

EN

EN

EN



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C (2009) XXX

Draft

COMMISSION DIRECTIVE ../.../EC

of [...]

**amending, for the purpose of adaptation to technical progress, Annexes II and III to
Council Directive 76/768/EEC concerning cosmetic products**

(Text with EEA relevance)

Draft

COMMISSION DIRECTIVE ../.../EC

of [...]

amending, for the purpose of adaptation to technical progress, Annexes II and III to Council Directive 76/768/EEC concerning 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 products¹, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Consumer Safety,

Whereas:

- (1) The substance Verbena oil (*Lippia citriodora* Kunth.) is currently banned for use in cosmetic products, being listed in Annex II to Directive 76/768/EEC, under reference number 450. The ban of this substance was introduced on the basis of an opinion of May 2000 of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP), subsequently replaced by the "Scientific Committee on Consumer Products (SCCP)" by Commission Decision 2004/210/EC², and later by the "Scientific Committee on Consumer Safety (SCCS)" by Commission Decision 2008/721/EC³. The SCCNFP recommended the prohibition of Verbena (*Lippia citriodora* Kunth.) essential oils and derivatives, e.g. concrete and absolute, when used as a fragrance ingredient, based on the sensitizing potential.
- (2) However, the SCCNFP later concluded in an opinion issued in 2001 that Verbena absolute obtained from *Lippia citriodora* Kunth. should not be used such that the level in the finished cosmetic products exceeds 0.2%. It is therefore appropriate to include Verbena absolute (*Lippia citriodora* Kunth.) together with its respective restriction in Annex III, Part 1 to Directive 76/768/EEC. It is also appropriate to amend reference number 450 of Annex II in order to specify that the substances Verbena essential oils (*Lippia citriodora* Kunth.) and derivatives other than absolute are prohibited when used as a fragrance ingredient.

¹ OJ L 262, 27.9.1976, p. 169.

² OJ L 66, 4.3.2004, p. 45. Decision as amended by Commission Decision 2007/263/EC (OJ L 114, 1.5.2007, p. 14).

³ OJ L 241, 10.9.2008, p. 21.

- (3) Directive 2008/42/EC of 3 April 2008 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and III thereto to technical progress⁴ included several allyl esters containing allyl alcohol as impurity in Annex III, Part 1 to Directive 76/768/EEC. The substance allyl phenethyl ether may contain allyl alcohol as impurity as well. For this substance, the SCCNFP issued an opinion in 2000 recommending an upper limit of 0.1% of allyl alcohol as impurity.
- (4) In the light of the SCCNFP opinion, as well as for consistency reasons, it is appropriate to include in Annex III, Part 1 to Directive 76/768/EEC the substance allyl phenethyl ether together with its respective restriction.
- (5) The group of substances Terpene terpenoids sinpine is currently regulated under reference number 130 in Annex III, Part 1 to Directive 76/768/EEC. However, the word "sinpine" is a trade name and should therefore be deleted from the designation of that group of substances.
- (6) Directive 76/768/EEC should therefore be amended accordingly.
- (7) In view of a smooth transition from existing formulae of cosmetic products to formulae which comply with the requirements laid down in this directive, it is necessary to provide for appropriate transitional periods.
- (8) 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 and III 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, as from [**Day, Month, Year = 12 months after the entry into force of this Directive**], 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, as from [**Day, Month, Year = 18 months after the entry into force of this Directive**], no cosmetic products which fail to comply with this Directive are sold or disposed of to the final consumer in the Community.

⁴ OJ L 93, 4.4.2008, p. 13.

Article 3

1. Member States shall adopt and publish, by **[insert concrete date = 6 months after the entry into force of this Directive]** at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from **[insert concrete date = 12 months after the entry into force of 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 twentieth 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, [...].

For the Commission

[...]

Member of the Commission

ANNEX

Directive 76/768/EEC is amended as follows:

(1) In Annex II, reference number 450, 'Verbena oil (*Lippia citriodora* Kunth.) (CAS No 8024-12-2), when used as a fragrance ingredient' is replaced by 'Verbena essential oils (*Lippia citriodora* Kunth.) and derivatives other than absolute (CAS No 8024-12-2), when used as a fragrance ingredient'.

(2) Part 1 of Annex III is amended as follows:

(a) the following entry is inserted after the entry with reference number 151:

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
"151 bis	Allyl phenethyl ether CAS No 14289-65-7 EC No 238-212-2			Level of free allyl alcohol in the ether should be less than 0.1 %"	

(b) the following entry is added:

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
"X	Verbena absolute <i>(Lippia citriodora</i> Kunth.) CAS No 8024-12-2		0.2%"		

(c) in column "b" of the entry relating to reference number 130, the words 'Terpene terpenoids sinpine' are replaced by 'Terpenes and terpenoids'.