II

(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 dichloromethane, 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 (1)
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-*p*-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	Pyrithione 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	

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