

DIRECTIVES

COMMISSION DIRECTIVE 2007/17/EC

of 22 March 2007

amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexes III and VI thereto to technical progress

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

symbol (*) when used in higher concentrations for other specific purposes.

Having regard to the Treaty establishing the European Community,

(5) On the basis of those safety-files, the SCCP concluded that the use of several of the preservative substances in Annex VI for other specific purposes in higher concentrations is safe.

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⁾, and in particular Article 8(2) thereof,

(6) The safe concentration limits for those preservative substances when used for other specific purposes should be included in Annex III to Directive 76/768/EEC. For the sake of clarity, it should be indicated for the relevant entries in Annex III that the same substance is listed in Annex VI to that Directive.

After consulting the Scientific Committee on Consumer Products,

Whereas:

(1) Annex VI to Directive 76/768/EEC establishes a list of preservatives allowed in cosmetic products. The substances listed in Annex VI marked with the symbol (*) may be used in concentrations other than those fixed in that Annex for non-preservative purposes, if the specific purpose is apparent from the presentation of the product. Nevertheless, the use of these substances may be restricted in other Annexes to that Directive.

(7) Substances that were not considered to be safe by the SCCP when used in concentrations other than those laid down in Annex VI for other specific purposes should be subject to the restrictions laid down in that Annex for use as preservatives. The symbol (*) should therefore be deleted from those substances in Annex VI.

(2) The substances listed in Annex VI without the symbol (*) may not be used in concentrations other than those listed in that Annex and the other restrictions set out therein also apply when those substances are used for other specific purposes.

(8) In order to ensure a coherent approach, all substances listed in Annex VI which may also be added to cosmetic products, for other specific purposes, in higher concentrations than those laid down in that Annex should be marked with the symbol (*).

(3) The Scientific Committee on Consumer Products, hereinafter 'the SCCP', has issued an opinion stating that the restrictions for usage level and warnings in Annex VI should also apply if the preservatives marked with the symbol (*) are used for other specific purposes.

(9) Moreover, the SCCP considered it safe to increase the maximum concentration of benzoic acid and its sodium salt in rinse-off products and oral-care products and to increase the maximum concentration of zinc pyrithione in rinse-off hair products for preservative use. It is therefore appropriate to amend reference numbers 1 and 8 of Annex VI to Directive 76/768/EEC accordingly.

(4) The Commission therefore called upon the industry to submit safety files for substances listed with the

(10) The SCCP is also of the opinion that methylidibromoglutaronitrile should not be present in any cosmetic products, as no safe use-levels in cosmetic leave-on and rinse-off products have been established. It is therefore necessary to delete that substance from reference number 36 of Annex VI to Directive 76/768/EEC.

⁽¹⁾ OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2007/1/EC (OJ L 25, 1.2.2007, p. 9).

- (11) Directive 76/768/EEC should therefore be amended accordingly.
- (12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes III and VI to Directive 76/768/EEC are amended in accordance with the Annex to this Directive.

Article 2

Member States shall take all necessary measures to ensure that from 23 March 2008 no cosmetic products which fail to comply with this Directive are placed on the market by Community manufacturers or by importers established within the Community.

Member States shall take all necessary measures to ensure that those products are not sold or disposed of to the final consumer after 23 June 2008.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this

Directive by 23 September 2007 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

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

Article 4

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 22 March 2007.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX

Directive 76/768/EEC is amended as follows:

(1) Annex III, Part 1, is amended as follows:

Reference numbers 98 to 101 are added as indicated below:

Reference No	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
'98	Salicylic acid ⁽¹⁾ (CAS No 69-72-7)	a) Rinse-off hair products b) Other products	a) 3,0 % b) 2,0 %	Not to be used in preparations for children under three years of age, except for shampoos. For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	Not to be used for children under three years of age ⁽²⁾
99	Inorganic sulfites and bisulfites ⁽³⁾	a) Oxidative hair dye products b) Hair straightening products c) Self tanning products for the face d) Other self tanning products	a) 0,67 % expressed as free SO ₂ b) 6,7 % expressed as free SO ₂ c) 0,45 % expressed as free SO ₂ d) 0,40 % expressed as free SO ₂	For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	
100	Triclocarban ⁽⁴⁾ (CAS No 101-20-2)	Rinse-off products	1,5 %	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene ≤ 1 ppm 3,3',4,4'-Tetrachloroazoxybenzene ≤ 1 ppm For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	
101	Zinc pyrithione ⁽⁵⁾ (CAS No 13463-41-7)	Leave-on hair products	0,1 %	For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	

⁽¹⁾ As a preservative, see Annex VI, Part 1, No 3.

⁽²⁾ Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin.

⁽³⁾ As a preservative, see Annex VI, Part 1, No 9.

⁽⁴⁾ As a preservative, see Annex VI, Part 1, No 23.

⁽⁵⁾ As a preservative, see Annex VI, Part 1, No 8.'

(2) Annex VI, Part 1, is amended as follows:

- a) In column b, the symbol '(*)' is deleted for the reference numbers 1, 2, 4, 7, 12, 14, 18, 19, 21, 22, 24, 25, 26, 27, 28, 29, 30, 32, 33, 35, 37, 42 and 47.
- b) In column b, the symbol '(*)' is added for the reference numbers 5 and 43.
- c) Reference number 1 is replaced by the following:

Reference No	Substance	Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
'1	Benzoic acid (CAS No 65-85-0) and its sodium salt (CAS No 532-32-1)	Rinse-off products, except oral care products: 2,5 % (acid) Oral care products: 1,7 % (acid) Leave-on products: 0,5 % (acid)		
1a	Salts of benzoic acid other than that listed under reference number 1 and esters of benzoic acid	0,5 % (acid)'		

d) Reference number 8 is replaced by the following:

Reference No	Substance	Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
'8	Zinc pyrithione (*) (CAS No 13463-41-7)	Hair products: 1,0 % Other products: 0,5 %	Rinse-off products only. No use in products for oral hygiene.'	

e) Reference number 36 is deleted.