

23rd COMMISSION DIRECTIVE 98/62/EC

of 3 September 1998

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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European 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 Commission Directive 98/16/EC⁽²⁾ and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Cosmetology,

Whereas, in the absence of fresh scientific data, in particular as regards long-term toxicity, the Scientific Committee on Cosmetology recommends that the use of muskene and musk tibetene should be prohibited in cosmetic products as they may present a risk to the health of consumers;

Whereas a further toxicological evaluation of strontium chloride, based on new data submitted by industry, shows that the use of this substance may be extended, without any safety risk, to shampoos and face care products provided a maximum concentration is not exceeded;

Whereas, on the basis of the latest scientific data, the use may be permitted of benzalkonium chloride, bromide and saccharinate as preservatives in cosmetic products subject to the requirements of the Directive;

Whereas, on the basis of the latest scientific research and data, 3-iodo-2-propynyl butylcarbamate (iodopropynyl butylcarbamate) may be provisionally used as a preservative in cosmetic products subject to certain conditions on concentrations and use;

Whereas, on the basis of the latest scientific data, phenol 2-(2H-benzotriazol-2-yl)-4-methyl-6-(2-methyl-3-(1,3,3,3-tetramethyl-1-(trimethylsilyloxy)-disiloxanyl)propyl) may be used as a UV filter in cosmetic products subject to the requirements of the Directive;

Whereas, on the basis of the latest scientific data, benzoic acid, 4,4'-((6-(((1,1-dimethylethyl)amino)carbonyl)phenyl)amino) 1,3,5-triazine-2,4-diyl)diamino)bis-,bis(2-ethylhexyl) ester may be used as a UV filter in cosmetic products;

Whereas, on the basis of the latest scientific research and data, ethoxylated ethyl-4-aminobenzoate, isopentyl-4-methoxycinnamate, 2,4,6-trianilino-(*p*-carbo-2'-ethylhexyl-1'-oxy)-1,3,5-triazine and 2-Ethylhexyl salicylate may be used as UV filters in cosmetic products subject to the requirements of the Directive;

Whereas, on the basis of the latest scientific research and data, 3-(4'-methylbenzylidene)-d-1camphor and 3-benzylidene camphor may be used as UV filters in cosmetic products;

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 shown in the Annex.

Article 2

1. Member States shall take the necessary measures to ensure that, as from 1 July 1999, for the substances set out in the Annex, neither manufacturers nor importers established in the Community place on the market products which do not comply with the requirements of this Directive.

2. Member States shall take the necessary measures to ensure that the products referred to in paragraph 1 containing the substances set out in the Annex are not sold or otherwise supplied to the final consumer after 30 June 2000.

⁽¹⁾ OJ L 262, 27. 9. 1976, p. 169.

⁽²⁾ OJ L 77, 14. 3. 1998, p. 44.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than 30 June 1999. They shall forthwith inform the Commission thereof. When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by the Member States.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

Article 4

This Directive shall enter into force on the third day following its publication in the *Official Journal of the European Communities*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 3 September 1998.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX

The Annexes to Directive 76/768/EEC are amended as follows:

1. *In Annex II*

The following reference numbers are added:

- '421. 1,1,3,3,5,-Pentamethyl-4,6-dinitroindane (moskene)
422. 5-tert-Butyl-1,2,3-trimethyl-4,6-dinitrobenzene (musk tibetene).'

2. *In Annex III*

Reference number 57 is amended as follows:

'57	Strontium chloride hexahydrate	(a) Toothpaste	3,5 % calculated as strontium. When mixed with other permitted strontium compounds the total strontium content must not exceed 3,5 %.		Contains strontium chloride. Frequent use by children is not advisable.'
		(b) Shampoo and face care products	2,1 % calculated as strontium. When mixed with other permitted strontium compounds the total strontium content must not exceed 2,1 %.		

3. *In Annex VI*

(a) Part one

The following reference number is added

a	b	c	d	e
'54	Benzalkonium chloride, bromide and saccharinate (+)	0,1 % calculated as benzalkonium chloride		Avoid contact with the eyes'

(b) Part two

Reference number 16 is deleted.

'30.6.1998' is replaced by '30.6.1999' for reference number 21 and 29.

Reference number 29 is also modified:

a	b	c	d	e
'29	3-Iodo-2-propynyl butylcarbamate (iodopropynyl butylcarbamate)	0,05 %	Not for oral hygiene and lip products'	

4. *In Annex VII*

(a) Part one

The following reference numbers are added

a	b	c	d	e
'13	Ethoxylated Ethyl-4-Aminobenzoate (PEG-25 PABA)	10 %		
14	Isopentyl-4-methoxycinnamate (Isoamyl p-Methoxycinnamate)	10 %		
15	2,4,6-Trianiilino-(p-Carbo-2'-Ethylhexyl-1'Oxy)-1,3,5-Triazine (Octyl Triazone)	5 %		
16	Phenol,2-(2H-Benzotriazol-2-yl)-4-Methyl-6-(2-Methyl-3-(1,3,3,3-Tetramethyl-1-(Trimethylsilyl)Oxy)-Disiloxanyl)Propyl (Drometrizole Trisiloxane)	15 %		
17	Benzoic acid, 4,4-(((6-(((1,1-dimethylethyl)amino)carbonyl)phenyl)amino)1,3,5-triazine-2,4-diyl)diimino)bis-,bis(2-ethylhexyl)ester)	10 %		
18	3-(4'-Methylbenzylidene)-d-l camphor (4-Methylbenzylidene Camphor)	4 %		
19	3-Benzylidene camphor (3-Benzylidene Camphor)	2 %		
20	2-Ethylhexyl salicylate (Octyl-salicylate)	5 %'		

(b) Part two

Reference numbers 2, 6, 12, 25, 26 and 32 are deleted.

'30.6.1998' is replaced by '30.6.1999' for reference numbers 5, 17 and 29.