

DIRECTIVES

COMMISSION DIRECTIVE 2009/36/EC

of 16 April 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,

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

After consulting the Scientific Committee on Consumer Products,

Whereas:

dye substances final opinions have already been given by the SCCP. Therefore, definitive regulation of these hair dye substances, on the basis of such evaluations, can take place.

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

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

HAS ADOPTED THIS DIRECTIVE:

(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 Products (hereinafter SCCP) ⁽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.

(2) The SCCP 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.

(3) Following the opinions of the SCCP, 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 required to submit files containing the scientific data on hair dye substances to be evaluated by the SCCP.

(4) Substances for which updated safety files were submitted are currently being evaluated by the SCCP. For 17 hair

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 November 2009 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 May 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.

⁽¹⁾ OJ L 262, 27.9.1976, p. 169.

⁽²⁾ The name of the committee was changed by Commission Decision 2004/210 (OJ L 66, 4.3.2004, p. 45).

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, 16 April 2009.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX

Directive 76/768/EEC is amended as follows:

1. In Part 1 of Annex III the following reference numbers 189 - 205 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 authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
'189	Trisodium 5-hydroxy-1-(4-sulphophenyl)-4-(4-sulphophenylazo)pyrazole-3-carboxylate and aluminium lake ⁽¹⁵⁾ Acid Yellow 23 CAS 1934-21-0 EINECS 217-699-5 Acid Yellow 23 Aluminum lake CAS 12225-21-7 EINECS 235-428-9 CI 19140	Hair dye substance in non-oxidative hair dye products	0,5 %		
190	Benzenemethanaminium, N-ethyl-N-[4-[[4-[ethyl-[(3-sulphophenyl)-methyl]-amino]-phenyl] [2-sulphophenyl)-methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfo, inner salt, disodium salt and its ammonium and aluminium salts ⁽¹⁵⁾ Acid Blue 9 CAS 3844-45-9 EINECS 223-339-8 Acid Blue 9 Ammonium salt CAS 2650-18-2 EINECS 220-168-0 Acid Blue 9 Aluminum lake CAS 68921-42-6 EINECS 272-939-6 CI 42090	Hair dye substance in non-oxidative hair dye products	0,5 %		

a	b	c	d	e	f
191	Disodium 6-hydroxy-5-[(2-methoxy-4-sulphonato-m-tolyl)azo]naphthalene-2-sulphonate ⁽¹⁵⁾ Curry Red CAS 25956-17-6 EINECS 247-368-0 CI 16035	Hair dye substance in non-oxidative hair dye products	0,4 %		
192	Trisodium 1-(1-naphthylazo)-2-hydroxynaphthalene-4',6,8-trisulphonate and aluminium lake ⁽¹⁵⁾ Acid Red 18 CAS 2611-82-7 EINECS 220-036-2 Acid Red 18 Aluminum lake CAS 12227-64-4 EINECS 235-438-3 CI 16255	Hair dye substance in non-oxidative hair dye products	0,5 %		
193	Hydrogen 3,6-bis(diethylamino)-9-(2,4-disulphonatophenyl)xanthylium, sodium salt ⁽¹⁵⁾ Acid Red 52 CAS 3520-42-1 EINECS 222-529-8 CI 45100	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 0,6 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 %.	(a) The mixing ratio must be printed on the label.
194	Disodium 5-amino-4-hydroxy-3-(phenylazo)naphthalene-2,7-disulphonate ⁽¹⁵⁾ Acid Red 33 CAS 3567-66-6 EINECS 222-656-9 CI 17200	Hair dye substance in non-oxidative hair dye products	0,5 %		

a	b	c	d	e	f
195	Sodium 1-amino-4-(cyclohexylamino)-9,10-dihydro-9,10-dioxoanthracene-2-sulphonate ⁽¹⁵⁾ Acid Blue 62 CAS 4368-56-3 EINECS 224-460-9 CI 62045	Hair dye substance in non-oxidative hair dye products	0,5 %	— Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
196	1-[(2'-Methoxyethyl)amino]-2-nitro-4-[di-(2'-hydroxyethyl)amino]benzene ⁽¹⁵⁾ HC Blue No 11 CAS 23920-15-2 EINECS 459-980-7	Hair dye substance in non-oxidative hair dye products	2,0 %	— Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
197	1,5-Di-(β-hydroxyethylamino)-2-nitro-4-chlorobenzene ⁽¹⁵⁾ HC Yellow No 10 CAS 109023-83-8 EINECS 416-940-3	Hair dye substance in non-oxidative hair dye products	0,1 %	— Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
198	3-Methylamino-4-nitrophenox-yethanol ⁽¹⁵⁾ 3-Methylamino-4-nitrophenox-yethanol (INCI) CAS 59820-63-2 EINECS 261-940-7	Hair dye substance in non-oxidative hair dye products	0,15 %	— Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
199	2,2'-[[4-[(2-hydroxyethyl)amino]-3-nitrophenyl]imino]bisethanol ⁽¹⁵⁾ HC Blue No 2 CAS 33229-34-4 EINECS 251-410-3	Hair dye substance in non-oxidative hair dye products	2,8 %	— Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	Can cause allergic reaction

a	b	c	d	e	f
200	1-Propanol, 3-[[4-[bis(2-hydroxyethyl)amino]-2-nitrophenyl]amino] ⁽¹⁵⁾ HC Violet No 2 CAS 104226-19-9 EINECS 410-910-3	Hair dye substance in non-oxidative hair dye products	2,0 %	— Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	Can cause allergic reaction
201	Phenol, 2-chloro-6-(ethylamino)-4-nitro- ⁽¹⁵⁾ 2-Chloro-6-ethylamino-4-nitrophenol CAS 131657-78-8 EINECS 411-440-1	Hair dye substance in non-oxidative hair dye products	3,0 %	— Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	Can cause allergic reaction
202	4,4'-[1,3-Propanediylbis(oxy)]-bisbenzene-1,3-diamine and its tetrahydrochloride salt ⁽¹⁵⁾ 1,3-bis-(2,4-Diaminophenoxy)propane CAS 81892-72-0 EINECS 279-845-4 1,3-bis-(2,4-Diaminophenoxy)propane HCl CAS 74918-21-1 EINECS 278-022-7	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 1,2 % as free base (1,8 % as tetrahydrochloride salt)	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,2 % calculated as free base (1,8 % as tetrahydrochloride salt). For (a) and (b): Can cause allergic reaction	(a) The mixing ratio must be printed on the label. For (a) and (b): Can cause allergic reaction
203	6-Methoxy-N2-methyl-2,3-pyridinediamine hydrochloride and dihydrochloride salt ⁽¹⁵⁾ 6-Methoxy-2-methylamino-3-aminopyridine HCl CAS 90817-34-8 (HCl) CAS 83732-72-3 (2HCl) EINECS 280-622-9 (2HCl)	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye	(b) 0,68 % as free base (1,0 % as dihydrochloride)	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,68 % calculated as free base (1,0 % as dihydrochloride). For a) and b): — Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) The mixing ratio must be printed on the label. For (a) and (b): Can cause allergic reaction

a	b	c	d	e	f
204	2,3-Dihydro-1H-indole-5,6-diol and its hydrobromide salt ⁽¹⁵⁾ Dihydroxyindoline CAS 29539-03-5 Dihydroxyindoline HBr CAS 138937-28-7 EINECS 421-170-6	Hair dye substance in non-oxidative hair dye products	2,0 %		Can cause allergic reaction
205	4-Hydroxypropylamino-3-nitrophenol ⁽¹⁵⁾ 4-Hydroxypropylamino-3-nitrophenol (INCI) CAS 92952-81-3 EINECS 406-305-9	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 2,6 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,6 % calculated as free base. For (a) and (b): — Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) The mixing ratio must be printed on the label.

⁽¹⁵⁾ The free base and salts of this hair colouring ingredient, unless prohibited under Annex II, are permitted for use.'

2. In columns 'c' and 'd' of entry 55 of Part 2 of Annex III section b is deleted.
3. In Part 2 of Annex III reference numbers 7, 9, 14, 24, 28, 47, and 58 are deleted.