COMMISSION DIRECTIVE 2003/83/EC

of 24 September 2003

adapting to technical progress Annexes II, III and VI 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 2003/80/EC [2], and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers,

Whereas:

(1) Benzoyl peroxide and hydroquinone methylether (synonym of 4-methoxyphenol) are currently listed in Annex II, hydroquinone is already subject to restrictions and conditions laid down in Annex III. The Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers (hereinafter SCCNFP) has come to the conclusion that, due to the very low exposure to the consumer, the use of benzoyl peroxide, hydroquinone and hydroquinone methylether in artificial nail systems does not pose a risk. Therefore, reference No 178 of Annex II and reference No 14 of Annex III, part 1 should be amended accordingly; reference No 382 of Annex II should be deleted and reference Nos 94 and 95 should be added in Annex III, part 1.

(2) It is the opinion of the SCCNFP that the toxicological effects of the dialkanolamine salts, and, in particular, their readiness for nitrosamines' formation are similar to the respective properties of the dialkanolamines and that dialkylamines and their salts have very similar properties with the respective dialkanolamines' analogues with respect to nitrosamines' formation. The terms 'dialkanolamines' and 'dialkylamines' and synonymous with 'secondary alkanolamines' and 'secondary alkylamines' and the latter are less ambiguous. Therefore, reference No 411 of Annex II and reference Nos 60, 61 and 62 of Annex III, part 1, should be amended accordingly.

(3) The SCCNFP has come to the conclusion that the compound 2,4-diamino-pyrimidine-3-oxide (CAS No 74638-76-9) can be used safely in cosmetic products at concentrations up to 1,5 %. Therefore, 2,4-diamino-pyrimidine-3-oxide should be included in Annex III, part 1 as reference No 93.

(4) The SCCNFP is of the opinion that the use of 1,2-dibromo-2,4-dicyanobutane should be restricted to rinse-off products at the current maximum permitted level of 0,1 %. Therefore reference No 36 of Annex VI, part 1 should be amended accordingly.

(5) Therefore, Directive 76/768/EEC should be amended accordingly.

(6) 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 II, III and VI to Directive 76/768/EEC shall be amended as set out in the Annex to this Directive.

Article 2

1. Member States shall take the necessary measures to ensure that from 24 March 2005 cosmetic products which fail to comply with this Directive shall not be placed on the market by Community manufacturers or by importers established within the Community.

2. Member States shall take the necessary measures to ensure that the products referred to in paragraph 1 shall not be sold or disposed of to the final consumer after 24 September 2005.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 24 September 2004 at the latest. They shall forthwith inform the Commission thereof.

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.

[1] OJ L 262, 27.9.1976, p. 169.
[2] OJ L 224, 6.9.2003, p. 27.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 24 September 2003.

For the Commission

Erkki LIIKANEN

Member of the Commission

ANNEX

The Annexes II, III and VI to Directive 76/768/EEC are amended as follows:

1. **Annex II is amended as follows:**

(a) reference No 178 is replaced by the following:

'178. 4-Benzoyloxyphenol and 4-ethoxyphenol'

(b) reference No 382 is deleted.

(c) reference number 411 is replaced by the following:

'411. Secondary alkyl- and alkanolamines and their salts'.

2. **Annex III, part 1 is amended as follows:**

(a) reference No 14 is replaced by the following:

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed in 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
'14	Hydroquinone (*)	(a) oxidising colouring agent for hair-dying:	0,3 %		(a) 1. — Do not use to dye eyelashes or eyebrows
		1. General use			— Rinse the eyes immediately if the product comes into contact with them — Contains hydroquinone
		2. Professional use			2. — For professional use only — Contains hydroquinone — Rinse the eyes immediately if the product comes into contact with them
		(b) artificial nail systems	0,02 % (after mixing for use)	Professional use only	(b) — For professional use only — Avoid skin contact — Read directions for use carefully'

(*) 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.

(b) reference Nos 60, 61 and 62 are replaced by the following:

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed in 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
‘60	Fatty acid dialkylamides and dialkanolamides		Maximum secondary amine content: 0,5 %	— Do not use with nitrosating systems — Maximum secondary amine content: 5 % (applies to raw materials) — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
61	Monoalkylamines, monoalkanolamines and their salts		Maximum secondary amine content: 0,5 %	— Do not use with nitrosating systems — Minimum purity: 99 % — Maximum secondary amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
62	Trialkylamines, trialkanolamines and their salts	(a) non-rinse-off products (b) other products	(a) 2,5 %	(a) (b) — Do not use with nitrosating systems — Minimum purity: 99 % — Maximum secondary amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers’	

(c) reference Nos 93, 94 and 95 are added:

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed in 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
‘93	2,4-Diamino-pyrimidine-3-oxide (CAS No 74638-76-9)	Hair care formulations	1,5 %		

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed in 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
94	Benzoyl peroxide	Artificial nail systems	0,7 % (after mixing)	Professional use only	— For professional use only — Avoid skin contact — Read directions for use carefully
95	Hydroquinone methylether	Artificial nail systems	0,02 % (after mixing for use)	Professional use only	— For professional use only — Avoid skin contact — Read directions for use carefully'

3. **In Annex VI, part 1, reference No 36 is replaced by the following:**

Reference number	Substance	Maximum authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
'36	1,2-Dibromo-2,4-dicyanobutane (methyldibromo glutaronitrile)	0,1 %	Rinse-off products only'	