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(Acts whose publication is not obligatory)

COMMISSION

EIGHTH COMMISSION DIRECTIVE

of 26 March 1986

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

(86/199/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 86/179/EEC⁽²⁾, and in particular Articles 5 and 8 (2) thereof,

Whereas, in order to protect public health, it is necessary to lay down purity criteria for hexachlorophene and triclocarban;

Whereas, on the basis of the available information, certain provisionally-permitted substances and preservatives 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, number 221 is replaced by: '221. Mercury and its compounds, except those special cases included in Annexes V and VI, Part 1'.

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

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 and 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, 26 March 1986.

For the Commission

Grigoris VARFIS

Member of the Commission

⁽¹⁾ OJ No L 262, 27. 9. 1976, p. 169.

⁽²⁾ OJ No L 138, 24. 5. 1986, p. 40.

ANNEX 1

ANNEX IV

PART ONE

LIST OF SUBSTANCES PROVISIONALLY ALLOWED

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
1	Methanol	Denaturant for ethanol and isopropyl alcohol	5 % calculated as a % of ethanol and isopropyl alcohol			31. 12. 1987
2	1,1,1-Trichloroethane (methyl chloroform)	Aerosol spray	35 % When mixed with dichloro-methane, total concentration must not exceed 35 %		Do not spray on a naked flame or any incandescent material	31. 12. 1987
3	3,4',5 Tribromosalicylanilide (Tribromsalan ("))	Deodorant soap	1 %	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 NaBr	Contains tribromosalicylanilide	31. 12. 1987
4	2,2'-Dithiobis (pyridine 1-oxide), addition product with magnesium sulphate trihydrate	Only for hair-care products rinse off	1 %	As preservative, see Annex VI, Part 2, No 13		31. 12. 1986
5	1-Phenoxypropan-2-ol	— Rinse-off products only — Prohibited in oral hygiene products	2 %	As preservative, see Annex VI, Part 2, No 14		31. 12. 1986

*ANNEX 2**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 concentration other than those laid down in this Annex for other specific purposes apparent from the presentation of the products, 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.
5. All finished products containing formaldehyde or substances in this Annex and which release formaldehyde must be labelled with the warning "contains formaldehyde" where the concentration of formaldehyde in the finished product exceeds 0,05 %.

PART 1

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 (*)
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts (*)	0,6 % (acid)		
5	Formaldehyde paraformaldehyde	0,2 % (except for products for oral hygiene) 0,1 % (products for oral hygiene) expressed as free formaldehyde	Prohibited in aerosol dispensers (sprays)	
6	Hexachlorophene (INN)	0,1 %	— Prohibited in products for children under three years of age, and intimate hygiene products — Purity criterion: absence of 2,3,7,8-tetrachlorodibenzo- <i>p</i> -dioxin	Not to be used for children under three years of age. Contains hexachlorophene
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 Forbidden in products for oral hygiene	
9	Inorganic sulphites and hydrogen-sulphites (*)	0,2 % expressed as free SO ₂		
10	Sodium iodate	0,1 %	Rinse-off products only	

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

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
11	Chlorobutanol (INN)	0,5 %	Prohibited in aerosol dispensers (sprays)	Contains chlorobutanol
12	4-Hydroxybenzoic acid and its salts and esters (*)	0,4 % (acid) for 1 ester, 0,8 % (acid) for mixtures of esters		
13	3-Acetyl-6-methylpyran-2,4 (3H)-dione (Dehydracetic acid) and its salts	0,6 % (acid)	Prohibited in aerosol dispensers (sprays)	
14	Formic acid (*)	0,5 % (acid)		
15	3,3'-Dibromo-4,4'-hexamethylene-dioxybenzamide (Dibromohexamidine) and its salts (including isethionate)	0,1 %		
16	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
17	Phenylmercuric salts (including borate)	Ditto	Ditto	Contains phenylmercuric compounds
18	Undec-10-enoic acid and salts (*)	0,2 % (acid)	See Annex VI, Part 2, No 8	
19	Hexetidine (INN) (*)	0,1 %	Rinse-off products only See Annex VI, Part 2, No 18	
20	5-Bromo-5-nitro-1,3-dioxane	0,1 %	Rinse-off products only Avoid formation of nitrosamines See Annex VI, Part 2, No 7	
21	Bronopol (INN) (*)	0,1 %	Avoid formation of nitrosamines	
22	2,4-Dichlorobenzyl alcohol (*)	0,15 %		
23	Triclocarban (INN) (*)	0,2 %	Purity criteria : 3,3',4,4'-Tetrachloroazobenzene < 1 ppm 3,3',4,4'-Tetrachloroazoxybenzene < 1 ppm	

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
24	4-Chloro-m-cresol (*)	0,2 %	Prohibited in the products intended to come into contact with mucous membranes	
25	Tricolosan (INN) (*)	0,3 %		
26	4-Chloro-3,5-xyleneol (*)	0,5 %		
27	3,3'-Bis (1-hydroxymethyl-2,5-dioximidazolidin-4-yl)-1,1'-methylenediurea ("Imidazolidinyl urea") (*)	0,6 %		
28	Poly (1-hexamethylenebiguanide hydrochloride) (*)	0,3 %		
29	2-Phenoxyethanol (*)	1 %		
30	Hexamethylenetetramine (*) (methenamine) (INN)	0,15 %		
31	Methenamine 3-chloroallylochloride (INN)	0,2 %		
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one (*)	0,5 %		
33	1,3-Bis (hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (*)	0,6 %		
34	Benzyl alcohol (*)	1 %		
35	1-Hydroxy-4-methyl-6(2,4,4-trimethylpentyl)-2-pyridon and its monoethanolamine salt (*)	1,0 % 0,5 %	Products rinsed off For other products	
36	1,2-Dibromo-2,4-dicyanobutane	0,1 %		Not to be used in cosmetic sunscreen products
37	6,6-Dibromo-4,4-dichloro-2,2'-methylene-diphenol (Bromochlorophen) (*)	0,1 %		
38	4-Isopropyl-m-cresol	0,1 %		
39	Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate	0,003 % (of a mixture in the ratio 3 : 1 of 5-chloro-2-methylisothiazol 3(2H)-one and 2-methylisothiazol-3 (2H)-one		

PART 2

LIST OF PRESERVATIVES PROVISIONALLY ALLOWED

Reference number	Substance	Maximum authorized concentration	Limitation and requirements	Conditions of use and warnings which must be printed on the label	Allowed until
a	b	c	d	e	f
1	Boric acid (*)	(a) 0,5 % (b) 3 %	(a) Products for oral hygiene (b) Other products		31. 12. 1988
2	Chlorphenesin (INN) (*)	0,5 %			31. 12. 1987
3	Dibromopropamide (INN) and its salts (including isethionate (INN))	0,1 %			31. 12. 1988
4	Alkyl (C12-C22) trimethyl-ammonium bromide and chloride (including Cetrimonium bromide (INN) (*)	0,1 %			31. 12. 1988
5	3-Heptyl-2-(3-heptyl-4-methyl-4-thiazolin-2-ylidenemethyl)-4-methyl-thiazolinium iodide	0,002 %	Creams, toilet lotions, shampoos		31. 12. 1988
6	4,4-Dimethyl-1,3-oxazolidine	0,1 %	Rinse-off products only. The pH of the finished product shall not be lower than 6		31. 12. 1989
7	5-Bromo-5-nitro-1,3-dioxane	0,1 %	Non rinse-off products. Avoid formation of nitrosamines. See Annex VI, Part 1, No 20		31. 12. 1987
8	Undec-10-enoic acid: esters, the amide, the mono- and bis (2-hydroxyethyl) amides and their sulphosuccinates (*)	0,2 % (acid)	See Annex VI, Part 1, No 18		31. 12. 1987
9	Clorofene (INN)	0,2 %			31. 12. 1987
10	2-Chloro-N-(hydroxymethyl) acetamide	0,3 % expressed as the chloracetamide	Products rinsed off		31. 12. 1987
11	Pyrithione aluminium camsilate (INN(M))	0,2 %			31. 12. 1986

Reference number	Substance	Maximum authorized concentration	Limitation and requirements	Conditions of use and warnings which must be printed on the label	Allowed until
a	b	c	d	e	f
12	N-(Trichloromethylthio) cyclohex-4-ene-1,2-dicarboximide (Captan — ISO)	0,06 %	Prohibited in the products intended to come into contact with mucous membranes		31. 12. 1986
13	2,2'-Dithiobis (pyridine 1-oxide), addition product with magnesium sulphate trihydrate	0,2 %	Products rinsed off		31. 12. 1986
14	1-Phenoxypropan-2-ol	1 %	Rinse-off products only		31. 12. 1986
15	Benzethonium chloride (INN)(^(*))	0,1 %	Prohibited in the products intended to come into contact with mucous membranes		31. 12. 1986
16	Benzalkonium chloride (INN), bromide and saccharinate (^(*))	0,25 %			31. 12. 1986
17	1-[1,3-Bis (hydroxymethyl)-2,5-dioximidazolidin-1-yl]-1,3-bis (hydroxymethyl) urea	0,5 %			31. 12. 1987
18	Hexetidine (INN)	0,1 %	See Annex VI, Part I, No 19		31. 12. 1987
19	4-Hydroxybenzoic acid benzyl ester	0,1 % (acid)			31. 12. 1988
20	Hexamidine (INN) and its salts (including isethionate and 4-hydroxybenzoate)(^(*))	0,1 %			31. 12. 1988
21	Benzylformal (a 1:1 mixture of benzyloxy-methanol and (benzyloxymethoxy) methanol)	0,2 %			31. 12. 1987
22	2-Chloroacetamide	0,3 %		Contains chloroacetamide	31. 12. 1987
23	1-Dodecylguanidinium acetate (Dodine — ISO)(^(*))	0,5 % 0,1 %	Products rinsed off For other products		31. 12. 1986
24	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (^(*))	0,3 %			31. 12. 1987
25	1,3,5-Tris (2-hydroxyethyl) hexahydro-1,3,5-triazine	0,2 %	Only for products rinsed off	Contains 1,3,5-Tris (2-hydroxyethyl) hexahydro-1,3,5-triazine	31. 12. 1988