

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 17 May 1982

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

(82/368/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 the implementation of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products ⁽⁴⁾, as amended by Directive 79/661/EEC ⁽⁵⁾, showed that certain amendments should be made to Annexes II, III, IV and V;

Whereas, in order to protect public health, measures should be taken with regard to mandatory warnings on the labels of cosmetic products containing thioglycollic acid, its salts and esters;

Whereas the use of hydrogen peroxide is not restricted to oxydizing colouring agents for hair dyeing; whereas the use of this substance should therefore also be authorized for hair care products, with the requirement that certain warnings be printed on the label to safeguard health;

Whereas in certain circumstances it is not necessary to mention the formaldehyde content on the label when this substance is not used as an ingredient of a cosmetic product but is inevitably present as a residue from the processing of raw materials;

Whereas the field of application and/or use of hydroquinone should be specified;

Whereas the maximum authorized concentration of potassium or sodium hydroxide in depilatories should be specified;

Whereas a decision may be taken with regard to the substances listed in Part I of Annex IV to Directive 76/768/EEC, in accordance with Article 5 thereof;

Whereas Parts 2 and 3 of Annex IV to the same Directive do not correspond with the list of colouring

⁽¹⁾ OJ No C 165, 2. 7. 1979, p. 52.

⁽²⁾ OJ No C 175, 14. 7. 1980, p. 88.

⁽³⁾ OJ No C 83, 2. 4. 1980, p. 7.

⁽⁴⁾ OJ No L 262, 27. 9. 1976, p. 169.

⁽⁵⁾ OJ No L 192, 31. 7. 1979, p. 35.

agents actually used in the preparation of cosmetic products; whereas this list should therefore be updated;

Whereas a list of substances authorized for use as preservatives can be drawn up on the basis of the latest scientific and technical research;

Whereas a procedure for updating the Annexes rapidly should be introduced;

Whereas the presence of traces of substances which cosmetic products must not contain according to Annex II to Directive 76/768/EEC is technologically inevitable with correct manufacturing processes; whereas therefore certain provisions should be made in this connection;

Whereas the English, German and Dutch versions of Directive 76/768/EEC of 27 July 1976 contain typographical errors which should be corrected,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 76/768/EEC shall be amended in accordance with the provisions set out hereinafter.

Article 2

Annex II shall be amended as follows:

— replace the title by:

‘List of substances which must not form part of the composition of cosmetic products’;

— replace ‘46 Barium salts’ by:

‘Barium salts, with the exception of barium sulphate, barium sulphide under the conditions laid down in Annex III, Part 1, lakes prepared from barium sulphate and pigments prepared from the colouring agents listed in Annex III, Part 2 and Annex IV, Parts 2 and 3 and marked 1 (Ba)’;

— replace ‘191 Hydrofluoric acid’ by:

‘Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in Annex III, Part 1’;

— replace ‘221 Mercury and its compounds’ by:

‘Mercury and its compounds, with the exception of those listed in Annex V and Annex VI, Part 2’;

— at 268 delete ‘Phenol and its alkali salts, excluding the exceptions listed in Annex III’ and replace by ‘Picric acid’;

— replace ‘321 Thiourea and its derivatives, with the exception of those listed in Annex IV, Part 1’ by:

‘Thiourea and its derivatives, with the exception of the one listed in Annex III, Part 1’;

— replace ‘350 Tetrabromosalicylanilides’ by:

‘Tetrabromosalicylanilides except as impurities of tribromosalicylanilide according to the criteria laid down in Annex IV, Part 1’;

— replace ‘351 Dibromosalicylanilides, e.g. metabromosalan (*) and dibromosalan (*)’ by:

‘Dibromosalicylanilides, except as impurities of tribromosalicylanilide according to the criteria laid down in Annex IV, Part 1’;

— replace ‘360 *Sassafras officinale* Nees oil containing safrole’ by:

‘Safrole except for normal content in the natural essences used and provided the concentration does not exceed:

100 ppm in the finished product,

50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children’.

Article 3

1. Part 1 of Annex III shall be replaced by the Annex given in Annex 1 to this Directive.

2. Part 2 of Annex III shall be amended as follows:

(a) **Reds**

— In the third and sixth columns delete:

— 'E 180' against colouring agent No 10 corresponding to colour index number 15 850,

— 'E 420' against colouring agent No 26 corresponding to colour index number 77 015.

— In the second column, replace:

'15 630 (Ba)' by '15 630: 1 (Ba)',
'15 630 (Sr)' by '15 630: 3 (Sr)',
'15 865 (Sr)' by '15 865: 3 (Sr)',
'45 170 (Ba)' by '45 170: 1 (Ba)'.

(b) Oranges and yellows

For colouring agent No 23, replace the colour index number '45 395' in the second column by '45 396'.

(c) Greens and blues

For colouring agent No 4 corresponding to colour index number 44 090 enter the number 'E 142' in the third and sixth columns.

(d) Violets, browns, blacks and whites

— Delete colouring agent No 8 corresponding to colour index number 77 005.

— In the third and sixth columns delete 'Part of E 153' and 'E 153' respectively for colouring agents Nos 12 and 13 corresponding to colour index numbers 77 266 and 77 267.

— Add reference number '26' and enter 'Part of E 153' and 'E 153' respectively in the third and sixth columns corresponding to this reference number.

(e) Footnote (4)

Add the following sentence:

'They shall continue to be subject to the general criteria set out in Annex III to the Directive of 1962 concerning colouring matter, where the "E" number has been deleted in that Directive.'

Article 4

1. Annex IV, Part 1 shall be replaced by the Annex given in Annex 2 to this Directive.

2. Annex IV, Part 2 shall be amended as follows:

(a) Reds

— Delete the following colouring agents:

Reference number	Colour index number
2	12 350
3	12 385
14	75 580

— For reference number 5 replace the numbers '15 500' and '15 500 (Ba)' in the second column by '17 200' and delete the reference to the field of application in the fourth column.

— For colouring agent No 6 replace '15 585 (Ba)' in the second column by '15 585 : 1 (Ba)'.

(b) Oranges and yellows

For reference number 2, replace colour index number '45 340' in the second column by '40 850' and add the number 'E 161g' in the third and sixth columns.

(d) Violets, browns, blacks and whites

Delete colouring agent No 8 corresponding to colour index number 77 718.

(e) Footnote (4)

Add the following sentence:

'They shall continue to be subject to the general criteria set out in Annex III to the said Directive, where the "E" number has been deleted in that Directive.'

3. Annex IV, Part 3 shall be replaced by the Annex given in Annex 3 to this Directive.

Article 5

In Annex V:

— Replace:

'2. Hexachlorophene (for all uses other than that stated in Part 1 of Annex III)'

by:

'2. Hexachlorophene (for all uses other than that stated in Annex VI, Part 1)';

— Replace:

'5. Strontium and its salts, with the exception of those used in the colouring agents listed in Part 2 of Annex III and Parts 2 and 3 of Annex IV'

by:

'5. Strontium and its salts, with the exception of strontium sulphide under the conditions laid down in Annex III, Part 1, and strontium salts used in the colouring agents listed in Annex III, Part 2 and Annex IV, Parts 2 and 3, and marked: 3 (Sr)';

— Replace:

'6. Zirconium and its derivatives'

by:

'6. Zirconium and its compounds';

— Add:

'10. Chloroform.

11. Hydroquinone, for use as a skin-lightener.'

Article 6

An Annex VI shall be added, listing the substances which may be used as preservatives in the manufacture of cosmetic products under the conditions set out in the said Annex and in the preamble thereto.

Article 7

Article 4 shall be amended as follows:

'Article 4

1. Without prejudice to their general obligations deriving from Article 2, Member States shall prohibit the marketing of cosmetic products containing:

(a) (unchanged)

(b) (unchanged)

(c) (unchanged)

(d) (unchanged)

(e) preservatives other than those listed in Annex VI, Part 1;

(f) preservatives listed in Annex VI, Part 1, beyond the limits and outside the conditions laid down, unless other concentrations are used for specific purposes apparent from the presentation of the product.

2. The presence of traces of the substances listed in Annex II shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 2.'

Article 8

Article 5 shall be amended as follows:

'Article 5

Until 31 December 1985 Member States shall allow the marketing of cosmetic products containing:

(a) (unchanged)

(b) (unchanged)

(c) (unchanged)

(d) the preservatives listed in Annex VI, Part 2, within the limits and under the conditions laid down; however, these substances may be used in other concentrations for specific purposes apparent from the presentation of the product.

On 1 January 1986 these substances, colouring agents and preservatives shall be:

— definitively permitted,

— or definitively prohibited (Annex II),

— or retained for a period as specified in Annex IV or VI,

— or deleted from all Annexes to this Directive.'

Article 9

In Article 6 (1) (d) the words 'in Annexes III and IV' shall be replaced by the words 'in Annexes III, IV and VI'.

Article 10

Article 8 shall be replaced by the following:

'Article 8

1. (unchanged)
2. The amendments necessary for adapting Annexes II to VI to technical progress shall be adopted in accordance with the same procedure, after consultation of the Scientific Committee for Cosmetology at the initiative of the Commission or of a Member State.

However, in the case of Annexes III to VI this procedure will apply until 31 December 1988. No later than six months before that date, the Council acting unanimously on a Commission proposal shall take the appropriate measures.'

Article 11

The following Article shall be inserted:

'Article 8a

1. Notwithstanding Article 4 and without prejudice to Article 8 (2), a Member State may authorize the use within its territory of other substances not contained in the lists of substances allowed, for certain cosmetic products specified in its national authorization, subject to the following conditions:

- (a) the authorization must be limited to a maximum period of three years;
- (b) the Member State must carry out an official check on cosmetic products manufactured from the substance or preparation use of which it has authorized;
- (c) cosmetic products thus manufactured must bear a distinctive indication which will be defined in the authorization.

2. The Member State shall forward to the Commission and to the other Member States the next of any authorization decision taken pursuant to paragraph 1 within two months of the date on which it came into effect.

3. Before expiry of the three-year period provided for in paragraph 1, the Member State may submit to the Commission a request for the inclusion in a list of permitted substances of the substance given national authorization in accordance with paragraph 1. At the same time, it shall supply

supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which the substance or preparation is intended. Within 18 months of submission of the request, a decision shall be taken on the basis of the latest scientific and technical knowledge, after consultation, at the initiative of the Commission or of a Member State, of the Scientific Committee for Cosmetology and in accordance with the procedure laid down in Article 10 as to whether the substance in question may be included in a list of permitted substances or whether the national authorization should be revoked. Notwithstanding paragraph 1 (a), the national authorization shall remain in force until a decision is taken on the request for inclusion in the list.'

Article 12

1. The English language version is corrected in accordance with Annex 5.
2. The German language version is corrected in accordance with Annex 6.
3. The Dutch language version is corrected in accordance with Annex 7.

Article 13

1. Member States shall take all necessary measures to ensure that as from 1 January 1986 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 all necessary measures to ensure that the products referred to in the first paragraph can no longer be sold or disposed of to the final consumer after 31 December 1987.

Article 14

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 1983 and shall forthwith inform the Commission thereof.
2. Member States shall ensure that the texts of the provisions of national law which they adopt in the field

governed by this Directive are communicated to the Commission.

Done at Brussels, 17 May 1982.

Article 15

This Directive is addressed to the Member States.

For the Council

The President

P. de KEERSMAEKER

ANNEX I

ANNEX III

PART I

LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS AND CONDITIONS LAID DOWN

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
1	Boric acid	(a) Talcs (b) Products for oral hygiene (c) Other products	(a) 5 % (b) 0.5 % (c) 3 %	(a) Not to be used in products for children under three years old	(a) Not to be used for children under three years of age
2	Thioglycolic acid, its salts and esters	(a) Hair waving or straightening products: — general use — professional use (b) Depilatories (c) Other hair care products which are removed after application	(a) — 8 % ready for use pH ≤ 9.5 — 11 % ready for use pH ≤ 9.5 (b) 5 % pH ≤ 12.7 (c) 2 % percentages calculated as thioglycolic acid		(a) Contains thioglycolate. Follow the instructions — For professional use only (b) Contains thioglycolate. Follow the instructions (c) Contains thioglycolate. Follow the instructions
3	Oxalic acid, its esters and alkaline salts	Hair care products	5 %		For professional use only

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
4	Ammonia		6 % calculated as NH ₃		Above 2 %: contains ammonia
5	Tosylchloramide sodium (*)		0.2 %		
6	Chlorates of alkali metals	(a) Toothpaste (b) Other uses	(a) 5 % (b) 3 %		
7	Dichloromethane		35 % (when mixed with 1,1,1-trichloroethane, total concentration must not exceed 35 %)	0.2 % as maximum impurity content	
8	<i>o</i> and <i>m</i> -Phenylenediamines, their <i>N</i> -substituted derivatives and their salts; <i>N</i> -substituted derivatives of <i>p</i> -phenylenediamines (1)	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	6 % calculated as free base		(a) Can cause an allergic reaction. Sensitivity test advisable before use Contains phenylenediamines. Do not use to dye eyelashes or eyebrows (b) For professional use only Contains phenylenediamines Can cause an allergic reaction. Sensitivity test advisable before use

(1) These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorized for each of them does not exceed 1.

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
9	Methylphenylenediamines, other N-substituted derivatives and their salts ⁽¹⁾	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	10 % calculated as free base		(a) Can cause an allergic reaction. Sensitivity test advisable before use Contains phenylenediamines. Do not use to dye eyelashes or eyebrows (b) For professional use only. Contains phenylenediamines Can cause an allergic reaction. Sensitivity test advisable before use
10	Diaminophenols ⁽¹⁾	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	10 % calculated as free base		(a) Can cause an allergic reaction. Sensitivity test advisable before use Contains diaminophenols. Do not use to dye eyelashes or eyebrows (b) For professional use only. Contains diaminophenols Can cause allergic reaction. Sensitivity test advisable before use
11	Dichlorophen (*)	Use other than as a preservative	0.5 %		Contains dichlorophen

⁽¹⁾ These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorized for each of them does not exceed 1.

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
12	Hydrogen peroxide	Hair care products	12 % H ₂ O ₂ (40 volumes)		Contains hydrogen peroxide. Avoid contact with eyes. Rinse eyes immediately if product comes into contact with them
13	Formaldehyde	Nail hardeners	5 % calculated as formaldehyde		Protect cuticles with grease or oil. Contains formaldehyde ⁽²⁾
14	Hydroquinone ⁽¹⁾	Oxidizing colouring agent for hair dyeing (a) general use (b) professional use	2 %		(a) Do not use to dye eyelashes or eyebrows Rinse eyes immediately if product comes into contact with them Contains hydroquinone (b) For professional use only Contains hydroquinone Rinse eyes immediately if product comes into contact with them

⁽¹⁾ These substances may be used singly or in combination provided that the sum of the ratios of each of them in the cosmetic product expressed with reference to the maximum level authorized for each of them does not exceed 2.

⁽²⁾ Only if the concentration exceeds 0.05 %.

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
15	Potassium or sodium hydroxide	(a) Nail cuticle solvent (b) Hair straightener 1. general use 2. professional use (c) pH adjuster — depilatories (d) Other uses as pH adjuster	(a) 5 % by weight ⁽¹⁾ (b) 1. 2 % by weight ⁽¹⁾ 2. 4.5 % by weight ⁽¹⁾ (c) up to pH 12.7 (d) up to pH 11		(a) Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children (b) 1. Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children 2. For professional use only. Avoid contact with eyes. Can cause blindness (c) Keep out of reach of children. Avoid contact with eyes
16	α -naphthol	Colouring agent for hair dyeing	0.5 %		Contains α -naphthol
17	Sodium nitrite	Rust inhibitor	0.2 %	Do not use with secondary and/or tertiary amines or other substances forming nitrosamines	
18	Nitromethane	Rust inhibitor	0.3 %		
19	Phenol and its alkali salts	Soaps and shampoos	1 % calculated as phenol		Contains phenol

⁽¹⁾ The sum of the two hydroxides expressed by weight as sodium hydroxide.

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
20	Pyrogallol (1)	Oxidizing colouring agent for hair dyeing (a) general use (b) professional use	5 %		(a) Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them. Contains pyrogallol (b) For professional use only. Contains pyrogallol. Rinse eyes immediately if product comes into contact with them
21	Quinine and its salts	(a) Shampoos (b) Hair lotions	(a) 0.5 % calculated as quinine base (b) 0.2 % calculated as quinine base		
22	Resorcinol (1)	(a) Oxidizing colouring agent for hair dyeing 1. general use	(a) 5 %		(a) 1. Contains resorcinol. Rinse hair well after application. Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them

(1) These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorized for each of them does not exceed 2.

Reference number	Substance	Restrictions				Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	
22 (cont'd)		2. professional use (b) Hair lotions and shampoos	(b) 0.5 %		2. For professional use only. Contains resorcinol. Rinse eyes immediately if product comes into contact with them (b) Contains resorcinol	
23	(a) Alkali sulphides (b) Alkaline earth sulphides	(a) Depilatories (b) Depilatories	(a) 2 % calculated as sulphur pH ≤ 12.7 (b) 6 % calculated as sulphur pH ≤ 12.7		(a) Keep out of reach of children. Avoid contact with eyes (b) Keep out of reach of children. Avoid contact with eyes	
24	Water-soluble zinc salts with the exception of zinc 4-hydroxy-benzenesulphonate and zinc pyrrithione		1 % calculated as zinc			
25	Zinc 4-hydroxybenzene sulphonate	Deodorants, antiperspirants and astringent lotions	6 % calculated as % of anhydrous substance		Avoid contact with eyes	
26	Ammonium monofluorophosphate	Oral hygiene products	0.15 % calculated as F when mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.15 %		Contains ammonium monofluorophosphate	

Reference number	Substance	Restrictions				Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	
27	Sodium monofluorophosphate	Ditto	0.15 % Ditto		Contains sodium monofluorophosphate	
28	Potassium monofluorophosphate	Ditto	0.15 % Ditto		Contains potassium monofluorophosphate	
29	Calcium monofluorophosphate	Ditto	0.15 % Ditto		Contains calcium monofluorophosphate	
30	Calcium fluoride	Ditto	0.15 % Ditto		Contains calcium fluoride	
31	Sodium fluoride	Ditto	0.15 % Ditto		Contains sodium fluoride	
32	Potassium fluoride	Ditto	0.15 % Ditto		Contains potassium fluoride	
33	Ammonium fluoride	Ditto	0.15 % Ditto		Contains ammonium fluoride	
34	Aluminium fluoride	Ditto	0.15 % Ditto		Contains aluminium fluoride	
35	Stannous fluoride	Ditto	0.15 % Ditto		Contains stannous fluoride	

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
36	Hexadecyl ammonium fluoride	Ditto	0·15 % Ditto		Contains hexadecyl ammonium fluoride
37	3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium difluoride	Ditto	0·15 % Ditto		Contains 3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium difluoride
38	NN' N' -Tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride	Ditto	0·15 % Ditto		Contains NN' N' -tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride
39	Octadecenyl-ammonium fluoride	Ditto	0·15 % Ditto		Contains octadecenyl-ammonium fluoride
40	Sodium fluorosilicate	Ditto	0·15 % Ditto		Contains sodium fluorosilicate
41	Potassium fluorosilicate	Ditto	0·15 % Ditto		Contains potassium fluorosilicate
42	Ammonium fluorosilicate	Ditto	0·15 % Ditto		Contains ammonium fluorosilicate

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
43	Magnesium fluorosilicate	Ditto	0.15 % Ditto		Contains magnesium fluorosilicate
44	1,3-Bis(hydroxymethyl)imidazolidene-2-thione	Hair care preparations	Up to 2 %	Prohibited in aerosol dispensers (sprays)	Contains 1,3-bis(hydroxymethyl)imidazolidene-2-thione
45	Benzyl alcohol	Solvents, perfumes and flavourings			

ANNEX 2

'ANNEX IV

Part 1

LIST OF SUBSTANCES PROVISIONALLY ALLOWED

Reference number	Substance	Field of application and/or use	Restrictions		Other limitations and requirements	Conditions of use and warnings which must be printed on the label
			Maximum authorized concentration in the finished cosmetic product			
a	b	c	d	e	f	
1	Methanol	Denaturant for ethanol and isopropyl alcohol	5 % calculated as a % of ethanol and isopropyl alcohol			
2	2,3-Dihydroxypropyl-4-aminobenzoate		5 %			Contains 2,3-dihydroxypropyl-4-aminobenzoate
3	Quinolin-8-ol and bis (8-hydroxyquinolinium) sulphate	Stabiliser for peroxides	0.3 % calculated as base			Not to be used for children under three years of age
4	1,1,1-Trichloroethane (methyl chloroform)	Solvent for aerosol dispensers	35 % When mixed with dichloromethane, total concentration must not exceed 35 %			Do not spray on a naked flame or any incandescent material
5	3,4',5 Tribromosalicylanilide (Tribromsalan (*))	Soaps	1 %			Contains tribromosalicylanilide' Purity criteria: 3,4',5 Tribromosalicylanilide: 98.5 % minimum Other bromosalicylanilides: 1.5 % maximum 4',5 dibromosalicylanilide: 0.1 % maximum Inorganic bromide: 0.1 % maximum expressed as Na Br

ANNEX 3

ANNEX IV

PART 3

A. LIST OF COLOURING AGENTS PROVISIONALLY ALLOWED FOR COSMETIC PRODUCTS WHICH DO NOT COME INTO CONTACT WITH THE MUCOUS MEMBRANES**Reds**

11 215, 12 310, 12 420, 16 150, 18 050, 18 065, 18 810, 26 105, 45 100, 50 240 and Acid Red 195.

Oranges and yellows

11 020, 11 021, 11 680, 11 700, 11 710, 13 065, 16 230, 18 690, 18 736, 19 120, 21 230, 71 105.

Blues and greens

10 006, 10 020, 42 045, 42 080, 44 025, 62 095, 63 000, 74 100, 74 220, 74 350, 77 420, Bromothymol Blue, Bromocrenol Green.

Violets, browns, blacks and whites

12 010, 12 480, 42 555, 46 500, 50 420, 51 319, 61 710, Brown FK.

B. LIST OF COLOURING AGENTS PROVISIONALLY ALLOWED FOR COSMETIC PRODUCTS WHICH COME INTO CONTACT ONLY BRIEFLY WITH THE SKIN**Reds**

11 210, 12 370, 12 459, 12 485, 12 512, 12 513, 12 715, 14 895, 14 905, 16 045, 18 125, 18 130, 23 266, 24 790, 27 300, 27 306, 28 160, 45 110, 45 150, 45 220, 60 710, 62 015, 69 025, 71 100, 73 312, 73 905, 73 915, Pigment Red 144, Pigment Red 166, Pigment Red 170, Pigment Red 188

Yellows and oranges

11 725, 11 730, 11 765, 11 767, 11 855, 11 870, 12 055, 12 140, 12 700, 12 790, 14 600, 14 690, 15 970, 18 820, 20 040, 21 096, 21 100, 21 105, 21 108, 21 110, 21 115, 22 910, 23 900, 25 135, 25 220, 26 090, 29 020, 40 215, 48 040, 48 045, 48 055, 56 205, 75 660, 77 199, 77 878, Acid yellow 127, Pigment Yellow 93, Pigment Yellow 98, Pigment Orange 31, 77 955.

Blues and greens

12 775, 34 230, 42 052, 42 085, 42 095, 42 100, 50 315, 50 405, 52 015, 52 020, 61 135, 61 505, 61 525, 61 585, 62 005, 62 045, 62 105, 62 560, 69 810, 74 180, 74 255, Solvent Blue 2, Solvent Blue 19, Acid Blue 82, Acid Blue 181, Acid Blue 272.

Violets, browns, blacks and whites

14 805, 17 580, 20 285, 20 470, 21 010, 25 410, 42 510, 42 520, 42 535, 42 650, 45 175, 50 325, 60 010, 60 730, 61 105, 62 030, Acid Brown 19, Acid Brown 82, Disperse Violet 23, Acid Brown 104, Acid Brown 106, Pigment Violet 37, Pigment Brown 30'.

ANNEX 4

'ANNEX VI

LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS MAY CONTAIN

PREAMBLE

1. Preservatives are substances which may be added to cosmetic products for the primary purpose of inhibiting the development of micro-organisms in such products.
2. The substances marked with the symbol (*) may also be added to cosmetic products in concentrations other than those laid down in this Annex for other specific purposes apparent from the presentation of the product, e.g. as deodorants in soaps or as anti-dandruff agents in shampoos.
3. Other substances used in the formulation of cosmetic products may also have anti-microbial properties and thus help in the preservation of the products, as, for instance, many essential oils and some alcohols. These substances are not included in this Annex.
4. For the purposes of this list:
 - 'Salts' is taken to mean: salts of the cations sodium, potassium, calcium, magnesium, ammonium and ethanolamines; salts of the anions chloride, bromide, sulphate, acetate.
 - 'Esters' is taken to mean: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl, phenyl.

PART I
LIST OF PRESERVATIVES ALLOWED

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	Benzoic acid, its salts and esters (*)	0.5 % (acid)		
2	Propionic acid and its salts (*)	2 % (acid)		
3	Salicylic acid and its salts (*)	0.5 % (acid)	Not to be used in preparations for children under three years of age, except for shampoos	Not to be used for children under three years of age (1)
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts (*)	0.6 % (acid) If mixed with sorbic acid esters, the maximum total concentration of the acids, salts and esters remains fixed at 0.6 % (acid)		
5	Formaldehyde and paraformaldehyde (*)	0.2 % (except for products for oral hygiene) 0.1 % (products for oral hygiene) expressed as free formaldehyde	Prohibited in aerosol dispensers, except for foams	Contains formaldehyde (2)
6	Hexachlorophene (INN) (*)	0.1 %	Prohibited in products for children under three years of age, and intimate hygiene products	Not to be used for children under three years of age. Contains hexachlorophene

(1) Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin.

(2) Only if in a concentration of more than 0.05 %.

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
7	Biphenyl-2-ol (o-phenylphenol) and its salts (*)	0.2 % expressed as the phenol		
8	Pyrrithione zinc (INN) (*)	0.5 %	Authorized in products rinsed off after use, forbidden in products for oral hygiene	
9	Inorganic sulphites and hydrogensulphites (*)	0.2 % expressed as free SO ₂		
10	Sodium iodate	0.1 %	Only for products rinsed off after use	
11	Chlorobutanol (INN)	0.5 %	Prohibited in aerosols, except for foams	Contains chlorobutanol
12	4-hydroxybenzoic acid and its salts and esters except benzyl ester (*)	0.4 % (acid) for 1 ester, 0.8 % (acid) for mixtures of esters		

PART 2
LIST OF PRESERVATIVES PROVISIONALLY ALLOWED

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	2,6-Dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane)	0.2 %		
2	Boric acid (*)	(a) 0.5 % (b) 3 %	(a) Products for oral hygiene (b) Other products	
3	Chlorphenesin (INN) (*)	0.5 %		
4	3-Acetyl-6-methylpyran-2,4(3H)-dione (Dehydroacetic acid) and its salts	0.6 % (acid)		
5	Formic acid (*)	0.5 % (acid)		
6	4-Hydroxybenzoic acid benzyl ester	0.1 % (acid)		
7	Hexamidine (INN) and its salts (including isethionate (INN) and 4-hydroxybenzoate) (*)	0.1 %		
8	3,3' Dibromo-4,4'-hexamethylenedioxybenzamide (Dibromohexamidine) and its salts (including isethionate)	0.1 %		
9	Dibromopropamide (INN) and its salts (including isethionate (INN))	0.1 %		

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
10	Thiomersal (INN)	0.007 % (of Hg) If mixed with other mercurial compounds authorized by this Directive, the maximum concentration of Hg remains fixed at 0.007 %	For eye make-up and eye make-up remover only	Contains thiomersal
11	Phenylmercuric salts (including borate)	Ditto	Ditto	Contains phenylmercuric compounds
12	Esters of sorbic acid (Hexa-2,4-dienoic acid) (*)	0.6 % (acid) If mixed with sorbic acid and/or its salts, the maximum total concentration of the acids, salts and esters remains fixed at 0.6 % (acid)		
13	Undec-10-enoic acids: salts, esters, the amide, the mono- and bis(2-hydroxyethyl) amides and their sulphosuccinates (*)	0.2 % (acid)		
14	2,6-Diacetyl-1,2,3,9b-tetrahydro-7,9-dihydroxy-8,9b-dimethylidibenzofuran-1,3-dione (usnic acid) and its salts (including the copper salt (*)	0.2 %		
15	Hexatidine (INN) (*)	0.2 %		
16	Benzylformal (a 1:1 mixture of benzyloxymethanol and (benzyloxy-methoxy) methanol)	0.2 %		
17	Clorofene (INN)	0.2 %		
18	5-Bromo-5-nitro-1,3 dioxane (*)	0.1 %	Only for products rinsed off after use	

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
19	Bronopol (INN) (*)	0.1 %		
20	6,6-Dibromo-4,4-dichloro-2,2'-methylene-diphenol (Bromochlorophen) (*)	0.1 %		
21	Tetrabromo- <i>o</i> -cresol (*)	0.3 %		
22	2-Chloroacetamide	0.3 %		Contains chloroacetamide
23	3,4-Dichlorobenzyl alcohol (*)	0.15 %		
24	2,4-Dichlorobenzyl alcohol (*)	0.15 %		
25	Triclocarban (INN) (*)	0.2 %		
26	4-Chloro- <i>o</i> -cresol (*)	0.2 %		
27	Halocarban (INN) (*)	0.3 %	Maximum concentration in aerosols: 0.2 %	
28	Triclosan (INN) (*)	0.3 %		
29	Dichlorophen (INN)	0.2 %		Contains dichlorophen
30	N-(Trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide (Captan (ISO)) (*)	0.5 %		

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
31	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (*)	0.3 %		
32	4-Chloro-3,5-xyleneol (*)	0.5 %		
33	2,4-Dichloro-3,5-xyleneol (*)	0.1 %		
34	Quinolin-8-ol and its salts (*)	0.3 %	Not to be used in products applied after sunbathing, or in talcum powders for children under three years of age	Not to be used for children under three years of age
35	1,3,5-Tris (2-hydroxyethyl)hexahydro-1,3,5-triazine	0.3 %		Contains 1,3,5-Tris (2-hydroxyethyl) hexahydro-1,3,5-triazine
36	3,3'-Bis (1-hydroxymethyl)-2,5-dioximidazolidin-4-yl)-1,1'-methyleneurea ("Imidazolidinyl urea") (*)	0.6 %		
37	4-Isopropyl- <i>m</i> -cresol	0.1 %		
38	2-Chloro- <i>N</i> -(hydroxymethyl)acetamide	0.3 % for the chloracetamide	For products rinsed off after use	
39	1-Hydroxymethyl-5,5-dimethylhydantoin (*)	0.2 % expressed as free formaldehyde or theoretically available formaldehyde	For products rinsed off after use	Contains formaldehyde (1)
40	Pyrrithione sodium (INM) (*)	0.5 %		

(1) Only if the concentration is greater than 0.05 %.

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
41	2,2'-Dithiobis(pyridine 1-oxide), addition product with magnesium sulphate trihydrate (*)	0.5 %		
42	Poly(1-hexamethylenebiguanide hydrochloride) (*)	0.3 %		
43	2-Phenoxyethanol (*)	1 %		
44	Hexamethylenetetramine (*) (methenamine) (INN)	0.2 % expressed as free formaldehyde or theoretically available formaldehyde		Contains formaldehyde (1)
45	Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate	0.005 % (of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one		
46	Pyridin-2-ol 1-oxide (*)	0.5 %	Only for products rinsed off after use	
47	Pyrithione aluminium camsilate (INN)	0.2 %		
48	Methanamine 3-chloroallylochloride (INN)	0.2 %		

(1) Only if the concentration is greater than 0.05 %.

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
49	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one (*)	0.5 %		
50	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (*)	0.2 % expressed as free formaldehyde or theoretically available formaldehyde		Contains formaldehyde (1)
51	Benzyl alcohol (*)	1 %		
52	1-Dodecylguanidinium acetate (Dodine — ISO) (*)	0.5 % 0.1 %	For products rinsed off after use For other uses	
53	Benzethonium chloride (INN) (*)	0.1 %		
54	Benzalkonium chloride (INN), 1-2-Benzisothiazol-3-(2H)-one 1,1-dioxide) (*), its bromide and saccharinate	0.5 %		
55	Alkyl (C12-C22) trimethylammonium bromide and chloride (including Cetrimonium bromide (INN) (*)	0.1 %		
56	1-Phenoxypropan-2-ol	1 %		

(1) Only if the concentration is greater than 0.05 %.

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
57	1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl) 2-pyridon and its monoethanolamine salt	1.0 % 0.5 %	For products rinsed off after use For other uses	
58	3-Heptyl-2-(3-heptyl-4-methyl-4-thiazolin-2-ylidenemethyl)-4-methylthiazolinium iodide	0.002 %	Creams, toilet lotions, shampoos'	

ANNEX 5

List referred to in Article 12 (1)

« ANNEX II (the following points read as indicated) :

2. 2-Acetoxyethyltrimethylammonium hydroxide (acetylcholine) and its salts
5. [4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid and its salts
29. 2-Amino-1,2-bis(4-methoxyphenyl)ethanol and its salts
34. Imperatorin (9-(3-methylbut-2-enyloxy)furo[3,2-g]chromen-7-one)
39. Antibiotics, with the exception of that given in Annex V
42. Apomorphine (R 5, 6, 6a, 7-tetrahydro-6-methyl-4*H*-dibenzo[de,g]quinoline-10,11-diol) and its salts
48. Benzimidazol-2(3*H*)-one
49. Benzazepines and benzodiazepines
50. 1-Dimethylaminomethyl-1-methylpropyl benzoate (amylocaine) and its salts
51. 2,2,6-Trimethyl-4-piperidyl benzoate (benzamine) and its salts
52. Isocarboxazid*
72. Nitroderivatives of carbazole
80. Diphenoxylate* hydrochloride
86. *N,N*-bis(2-chloroethyl)methylamine *N*-oxide and its salts
91. Chlormezanone*
95. 2-[2-(4-Chlorophenyl)-2-phenylacetyl]indan 1,3-dione (chlorophacinone — ISO)
112. 2- α -Cyclohexylbenzyl(*N,N,N',N'*-tetraethyl)trimethylenediamine (phenetamine)
117. *O,O'*-Diacetyl-*N*-allyl-*N*-normorphine
119. 5-($\alpha\beta$ -Dibromophenethyl)-5-methylhydantoin
120. *N,N'*-Pentamethylenebis (trimethylammonium) salts, e.g. pentamethonium bromide*
121. *N,N'*-[(Methylimino)diethylene]bis(ethyltrimethylammonium) salts, e.g. azamethonium bromide*
124. *N,N'*-Hexamethylenebis(trimethylammonium) salts, e.g. hexamethonium bromide*
128. 2-Diethylaminoethyl 3-hydroxy-4-phenylbenzoate and its salts
131. *O,O'*-Diethyl *O*-4-nitrophenyl phosphorothioate (parathion—ISO)
132. [Oxalylbisiminoethylene]bis[(*o*-chlorobenzyl)diethylammonium] salts, e.g. ambenonium chloride *
143. 1,1-Bis(dimethylaminomethyl)propyl benzoate (amydracaine, alypine) and its salts
156. *N*-(3-Carbamoyl-3,3-diphenylpropyl)-*N,N*-diisopropylmethylammonium salts, e.g. isopropamide iodide*
160. 5,5-Diphenyl-4-imidazolidone

196. (1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4:5,8-dime-
thanonaphthalene (endrin — ISO)
204. Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl) acetate and salts of the acid
207. 4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene)dicoumarin
214. Decamethylenebis(trimethylammonium) salts, e.g. decamethonium bromide
217. α -Santonin [(3S,5aR,9bS)-3,3a,4,5,5a,9b-hexahydro-3,5a,9-trimethylnaphto [1,2-b] furan-
2,8-dione]
234. 3,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2H,5H, pyrano[3,2-c]-[1]benzopyran-5-one
(cyclocoumarol)
243. 3-(1-Naphthyl)-4-hydroxycoumarin
271. 2-Phenylindan-1,3-dione (phenindione)
276. Tetraethyl pyrophosphate; TEPP (ISO)
284. α -Piperidin-2-ylbenzyl acetate levorotatory threoform (levopropacetoperane) and its salts
307. Sulphonamides (sulphanilamide and its derivatives ...) and their salts (rest of entry is correct)
313. Xylometazoline* and its salts
346. 2-[4-Methoxybenzyl-N-(2-pyridyl)amino]ethyl dimethylamine maleate
358. Furo[3,2-g]chromen-7-one and its ... (rest of entry is correct)

ANNEX 6

List referred to in Article 12 (2)

« Nachstehende Punkte werden wie folgt berichtigt :

ANHANG II

51. 2,2,6-Trimethyl-piperidin-4-yl-benzoat
67. Phenylbutazonum*
72. Nitroderivate des Carbazols
81. 2,4-Diaminoazobenzol-hydrochlorid-citrat (Chrysoidin-hydrochlorid-citrat)
128. 2-Diäthylaminoäthyl-4-phenyl-3-hydroxy-benzoat und seine Salze
130. 3-Diäthylaminopropyl-cinnamat
132. N,N'-Bis-(diäthyl)-N,N'-bis- (o-chlorbenzyl)-N,N'-(4,5-dioxo-3,6-diaza-octamethylen)-diammo-
nium-Salze (z. B. Ambenonii chloridum*)
143. 1,1-Bis-(dimethylaminomethyl)-propyl-benzoat (Amydracaine) und seine Salze
156. N-(4-Amino-4-oxo-3,3-diphenyl-butyl)- ...
196. ... (Endrin)

204. Äthyl-2,2-bis-(4-hydroxy-3-cumarinyl)- ...
216. 2-Isopropyl-4-pentenyl-harnstoff (Apronalid)
234. 3,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2H,5H-pyrano [3,2-c] [1] benzopyran-5-on
(Cyclocumarol)
254. Acenocoumarolum*
281. Physostigma venenosum Balf.
284. (—)-L-Threo- α -phenyl-2-piperidinomethanol-acetat (Levophacetoperan) und seine Salze
318. Glycoside der Thevetia nerifolia Juss.
340. p-tert.-Butyl-phenol und seine Derivate
341. p-tert.-Butyl-brenzcatechin
347. Pyribenzaminum*
351. Dibromsalicylanilide ...
358. Eurocumarine [z. B. Trioxysalenum* 8-Methoxypsoralen], ausgenommen normale Gehalte in natürlichen ätherischen Ölen

ANHANG III — Teil 2

- | | | |
|-------------|--------|---|
| d) Violett, | braun, | schwarz und weiss: |
| Nr. 21 | 77 891 | E 171, Titandioxid (und seine Gemische mit Glimmer) |
| Nr. 23 | 75 170 | Guanin oder Perlglanz-Mittel |

ANHANG IV — Teil 2

Fußnote 2 zur Überschrift:

..., daß der Farbstoff nicht zur Herstellung von kosmetischen Mitteln verwendet werden darf, die mit den Schleimhäuten des Auges in Berührung kommen können

- | | | |
|-------------|--------|---|
| d) Violett, | braun, | schwarz und weiß: |
| Nr. 6 | 77 163 | Wismutoxichlorid (und seine Verbindungen mit Glimmer) |

ANHANG V

4. p-Phenylendiamin und seine Salze

ANNEX 7

List referred to in Article 12 (3)

<i>« BIJLAGE II</i>	<i>Wordt gelezen:</i>
15. ...Rouwolfia	Rauwolfia
34. ...genzopyran	benzopyran
182. Etheenoxyde	Ethyleenoxide
215. Ipecacuanha Uragoga Bailloen	Uragoga ipecacuanha Baill.
220. Babituurzuur	Barbituurzuur
221. ... bijlage IV	bijlagen IV en V
250. ... alkalische zouten	alkalizouten
268. ... alkalische zouten	alkalizouten
291. Prunus Laurocerasus	Prunus laurocerasus
314. Tetrachloortetheen	Tetrachloorethyleen
315. Tetrachloorkoolstof	Tetrachloorkoolstof
340. p-butyltert.-	p-tert. butyl ...
341. p-butyl tert.-	p-tert. butyl ... »
