

COMMISSION

TWELFTH COMMISSION DIRECTIVE

of 20 February 1990

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

(90/121/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 89/679/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 certain colouring agents, 11- α -hydroxypregn-4-ene-3,20-dione and its esters, hormones, zirconium with the exception of certain complexes, tyrothricin, antiandrogens of steroid structure, acetonitrile and tetrahydrozoline;

Whereas, on the basis of the latest scientific and technical research, the use of lead acetate as a hair dye may be permitted in cosmetic products subject to certain limitations and requirements, provided that certain warnings are given on the labelling for the purpose of protecting public health;

Whereas the use of the lakes of colouring agent CI 17 200 should be authorized;

Whereas, on the basis of the latest scientific and technical research, the use of 3-decyloxy-2-hydroxy-1-aminopropane-hydrochloride as a preservative in cosmetic products and the use of Solvent yellow 98 as a colouring agent in

nail care products, permitted subject to certain limitations and requirements;

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 amended as follows:

1. In Annex II:

- in No 39, 'with the exception of that given in Annex V' is deleted,
- in No 194, 'with the exception of those listed in Annex V' is deleted,
- in No 289, 'compounds, with the exception of that mentioned in Annex V' is replaced by 'compounds, with the exception of that mentioned in Annex III, No 55 under the conditions stated',
- in Nos 376 and 377, 'and their salts' is added,
- the following substances are added:
 - '385. 11 α -Hydroxypregn-4-ene-3,20-dione and its esters
 - 386. Colouring agent CI 42 640
 - 387. Colouring agent CI 13 065
 - 388. Colouring agent CI 42 535
 - 389. Colouring agent CI 61 554
 - 390. Antiandrogens with steroid structure
 - 391. Zirconium and its compounds, with the exception of the complexes under reference number 50 in Annex III (Part 1) and of zirconium lakes, salts and pigments of colouring agents listed with reference number 3 in Annex IV (Part 1)

⁽¹⁾ OJ No L 262, 27. 9. 1976, p. 169.

⁽²⁾ OJ No L 398, 30. 12. 1989, p. 25.

392. Thyrothricine

393. Acetonitrile

394. Tetrahydrozoline and its salts.

replaced by 'ne pas employer dans des produits d'hygiène pour enfants en dessous de 3 ans' (the English text remains unchanged);

2. In Annex III, Part 1, in the French version only, under reference number 1, Boric acid:

(a) in column (e), 'ne pas employer dans des produits de soins pour enfants en dessous de 3 ans' is

(b) in column (f), 'ne pas employer pour les soins d'enfants en dessous de 3 ans' is replaced by 'ne pas employer pour l'hygiène des enfants en dessous de 3 ans' (the English text remains unchanged).

3. In Annex III, Part 1, reference number 55 is added as follows:

a	b	c	d	e	f
'55	Lead acetate	Only for hair-dyeing	0,6 % calculated in lead		Keep away from children. Avoid all contact with the eyes. Wash hands after use. Contains lead acetate. Do not use to dye eyelashes, eyebrows or moustaches. If irritation develops, discontinue use.

4. In Annex III, Part 2, '31.12.1989' in the column headed 'Allowed until' is replaced by '31.12.1990' for the following reference numbers:

2. 1,1,1-Trichloroethane (methyl chloroform), and

4. 2,2'-Dithiobis (pyridine 1-oxide), addition product with magnesium sulphate trihydrate.

(b) for the colour index numbers 42 045 and 44 045 the cross sign 'X' is deleted from column 4 and inserted in column 3;

(c) 'Other limitations and requirements' is deleted for colour index numbers 42 045 and 44 045;

(d) a footnote reference ⁽³⁾ is added to the entry for colour index number 17 200.

5. In Annex IV, Part 1:

(a) colour index number 42 640 is deleted;

6. In Annex IV, Part 2:

(a) the following colouring agent is added:

Colour index-number or denomination	Colour	Field of application				Other limitations and requirements ⁽²⁾	Admitted until
		1	2	3	4		
'Solvent yellow 98	Yellow			X		Only in nail care preparations maximum 0,5 % in the final product	31. 12. 1991

(b) colour index numbers 13 065, 21 110, 42 045, 42 535, 44 045, 61 554 are deleted;

(d) '31.12.1990' in the column headed 'Authorization valid until' is replaced by '31.12.1991' in so far as colour index number 74 180 is concerned;

(c) '31.12.1989' in the column headed 'Authorization valid until' is replaced by '31.12.1990' in so far as colour index numbers 26 100 and 73 900 are concerned;

7. In Annex V, numbers 1, 3, 6, 9 are deleted.

8. (a) In Annex VI, Part 2, number 27 is added:

a	b	c	d	e	f
27	3-Decyloxy-2-hydroxy-1-amino propane-hydro-chloride (Decominol) (INN)	0,5 %			31. 12. 1990

(b) in Annex VI, Part 2, '31.12.1989' in column (f) is replaced by '31.12.1990' for the following substances:

2. Chlorphenesin (INN),
4. Alkyl (C12-C22) trimethyl-ammonium bromide and chloride (including Cetrimonium bromide) (*),
6. 4,4-Dimethyl-1,3-oxazolidine,
15. Benzethonium chloride (INN) (*),
16. Benzalkonium chloride (INN), bromide and saccharinate (*),
17. 1-[1,3-Bis (hydroxymethyl)2,5-dioximidazolidin-1-yl]-1,3-bis (hydroxymethyl) urea,
20. Hexamidine (INN) and its salts (including isethionate and 4-hydroxybenzoate) (*),
21. Benzylhemiformal (a 1 : 1 mixture of benzyloxymethanol and (benzyloxymethoxy) methanol).

Article 2

1. Regardless of the dates of admission referred to in Article 1, points 4, 6 and 8, the Member States shall take all necessary measures to ensure that as from 1 January 1991, for the substances mentioned in Article 1, point 1, and as from 1 January 1992, for the substances mentioned in Article 1, points 3, 5, 6 and 8, neither manufacturers nor importers established in the Community shall place on the market products which do not comply with the requirements of this Directive.

2. The Member States shall take all necessary measures to ensure that the products referred to in paragraph 1

containing the substances mentioned in Article 1, point 1 shall no longer be sold or otherwise disposed of to the final consumer after 31 December 1991 and that the products containing the substances mentioned in Article 1, points 3, 5, 6 and 8 shall no longer be sold or disposed of to the final consumer after 31 December 1993, if they do not comply with the requirements of this Directive.

Article 3

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the provisions of this Directive no later than 31 December 1990. They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission 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, 20 February 1990.

For the Commission

Karel VAN MIERT

Member of the Commission