Field of application				Other limitations and requirements (2)	Authorization valid until
		1	2	3	4		
61554	Blue			X		only in hair-care preparations in a maximum concentration of 50 ppm	31. 12. 1987
73312	Red				X		31. 12. 1987
73900	Violet			X		see Annex III, Part 2	31. 12. 1987
73905	Red				X		31. 12. 1988
74180	Blue			X		see Annex III, Part 2	31. 12. 1988
75660	Yellow				X		31. 12. 1988
77288	Green	X				free from chromate ions	31. 12. 1986
77289	Green	X				free from chromate ions	31. 12. 1986
Acid red 195	Red			X			31. 12. 1987

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