

COMMISSION DIRECTIVE 2004/88/EC**of 7 September 2004****amending Council Directive 76/768/EEC concerning cosmetic products for the purpose of adapting Annex III thereto to technical progress****(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⁾, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers,

Whereas:

- (1) As the risk assessment had not been completed in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances⁽²⁾, the period of inclusion in part 2 of Annex III to Directive 76/768/EEC for musk xylene and musk ketone was extended until 30 September 2004.
- (2) On 8 January 2004, the Scientific Committee on Toxicity, Ecotoxicity and the Environment adopted an opinion on the results of the risk assessment of musk xylene and musk ketone that was carried out in accordance with Regulation (EEC) 793/93.
- (3) The Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers (SCCNFP) has confirmed that musk xylene can be safely used in cosmetic products, excluding oral care products, up to a maximum concentration in the final product of 1% in fine fragrance, 0,4% in eau de toilette and 0,03% in other products and that musk ketone can be safely used in cosmetic products, excluding oral care products, up to a maximum concentration in the final product of 1,4% in fine fragrance, 0,56% in eau de toilette and 0,042% in other products.

(4) It is therefore necessary to include musk xylene and musk ketone in part 1 of Annex III to Directive 76/768/EEC while the corresponding entries in part 2 of that Annex should be deleted.

(5) Directive 76/768/EEC should therefore 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

Annex III to Directive 76/768/EEC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 October 2004 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 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 7 September 2004.

For the Commission

Olli REHN

Member of the Commission

⁽¹⁾ OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2003/83/EC (OJ L 238, 25.9.2003, p. 23).

⁽²⁾ OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

ANNEX

Annex III to Directive 76/768/EEC is amended as follows:

1. In part 2, the entries under reference numbers 61 and 62 are deleted.
2. In part 1, the following entries are added as reference numbers 96 and 97:

Reference number	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
'96	Musk xylene (CAS No 81-15-2)	All cosmetic products, with the exception of oral care products	(a) 1,0 % in fine fragrance (b) 0,4 % in eau de toilette (c) 0,03 % in other products		
97	Musk ketone (CAS No 81-14-1)	All cosmetic products, with the exception of oral care products	(a) 1,4 % in fine fragrance (b) 0,56 % in eau de toilette (c) 0,042 % in other products'		