

EN

EN

EN



EUROPEAN COMMISSION

Brussels, 17.12.2009

Draft

COMMISSION DIRECTIVE ../.../EU

of [...]

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

Draft

COMMISSION DIRECTIVE ../.../EU

of

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 Products,

Whereas:

- (1) The Scientific Committee on Consumer Products (SCCP), subsequently replaced by the Scientific Committee on Consumer Safety (SCCS) by Commission Decision 2008/721/EC², concluded in its opinion of 2 October 2007 that the data included in the dossier demonstrate that polidocanol (laureth-9) is of low toxicity and does not pose a risk to the health of the consumer when used up to 3% in leave-on and up to 4% in rinse-off cosmetic products. As a result of this assessment, it should be included in Annex III to Directive 76/768/EEC.
- (2) Directive 76/768/EEC should therefore be amended accordingly.
- (3) 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.

¹ OJ L 262, 27.9.1976, p. 169.

² OJ L 241, 10.9.2008, p. 21.

Article 2

1. Member States shall adopt and publish, by [Day, Month, Year = Six months after the entry into force of the 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 [Day, Month, Year = Twelve months after the entry into force of the 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 twentieth 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,

*For the Commission
The President*

ANNEX

In Part 1 of Annex III to Directive 76/768/EEC, 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 authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
x ³	Polidocanol (INN) Laureth-9 (INCI) CAS No 3055-99-0 EC No 221-284-4	Leave-on products Rinse-off products	3.0% 4.0%		

³

MESSAGE FOR OPOCE NOT TO BE TRANSLATED! Please replace x with the correct number which will appear in the consolidated version of directive 76/768/EEC. Thank you very much!