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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
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Draft

COMMISSION DIRECTIVE ../.../EC

of [...]

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

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COMMISSION DIRECTIVE ../.../EC

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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,

Whereas:

- (1) The Scientific Committee on Consumer Products ("SCCP") concluded in its opinion of 15 April 2008 that Ethyl Lauroyl Arginate HCl is safe for the consumers, when used up to a maximum authorised concentration of 0.8% in soap, anti-dandruff shampoos, and non-spray deodorants. It should therefore be included in Annex III to Directive 76/768/EEC.
- (2) The SCCP concluded in the same opinion that Ethyl Lauroyl Arginate HCl is safe for the consumers, when used up to a maximum authorised concentration of 0.4% as a preservative in cosmetic products. However, the Committee considered that it should not be used in lip products, oral products and spray products due to mucosal and respiratory tract irritation potential. It should therefore be included along with these restrictions in Annex VI to Directive 76/768/EEC.
- (3) Directive 76/768/EEC should therefore be amended accordingly.
- (4) 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

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.

¹ OJ L 262, 27.9.1976, p. 169.

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

Member of the Commission

ANNEX

- (1) In the table set out 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
206	Ethyl Lauroyl Arginate HCl ⁽²⁾ CAS No. 60372-77-2 EC No. 434-630-6	(a) soap (b) anti-dandruff shampoos (c) deodorants, non-spray	0.8%	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.	

- (2) In the table set out in Part 1 of Annex VI to Directive 76/768/EEC, the following entry is added:

Reference number	Substance	Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
A	b	C	d	e
58	Ethyl Lauroyl Arginate HCl (*) ³ CAS No. 60372-77-2 EC No. 434-630-6	0.4%	Not to be used in lip products, oral products and spray products.	

² For use as a preservative, see Annex VI, Part 1, entry No. 58.

³ For other uses than preservatives, see Annex III, Part I, entry No. 206.

