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**COMMISSION DIRECTIVE ..../.../EC**

**of [...]**

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

**(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 products <sup>1</sup>, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers,

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 (the SCCNFP) concluded that the potential risks were of concern. It recommended that the Commission takes further steps to control the use of hair dye chemicals.
- (2) The SCCNFP recommended further an overall safety assessment strategy for hair dyes including the requirements for testing hair dye cosmetic ingredients for their potential genotoxicity/mutagenicity.
- (3) Following the opinions of the SCCNFP, the Commission together with Member States and stakeholders agreed on an overall strategy to regulate hair dyes according to which, the industry was required to submit the files with scientific data on hair dyes to be evaluated by the SCCNFP.
- (4) As a first step for the implementation of the strategy it was decided to give priority to permanent hair dye substances for which no explicit interest was expressed during the public consultation in defence of their use in hair dyes. Those substances should therefore be banned.

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<sup>1</sup> OJ L 262, 27.9.1976, p. 169. Directive as last amended by Directive \_\_\_\_ (OJ L \_\_\_\_).

- (5) According to the opinion of the SCCNFP certain azo dyes pose a risk to the health of the consumer. They were therefore deleted from the positive list of colouring agents allowed for use in cosmetic products in Annex IV to Directive 76/768/EEC. For the same reason they should also be banned for use in hair dyes.
- (6) For hair dye substances provisionally allowed in part 2 of Annex III to Directive 76/768/EEC the provisional period should be extended.
- (7) Annexes II and III to 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,

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 from 1 December 2006 at the latest 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, nor sold or disposed of to the final consumer.

#### *Article 3*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 September 2006 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation between those provisions and 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 are amended as follows:

(1) in Annex II the following reference numbers [X]<sup>2</sup> and [Y]<sup>3</sup> are added:

Ref. No	Chemical name	CAS No
[X] <sup>2</sup>	6-Methoxy-2,3-Pyridinediamine and its HCl salt, when used as a hair dye	CAS No 94166-62-8
	2,3-Naphthalenediol, when used as a hair dye	CAS No 92-44-4
	2,4-Diaminodiphenylamine, when used as a hair dye	CAS No 136-17-4
	2,6-Bis(2-Hydroxyethoxy)-3,5-Pyridinediamine and its HCl salt, when used as a hair dye	CAS No 117907-42-3
	2-Methoxymethyl- <i>p</i> -Aminophenol and its HCl salt, when used as a hair dye	CAS No 29785-47-5
	4,5-Diamino-1-Methylpyrazole and its HCl salt, when used as a hair dye	CAS No 20055-01-0
	4,5-Diamino-1-((4-Chlorophenyl)Methyl)-1H-Pyrazole Sulfate, when used as a hair dye	CAS No 163183-00-4
	4-Chloro-2-Aminophenol, when used as a hair dye	CAS No 95-85-2
	4-Hydroxyindole, when used as a hair dye	CAS No 2380-94-1
	4-Methoxytoluene-2,5-Diamine and its HCl salt, when used as a hair dye	CAS No 56496-88-9
	5-Amino-4-Fluoro-2-Methylphenol Sulfate, when used as a hair dye	CAS No 163183-01-5
	N,N-Diethyl- <i>m</i> -Aminophenol, when used as a hair dye	CAS No 91-68-9
	N,N-Dimethyl-2,6-Pyridinediamine and its HCl salt, when used as a hair dye	
	N-Cyclopentyl- <i>m</i> -Aminophenol, when used as a hair dye	CAS No 104903-49-3
	N-(2-Methoxyethyl)- <i>p</i> -phenylenediamine and its HCl salt, when used as a hair dye	CAS No 72584-59-9
	2,4-Diamino-5-methylphenetol and its HCl salt, when used as a hair dye	CAS No 113715-25-6
	1,7-Naphthalenediol, when used as a hair dye	CAS No 575-38-2
	3,4-Diaminobenzoic acid, when used as a hair dye	CAS No 619-05-6
	2-Aminomethyl- <i>p</i> -aminophenol and its HCl salt, when used as a hair dye	CAS No 79352-72-0
	Solvent Red 1 (CI 12150), when used as a hair dye	CAS No 1229-55-6
	Acid Orange 24 (CI 20170), when used as a hair dye	CAS No 1320-07-6
Y <sup>3</sup>	Acid Red 73 (CI 27290), when used as a hair dye	CAS No 5413-75-2

(2) Column g in Part 2 of Annex III is amended as follows:

- (a) the reference numbers 17, 23, 40, 42 are deleted.
- (b) in reference numbers 1, 2, 8, 13, 15, 30, 34, 41, 43, 45, 46, 51, 52, 53, 54, 57, 59, 60 the date '31.8.2006' is replaced by '31.12.2007'.

<sup>2</sup> the relevant reference numbers will be introduced at the time of the publication

<sup>3</sup> the relevant reference numbers will be introduced at the time of the publication

- (c) in reference numbers 3, 4, 5, 6, 7, 9, 10, 11, 12, 14, 16, 18, 19, 20, 21, 22, 24, 25, 26, 27, 28, 29, 31, 32, 33, 35, 36, 37, 38, 39, 44, 47, 48, 49, 50, 55, 56 and 58 the date '31.12.2006' is replaced by '31.12.2007'.