

DIRECTIVES

COMMISSION DIRECTIVE 2009/130/EC

of 12 October 2009

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,

required to submit files containing the scientific data on hair dye substances to be evaluated by the SCCS.

Having regard to the Treaty establishing the European Community,

- (4) Substances p-Phenylenediamine (PPD) and toluene-2,5-diamine (PTD) are currently regulated under generic entries 8 and 9 in part 1 of Annex III to Council Directive 76/768/EEC. The SCCS classified these substances as extreme sensitizers contributing to a great extent to the incidence of skin allergies among consumers to hair dye products. The risk assessment of the submitted additional data on PPD and PTD, and final decisions made by the SCCS on the safety of these substances might still require a considerable amount of time. As a precautionary measure to reduce the risk of allergies to hair dye products among consumers, the maximum authorised concentrations of PPD and PTD should be immediately decreased to the levels for which the industry submitted the safety files.

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) Following the publication of a scientific study in 2001, entitled 'Use of permanent hair dyes and bladder cancer risk', the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, currently the Scientific Committee on Consumer Safety (hereinafter SCCS) ⁽²⁾, concluded that the potential risks were of concern. It recommended that the Commission take further steps to control the use of hair dye substances.

- (5) Since substances PPD and PTD are currently regulated under generic entries in part 1 of Annex III separate reference numbers should be created for these substances with decreased maximum authorised concentrations.

(2) The SCCS further recommended an overall safety assessment strategy for hair dye substances including the requirements for testing substances used in hair dye products for their potential genotoxicity/mutagenicity.

- (6) Commission Directive 2008/88/EC ⁽³⁾ banned the use of hydroquinone in oxidative hair dye products by deleting the respective field of application in column 'c' of reference number 14 in Annex III, part 1. For the sake of clarity, the authorised concentration of 0,3 % in column 'd' and the conditions of use and warnings which must be printed on the label listed in paragraph (a) in column 'f' of reference number 14 should be deleted as well.

(3) Following the opinions of the SCCS, the Commission, together with Member States and stakeholders, agreed on an overall strategy to regulate substances used in hair dye products, according to which the industry was

- (7) Directive 76/768/EEC should therefore be amended accordingly.

- (8) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

⁽¹⁾ OJ L 262, 27.9.1976, p. 169.

⁽²⁾ The name of the committee was changed by Commission Decision 2008/721/EC (OJ L 241, 10.9.2008, p. 21).

⁽³⁾ OJ L 256, 24.9.2008, p. 12.

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 adopt and publish, by 15 April 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.

They shall apply the provisions set out in the Annex to this Directive from 15 July 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

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 12 October 2009.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX

Directive 76/768/EEC is amended as follows:

Part 1 of Annex III is amended as follows:

- (a) In column 'b' of reference number 8, the words 'p-Phenylenediamine, its N-substituted derivatives and its salts; N-substituted derivatives of o-Phenylenediamine ⁽⁵⁾, with exception of those derivatives listed elsewhere in this Annex and under reference numbers 1309, 1311, and 1312 in Annex II' are replaced by the following:

'N-substituted derivatives of p-Phenylenediamine and their salts; N-substituted derivatives of o-Phenylenediamine ⁽⁵⁾, with exception of those derivatives listed elsewhere in this Annex and under reference numbers 1309, 1311, and 1312 in Annex II'.

- (b) The following reference number 8a is inserted after reference number 8:

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
'8a	p-Phenylenediamine and its salts ⁽⁵⁾ CAS No 106-50-3 Einecs 203-404-7 p-Phenylenediamine HCl CAS No 624-18-0 Einecs 210-834-9 p-Phenylenediamine sulphate CAS No 16245-77-5 Einecs 240-357-1	Hair dye substance in oxidative hair dye products (a) general use (b) professional use		(a) and (b) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2 % calculated as free base.	(a) Can cause an allergic reaction. Contains phenylenediamines. Do not use to dye eyelashes or eyebrows. (b) For professional use only. Contains phenylenediamines. Can cause an allergic reaction. Wear suitable gloves.'

- (c) In column 'b' of reference number 9, the words 'Methylphenylenediamines, their N-substituted derivatives and their salts ⁽¹⁾ with the exception of substances under reference numbers 364, 1310 and 1313 in Annex II' are replaced by the following:

'Methylphenylenediamines, their N-substituted derivatives and their salts ⁽¹⁾, with the exception of the substance under reference number 9a in this Annex and substances under reference numbers 364, 1310 and 1313 in Annex II'.

(d) The following reference number 9a is inserted after reference number 9:

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
'9a	Toluene-2,5-diamine and its salts ⁽¹⁾ CAS No 95-70-5 EINECS 202-442-1 Toluene-2,5-diamine sulphate CAS No 615-50-9 EINECS 210-431-8	Hair dye substance in oxidative hair dye products (a) general use (b) professional use		(a) and (b) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 4 % calculated as free base.	As mentioned in reference number 9, column f.

(e) In reference number 14, the maximum authorised concentration in the finished cosmetic product of 0,3 % in column 'd' and paragraph (a) in column 'f' are deleted.