

COUNCIL DIRECTIVE

of 26 October 1983

amending for the third time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

(83/574/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas Article 11 of Directive 76/768/EEC ⁽⁴⁾, as last amended by Directive 83/496/EEC ⁽⁵⁾, provides that the Commission shall, on the basis of the results of the latest scientific and technical research, submit to the Council appropriate proposals establishing lists of permitted substances;

Whereas, on the basis of the latest scientific and technical research, a list of substances authorized as ultra-violet filters can be established;

Whereas the amendments necessary to adapt Annex VII to technical progress must also be adopted in accordance with the procedure of the Committee established by Directive 76/768/EEC;

Whereas the indication of the expiry date for cosmetic products whose period of stability is less than three years, provided for in Article 6 (1) (c) of Directive 76/768/EEC, is not justified in the case of cosmetic products which may still be used after that period; whereas indication of the date of minimum durability is therefore more appropriate,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

1. Annex VII, in the form of the Annex hereto, is added. It lists the ultra-violet filters which may be included in cosmetic products under the conditions laid down therein.
2. The following items shall be added to Article 4:
 - '(g) UV filters other than those listed in Part 1 of Annex VII;
 - (h) UV filters listed in Part 1 of Annex VII, beyond the limits and outside the conditions laid down therein.'
3. The following paragraphs shall be added to Article 5:
 - 'Until 31 December 1988, Member States shall permit the marketing of cosmetic products containing the UV filters listed in Part 2 of Annex VII, within the limits and under the conditions laid down therein.
 - On 1 January 1989, these UV filters shall be:
 - definitively permitted (Part 1 of Annex VII),
 - definitively prohibited (Annex II),
 - retained in part 2 of Annex VII for a specified period, or
 - deleted from all Annexes.'
4. Paragraph 1 (c) of Article 6 shall be replaced by:

'(c) the date of minimum durability. The date of minimum durability of a cosmetic product shall be the date until which this product, stored under appropriate conditions, con-

⁽¹⁾ OJ No C 32, 9. 2. 1982, p. 2.

⁽²⁾ OJ No C 307, 14. 11. 1983, p. 105.

⁽³⁾ OJ No C 310, 30. 11. 1981, p. 5.

⁽⁴⁾ OJ No L 262, 27. 9. 1976, p. 169.

⁽⁵⁾ OJ No L 275, 8. 10. 1983, p. 20.

tinues to fulfil its initial function and in particular remains in conformity with Article 2.

It shall be indicated by the words 'Best used before the end of ...' followed by:

- either the date itself
- or an indication of where it appears in the labelling.

If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

The date shall be clearly expressed and comprise the month and the year, in that order. Indication of the date of durability shall not be mandatory for cosmetic products the minimum durability of which exceeds 30 months;

5. (a) In Article 6 (1) (d), 'Annexes III, IV and VI' is replaced by 'Annexes III, IV, VI and VII';
- (b) In the first subparagraph of Article 8 (2), 'Annexes II to VI' is replaced by 'Annexes II to VII';
- (c) In the second subparagraph of Article 8 (2), 'Annexes III to VI' is replaced by 'Annexes III to VII'.

Article 2

1. Member States shall take all measures necessary to ensure that, with effect from 1 January 1987,

neither manufacturers nor importers established in the Community place on the market products which do not meet the requirements of this Directive.

2. Member States shall adopt all measures necessary to ensure that the products referred to in paragraph 1 are not sold or disposed of to the final consumer after 31 December 1988.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1984 at the latest. They shall forthwith inform the Commission thereof.
2. Member States shall ensure that they communicate to the Commission the text of such provisions of national law as they adopt in the field governed by this Directive.

Article 4

This Directive is addressed to the Member States.

Done at Luxembourg, 26 October 1983.

For the Council
The President
G. MORAITIS

ANNEX

ANNEX VII

List of UV filters which cosmetic products may contain

For the purposes of this Directive, UV filters are substances which, contained in cosmetic sun-screen products, are specifically intended to filter certain UV rays in order to protect the skin from certain harmful effects of these rays.

These UV filters may be added to other cosmetic products within the limits and under the conditions laid down in this Annex.

Other UV filters used in cosmetic products solely for the purpose of protecting the product against UV rays are not included in this list.

PART I

List of permitted UV filters which cosmetic products may contain

Reference No	Substances	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	4-Aminobenzoic acid	5 %		
2	<i>N,N,N</i> -Trimethyl-4-(2-oxoborn-3-ylidenemethyl) anilinium methyl sulphate	6 %		
3	Homosalate (INN)	10 %		
4	Oxybenzone (INN)	10 %		Contains oxybenzone ⁽¹⁾
5	3-Imidazol-4-ylacrylic acid and its ethyl ester	2 % (expressed as acid)		
6	2-phenylbenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts	8 % (expressed as acid)		

⁽¹⁾ Not required if concentration is 0,5 % or less and when it is used only for product protection purposes.

PART 2

List of UV filters which cosmetic products may provisionally contain

Reference No	Substances	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	Ethyl-4- <i>bis</i> (hydroxypropyl) aminobenzoate, mixed isomers	5 %		
2	Ethoxylated 4-aminobenzoic acid	10 %		
3	Padimate (INN)	5 %		Contains padimate (!)
4	Glycerol 1-(4-aminobenzoate)	5 %	Free from benzocaine (INN)	
5	2-Ethylhexyl 4-dimethylaminobenzoate	8 %		
6	2-Ethylhexyl salicylate	5 %		
7	3,3,5-Trimethylcyclohexyl-2-acetamidobenzoate	2 %		
8	Potassium cinnamate	2 %		
9	4-Methoxycinnamic acid salts (potassium, sodium and diethanolamine salts)	8 % (expressed as acid)		
10	Propyl 4-methoxycinnamate	3 %		
11	Salicylic acid salts (potassium, sodium and triethanolamine salts)	2 % (expressed as acid)	The pH of the finished product shall be such that the acid is not liberated	Not to be used for children under three years of age
12	Amyl 4-methoxycinnamate, mixed isomers	10 %		
13	2-Ethylhexyl 4-methoxycinnamate	10 %		
14	Cinoxate (INN)	5 %		
15	3,4-Dihydroxy-5-(3, 4, 5-trihydroxybenzoyloxy) benzoic acid, trioleate	4 %		
16	Mexenone (INN)	4 %		Contains mexenone (!)

(!) Not required if concentration is 0,5 % or less and when it is used only for product protection purposes.

Reference No	Substances	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
17	Sulisobenzone (INN) and sulisobenzone sodium (INN)	5 % (expressed as acid)		
18	2-Ethylhexyl 2-(4-phenylbenzoyl)-benzoate	10 %		
19	5-Methyl-2-phenylbenzoxazole	4 %		
20	Sodium 3,4-dimethoxyphenylglyoxylate	5 %		
21	1,3-bis(4-methoxyphenyl) propane-1,3-dione	6 %		
22	5-(3,3-Dimethyl-8,9,10-trinorborn-2-ylidene) pent-3-en-2-one	3 %		
23	alpha'-(2-Oxoborn-3-ylidene)-p-xylene-2-sulphonic acid	6 %		
24	alpha-(2-Oxoborn-3-ylidene) toluene-4-sulphonic acid and its salts	6 % (expressed as acid)		
25	3-(4-Methylbenzylidene) bornan-2-one	6 %		
26	3-Benzylidenebornan-2-one	6 %		
27	alpha-Cyano-4-methoxycinnamic acid and its hexyl ester	5 %		
28	1-p-Cumenyl-3-phenylpropane-1,3-dione	5 %		
29	4-Isopropylbenzyl salicylate	4 %		
30	Cyclohexyl 4-methoxycinnamate	1 %		
31	1-(4-tert-Butylphenyl)-3-(4-methoxyphenyl) propane-1,3-dione	5 %		