

Commission Directive 2010/4/EU of 8 February 2010 amending, for the purpose of adaptation to technical progress, Annex III to Council Directive 76/768/EEC concerning cosmetic products (Text with EEA relevance)

COMMISSION DIRECTIVE 2010/4/EU

of 8 February 2010

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(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 products⁽¹⁾, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Consumer Safety,

Whereas:

- (1) Presently, there are two non-oxidative hair dye substances which are provisionally allowed for use in cosmetic products until 31 December 2010 under the restrictions and conditions laid down in Part 2 of Annex III to Directive 76/768/EEC.
- (2) For these two non-oxidative hair dye substances, HC Orange No 2 and 2-hydroxyethylamino-5-nitroanisole, listed under reference Nos 26 and 29 in Part 2 of Annex III, the Scientific Committee on Consumer Safety (hereinafter 'SCCS') gave its final opinions on their safety. The SCCS recommended maximum authorised concentrations in the finished cosmetic product of 1,0 % for HC Orange No 2 and of 0,2 % for 2-hydroxyethylamino-5-nitroanisole. Therefore, HC Orange No 2 and 2-hydroxyethylamino-5-nitroanisole can be definitively regulated in Part 1 of Annex III.
- (3) Directive 76/768/EEC should therefore be amended accordingly.
- (4) In view of a smooth transition for the marketing of products containing HC Orange No 2 not complying with the labelling requirements laid down in this Directive, it is necessary to provide for appropriate transitional periods.
- (5) 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

Amendment to Directive 76/768/EEC

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

Article 2

Transposition

1 Member States shall adopt and publish, by 1 September 2010 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.

Member States shall apply the provisions set out in the Annex to this Directive, except the obligations concerning the labelling set out in column (f) of entry 208, from 1 December 2010.

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

Transitional provisions

Member States shall take all necessary measures to ensure that after 1 November 2011 no cosmetic products which fail to comply with the obligations concerning the labelling set out in column (f) of entry 208 of Part I of Annex III to Directive 76/768/EEC, as amended by this Directive, are placed on the market by Union manufacturers or by importers established within the Union.

Member States shall take all necessary measures to ensure that after 1 November 2012 no cosmetic products which fail to comply with the obligations concerning the labelling set out in column (f) of entry 208 of Part I of Annex III to Directive 76/768/EEC, as amended by this Directive, are sold or disposed of to the final consumer in the Union.

Article 4

Entry into force

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

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IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.*

Article 5

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 8 February 2010.

For the Commission

The President


José Manuel BARROSO

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ANNEX

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

1. in Part 1 the following entries are 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
'208	1-(beta-Aminoethyl)amine (beta-hydroxyethyl)nitrobenzene and its salts HC Orange No 2 CAS No 85765-48-6 EINECS 416-410-1	Hair dye substance in non-oxidative hair dye products	1,0 %	—	 <p>Do not use with nitrosamine systems. Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary "black henna" tattoos may increase your risk of allergy. Do not colour your hair if:</p> <p>— You have a rash on your face</p>

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						or sensitive, irritated and damaged scalp. You have ever experienced any reaction after colouring your hair. You have experienced a reaction to a temporary "black henna" tattoo in the past.'
209	2-[(2-methoxy-4-nitrophenyl)amino]ethanol and its salts 2-Hydroxyethyl-4-nitroanisole CAS No 66095-81-6 EINECS 266-138-0	Hair dye substance oxidative hair dye aminoethanol hydroxyethyl-4-nitroanisole	0,2 %	—	Do not use with nitrosating systems Maximum nitrosamine content: 50 µg/kg Keep in nitrite-free containers	

2. in Part 2 the entries relating to reference Nos 26 and 29 are deleted.

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- (1) [OJ L 262, 27.9.1976, p. 169.](#)