



STATUTORY INSTRUMENTS.

S.I. No. 552 of 2009

EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)
(AMENDMENT) (No. 2) REGULATIONS 2009

(Prn. A9/1894)

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EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)
(AMENDMENT) (No. 2) REGULATIONS 2009

I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972), and for the purpose of giving effect to Commission Directive 2009/36/EC¹ of 16 April 2009 hereby make the following regulations:

1. These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) (No. 2) Regulations 2009.

2. These Regulations shall be construed as one with the European Communities (Cosmetic Products) Regulations 2004 to 2009.

3. (1) In these Regulations, “Principal Regulations” mean the European Communities (Cosmetic Products) Regulations 2004 (S.I. No. 870 of 2004), as amended.

(2) (a) A reference in these Regulations to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other Regulations is intended.

(b) A reference in these Regulations to a Schedule is to a Schedule to these Regulations, unless it is indicated that reference to some other Regulations is intended.

4. Subject to Regulation 6, Regulation 4(1) of the Principal Regulations is amended by the addition to the definition of “Directive” of reference to the following Commission Directive: “2009/36/EC”.

5. Subject to Regulation 6, Schedule 3 to the Principal Regulations is amended in the manner set out in the Schedule.

6. The provisions of these Regulations shall come into operation on 15 May 2010.

¹OJ No. L345, 23.12.2008, p68

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 5th January, 2010.*

SCHEDULE

1. Part 1 of Schedule 3 to the Principal Regulations is amended by the insertion of the following reference numbers 189 to 205

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-sulfo-phenyl)-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 %		
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 %		

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
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 %		
195	Sodium 1-amino-4-(cyclohexylamino)-9,10-dihydro-9,10-dioxanthracene-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 nitro-sating 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 nitro-sating 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 nitro-sating 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 product	0,15 %	- Do not use with nitro-sating systems - Maximum nitrosamine content: 50 µg/kg - Keep in nitrite-free containers	

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
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 nitro-sating systems - Maximum nitrosamine content: 50 µg/kg - Keep in nitrite-free containers	Can cause allergic reaction
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 nitro-sating systems - Maximum nitrosamine content: 50 µg/kg - Keep in nitrite-free containers	Can cause allergic reaction
201	Phenol, 2-chloro-6-(ethyl-amino)-4-nitro- (15) 2-Chloro-6-ethylamino-4-nitro-phenol CAS 131657-78-8 EINECS 411-440-1	Hair dye substance in non-oxidative hair dye products	3,0 %	- Do not use with nitro-sating 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). (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 nitro-sating 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
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

Reference number	Substance	Restrictions		Conditions of use and warnings which must be printed on the label
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
(15) The free base and salts of this hair colouring ingredient, unless prohibited under Schedule II, are permitted for use.¹.				

2. Part 2 of Schedule 3 to the Principal Regulations is amended as follows:—

- (a) In columns 'c' and 'd' of Reference number 55, (b) is deleted;
- (b) Reference numbers 7, 9, 14, 24, 28, 47, and 58 are deleted.



GIVEN under my Official Seal,
22 December 2009

MARY HARNEY,
Minister for Health and Children.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation).

These Regulations further amend the European Communities (Cosmetic Products) Regulations 2004, as amended. The purpose of these Regulations is to update the law in relation to the manufacture, marketing and sale of cosmetic products by the implementation of Commission Directive 2009/36/EC with a view to improving the safety of those products. These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) (No. 2) Regulations 2009.

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