



STATUTORY INSTRUMENTS.

S.I. No. 161 of 2013



EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)
(AMENDMENT) REGULATIONS 2013

EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)
(AMENDMENT) REGULATIONS 2013

I, JAMES REILLY, Minister for Health, 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 further effect to Council Directive 76/768/EEC of 27 July 1976¹, as amended by Commission Implementing Directive 2012/12/EU of 2 August 2012², hereby make the following regulations:

Citation

1. These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) Regulations 2013.

Collective citation and construction

2. These Regulations, the European Communities (Cosmetic Products) Regulations 2004 to 2010, the European Communities (Cosmetic Products) (Amendment) Regulations 2011 (S.I. No. 723 of 2011) and the European Communities (Cosmetic Products) (Amendment) Regulations 2012 (S.I. No. 396 of 2012) may be cited together as the European Communities (Cosmetic Products) Regulations 2004 to 2013 and shall be construed together as one.

Interpretation

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

Amendment of Regulation 4(1) of Principal Regulations

4. Regulation 4(1) (as amended by Regulation 5 of the European Communities (Cosmetic Products) (Amendment) Regulations 2012 (S.I. No. 396 of 2012)) of the Principal Regulations is amended by substituting for the definition of “Directive” the following definition:

“ ‘Directive’ means Directive 76/768/EEC, as amended by Council Directive 79/661/EEC of 24 July 1979³, Commission Directive 82/147/EEC of 11 February 1982⁴, Council Directive 82/368/EEC of 17 May 1982⁵, Commission Directive 83/191/EEC of 30 March 1983⁶, Commission Directive 83/341/EEC of 29 June 1983⁷, Commission Directive 83/496/EEC of 22

¹O.J No. L 262, 27.9.1976, p. 169.

²O.J. No. L 208, 3.8.2012, p. 8.

³OJ No. L 192, 31.7.1979, p. 35.

⁴OJ No. L 63, 6.3.1982, p. 26.

⁵OJ No. L 167, 15.6.1982, p. 1.

⁶OJ No. L 109, 26.4.1983, p. 25.

⁷OJ No. L 188, 13.7.1983, p. 15.

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 21st May, 2013.*

September 1983⁸, Council Directive 83/574/EEC of 26 October 1983⁹, Commission Directive 84/415/EEC of 18 July 1984¹⁰, Commission Directive 85/391/EEC of 16 July 1985¹¹, Commission Directive 86/179/EEC of 28 February 1986¹², Commission Directive 86/199/EEC of 26 March 1986¹³, Commission Directive 87/137/EEC of 2 February 1987¹⁴, Commission Directive 88/233/EEC of 2 March 1988¹⁵, Council Directive 88/667/EEC of 21 December 1988¹⁶, Commission Directive 89/174/EEC of 21 February 1989¹⁷, Council Directive 89/679/EEC of 21 December 1989¹⁸, Commission Directive 90/121/EEC of 20 February 1990¹⁹, Commission Directive 91/184/EEC of 12 March 1991²⁰, Commission Directive 92/8/EEC of 18 February 1992²¹, Commission Directive 92/86/EEC of 21 October 1992²², Council Directive 93/35/EEC of 14 June 1993²³, Commission Directive 93/47/EEC of 22 June 1993²⁴, Commission Directive 94/32/EC of 29 June 1994²⁵, Commission Directive 95/34/EC of 10 July 1995²⁶, Commission Directive 96/41/EC of 25 June 1996²⁷, Commission Directive 97/1/EC of 10 January 1997²⁸, Commission Directive 97/45/EC of 14 July 1997²⁹, Commission Directive 98/16/EC of 5 March 1998³⁰, Commission Directive 98/62/EC of 3 September 1998³¹, Commission Directive 2000/6/EC of 29 February 2000³², Commission Directive 2000/11/EC of 10 March 2000³³, Commission Directive 2002/34/EC of 15 April 2002³⁴, Commission Directive 2003/1/EC of 6 January 2003³⁵, Commission Directive 2003/16/EC of 19 February 2003³⁶, Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003³⁷, Commission Directive 2003/80/EC of 5

⁸OJ No. L 275, 8.10.1983, p. 20.

⁹OJ No. L 332, 28.11.1983, p. 38.

¹⁰OJ No. L 228, 25.8.1984, p. 31.

¹¹OJ No. L 224, 22.8.1985, p. 40.

¹²OJ No. L 138, 24.5.1986, p. 40.

¹³OJ No. L 149, 3.6.1986, p. 38.

¹⁴OJ No. L 56, 26.2.1987, p. 20.

¹⁵OJ No. L 105, 26.4.1988, p. 11.

¹⁶OJ No. L 382, 31.12.1988, p. 46.

¹⁷OJ No. L 64, 8.3.1989, p. 10. As affected by Corrigendum to Commission Directive 89/174/EEC, OJ No. L 199, 13.7.1989, p. 23.

¹⁸OJ No. L 398, 30.12.1989, p. 25.

¹⁹OJ No. L 71, 17.3.1990, p. 40.

²⁰OJ No. L 91, 12.4.1991, p. 59.

²¹OJ No. L 70, 17.3.1992, p. 23.

²²OJ No. L 325, 11.11.1992, p. 18.

²³OJ No. L 151, 23.6.1993, p. 32.

²⁴OJ No. L 203, 13.8.1993, p. 24.

²⁵OJ No. L 181, 15.7.1994, p. 31. As affected by Corrigendum to Commission Directive 94/32/EC, OJ No. L 273, 25.10.1994, p. 38.

²⁶OJ No. L 167, 18.7.1995, p. 19.

²⁷OJ No. L 198, 8.8.1996, p. 36.

²⁸OJ No. L 16, 18.1.1997, p. 85.

²⁹OJ No. L 196, 24.7.1997, p. 77.

³⁰OJ No. L 77, 14.3.1998, p. 44.

³¹OJ No. L 253, 15.9.1998, p. 20.

³²OJ No. L 56, 1.3.2000, p. 42.

³³OJ No. L 65, 14.3.2000, p. 22.

³⁴OJ No. L 102, 18.4.2002, p. 19. As affected by Corrigenda to Commission Directive 2002/34/EC, OJ No. L 341, 17.12.2002, p. 71 and OJ No. L 151, 19.6.2003, p. 44.

³⁵OJ No. L 5, 10.1.2003, p. 14.

³⁶OJ No. L 46, 20.2.2003, p. 24.

³⁷OJ No. L 66, 11.3.2003, p. 26.

September 2003³⁸, Commission Directive 2003/83/EC of 24 September 2003³⁹, Commission Directive 2004/87/EC of 7 September 2004⁴⁰, Commission Directive 2004/88/EC of 7 September 2004⁴¹, Commission Directive 2004/93/EC of 21 September 2004⁴², Commission Directive 2004/94/EC of 15 September 2004⁴³, Commission Directive 2005/9/EC of 28 January 2005⁴⁴, Commission Directive 2005/42/EC of 20 June 2005⁴⁵, Commission Directive 2005/52/EC of 9 September 2005⁴⁶, Commission Directive 2005/80/EC of 21 November 2005⁴⁷, Commission Directive 2006/65/EC of 19 July 2006⁴⁸, Commission Directive 2006/78/EC of 29 September 2006⁴⁹, Commission Directive 2007/1/EC of 29 January 2007⁵⁰, Commission Directive 2007/17/EC of 22 March 2007⁵¹, Commission Directive 2007/22/EC of 17 April 2007⁵², Commission Directive 2007/53/EC of 29 August 2007⁵³, Commission Directive 2007/54/EC of 29 August 2007⁵⁴, Commission Directive 2007/67/EC of 22 November 2007⁵⁵, Commission Directive 2008/14/EC of 15 February 2008⁵⁶, Commission Directive 2008/42/EC of 3 April 2008⁵⁷, Commission Directive 2008/88/EC of 23 September 2008⁵⁸, Directive 2008/112/EC of the European Parliament and of the Council of 16 December 2008⁵⁹, Commission Directive 2008/123/EC of 18 December 2008⁶⁰, Commission Directive 2009/6/EC of 4 February 2009⁶¹, Commission Directive 2009/36/EC of 16 April 2009⁶², Commission Directive 2009/129/EC of 9 October 2009⁶³, Commission Directive 2009/130/EC of 12 October 2009⁶⁴, Commission Directive 2009/134/EC of 28 October 2009⁶⁵, Commission Directive 2009/159/EU of 16 December 2009⁶⁶, Commission

³⁸OJ No. L 224, 6.9.2003, p. 27. As affected by Corrigendum to Commission Directive 2003/80/EC, OJ No. L 58, 26.2.2004, p. 28.

³⁹OJ No. L 238, 25.9.2003, p. 23. As affected by Corrigendum to Commission Directive 2003/83/EC, OJ No. L 58, 26.2.2004, p. 28

⁴⁰OJ No. L 287, 8.9.2004, p. 4.

⁴¹OJ No. L 287, 8.9.2004, p. 5.

⁴²OJ No. L 300, 25.9.2004, p. 13. As affected by Corrigendum to Commission Directive 2004/93/EC, OJ No. L 97, 15.4.2005, p. 63.

⁴³OJ No. L 294, 17.9.2004, p. 28.

⁴⁴OJ No. L 27, 29.1.2005, p. 46.

⁴⁵OJ No. L 158, 21.6.2005, p. 17.

⁴⁶OJ No. L 234, 10.9.2005, p. 9.

⁴⁷OJ No. L 303, 22.11.2005, p. 32.

⁴⁸OJ No. L 198, 20.7.2006, p. 11.

⁴⁹OJ No. L 271, 30.9.2006, p. 56.

⁵⁰OJ No. L 25, 1.2.2007, p. 9.

⁵¹OJ No. L 82, 23.3.2007, p. 27.

⁵²OJ No. L 101, 18.4.2007, p. 11.

⁵³OJ No. L 226, 30.8.2007, p. 19. As affected by Corrigendum to Commission Directive 2007/53/EC, OJ No. L 22, 25.1.2008, p. 21.

⁵⁴OJ No. L 226, 30.8.2007, p. 21. As affected by Corrigendum to Commission Directive 2007/54/EC, OJ No. L 258, 4.10.2007, p. 44.

⁵⁵OJ No. L 305, 23.11.2007, p. 22.

⁵⁶OJ No. L 42, 16.2.2008, p. 43.

⁵⁷OJ No. L 93, 4.4.2008, p. 13. As affected by Corrigendum to Commission Directive 2008/42/EC, OJ No. L 136, 24.5.2008, p. 52.

⁵⁸OJ No. L 256, 24.9.2008, p. 12. As affected by Corrigendum to Commission Directive 2008/88/EC, OJ No. L 263, 2.10.2008, p. 26.

⁵⁹OJ No. L 345, 23.12.2008, p. 68.

⁶⁰OJ No. L 340, 19.12.2008, p. 71

⁶¹OJ No. L 36, 5.2.2009, p. 15.

⁶²OJ No. L 98, 17.4.2009, p. 31. As affected by Corrigendum to Commission Directive 2009/36/EC, OJ No. L 103, 23.4.2009, p. 30.

⁶³OJ No. L 267, 10.10.2009, p. 18.

⁶⁴OJ No. L 268, 13.10.2009, p. 5.

⁶⁵OJ No. L 282, 29.10.2009, p. 15.

Directive 2009/164/EU of 22 December 2009⁶⁷, Commission Directive 2010/3/EU of 1 February 2010⁶⁸, Commission Directive 2010/4/EU of 8 February 2010⁶⁹, Commission Directive 2011/59/EU of 13 May 2011⁷⁰, Council Directive 2011/84/EU of 20 September 2011⁷¹ and Commission Implementing Directive 2012/12/EU of 2 August 2012².”

Amendments to the Schedule in Principal Regulations

5. The Schedules (as amended by Regulation 6 of the European Communities (Cosmetic Products) (Amendment) Regulations 2012 (S.I. No. 396 of 2012)) to the Principal Regulations are amended as provided for in the Schedule.

⁶⁶OJ No. L 336, 18.12.2009, p. 29.

⁶⁷OJ No. L 344, 23.12.2009, p. 41. As affected by Corrigendum to Commission Directive 2009/164/EU, OJ No. L 3, 7.1.2010, p. 30.

⁶⁸OJ No. L 29, 2.2.2010, p. 5.

⁶⁹OJ No. L 36, 9.2.2010, p. 21.

⁷⁰OJ No. L 125, 14.5.2011, p.17

⁷¹OJ No. L. 283, 29.10.2011, p. 36

SCHEDULE

1. Schedule 2 to the Principal Regulations is amended by inserting the following entry:

Reference Number	Chemical Name/INCI-Name	CAS Number EC Number
'1373	N-(2-Nitro-4-aminophenyl)-allylamine (HC Red No 16) and its salts	CAS No 160219-76-1'

2. Part 1 of Schedule 3 to the Principal Regulations is amended—

(a) by inserting the following entries:

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
253	2,2'-[(4-Aminophenyl)-imino]bis (ethanol) sulphate N,N-bis(2-Hydroxyethyl)- p-Phenylenediamine Sulfate CAS No 54381-16-7 EC No 259-134-5	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.5 % (calculated as sulphate) — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	As mentioned in reference number 205, column f (a)

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
254	1,3-Benzenediol, 4-chloro- 4-Chlororesorcinol CAS No 95-88-5 EC No 202-462-0	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.5 %	As mentioned in reference number 205, column f (a)
255	2,4,5,6-Tetraamino-pyrimidine sulphate Tetraamino-pyrimidine Sulfate CAS No 5392-28-9 EC No 226-393-0	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non- oxidative hair dye products	(b) 3.4 % (calculated as sulphate)	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 3.4 % (calculated as sulphate)	(a) As mentioned in reference number 205, column f (a)
256	3-(2-Hydroxyethyl)-p-phenylene-diammonium sulphate Hydroxyethyl-p-Phenylene-diamine Sulfate CAS No 93841-25-9 EC No 298-995-1	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0 % (calculated as sulphate)	As mentioned in reference number 205, column f (a)

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
257	1H-Indole-5,6-diol Dihydroxyindole CAS No 3131-52-0 EC No 412-130-9	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 0.5 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.5 %	(a) As mentioned in reference number 205, column f (a) (b) As mentioned in reference number 208, column f
258	5-Amino-4-chloro-2-methylphenol hydrochloride 5-Amino-4-Chloro-o-Cresol HCl CAS No 110102-85-7	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 % (calculated as hydrochloride)	As mentioned in reference number 205, column f (a)
259	1H-Indol-6-ol 6-Hydroxyindole CAS No 2380-86-1 EC No 417-020-4	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.5 %	As mentioned in reference number 205, column f (a)
260	1H-Indole-2,3-Dione Isatin CAS No 91-56-5 EC No 202-077-8	Hair dye substance in non-oxidative hair dye products	1.6 %		As mentioned in reference number 208, column f

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
261	2-Aminopyridin-3-ol 2-Amino-3-Hydroxypyridine CAS No 16867-03-1 EC No 240-886-8	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.0 %	As mentioned in reference number 205, column f (a)
262	2-Methyl-1-naphthyl acetate 1-Acetoxy-2-Methylnaphthalene CAS No 5697-02-9 EC No 454-690-7	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0 % (When both 2-Methyl-1-Naphthol and 1-Acetoxy-2-Methylnaphthalene are present in a hair dye formulation, the maximum concentration on the head of 2-Methyl-1-Naphthol should not exceed 2.0%.)	As mentioned in reference number 205, column f (a)

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
263	1-Hydroxy-2-methylnaphthalene 2-Methyl-1-Naphthol CAS No 7469-77-4 EC No 231-265-2	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0 % (When both 2-Methyl- 1-Naphthol and 1-Acetoxy-2-Methylnaphthalene are present in a hair dye formulation, the maximum concentration on the head of 2-Methyl-1-Naphthol should not exceed 2.0%.)	As mentioned in reference number 205, column f (a)
264	Disodium 5,7-dinitro-8-oxido-2-naphthalene-sulfonate Acid Yellow 1 CAS No 846-70-8 EC No 212-690-2 CI 10316	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non- oxidative hair dye products	(b) 0.2 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.0 %	(a) As mentioned in reference number 205, column f (a) (b) As mentioned in reference number 208, column f
265	4-Nitro-1,2-phenylenediamine 4-Nitro-o-Phenylenediamine CAS No 99-56-9 EC No 202-766-3	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.5 %	As mentioned in reference number 205, column f (a)

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
266	2-(4-Amino-3-nitroanilino) ethanol HC Red No 7 CAS No 24905-87-1 EC No 246-521-9	Hair dye substance in non-oxidative hair dye products	1.0 %	— Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	As mentioned in reference number 208, column f
267	2-[bis(2-Hydroxyethyl) amino]-5-nitrophenol HC Yellow No 4 CAS No 59820-43-8 EC No 428-840-7	Hair dye substance in non-oxidative hair dye products	1.5 %	— Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
268	2-[(2-Nitrophenyl) amino] ethanol HC Yellow No 2 CAS No 4926-55-0 EC No 225-555-8	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 1.0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.75 % For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)

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
269	4-[(2-Nitrophenyl) amino]phenol HC Orange No 1 CAS No 54381-08-7 EC No 259-132-4	Hair dye substance in non-oxidative hair dye products	1.0 %		
270	2-Nitro-N1-phenylbenzene-1,4-diamine HC Red No 1 CAS No 2784-89-6 EC No 220-494-3	Hair dye substance in non-oxidative hair dye products	1.0 %		As mentioned in reference number 208, column f
271	1-Methoxy-3-(β -aminoethyl) amino-4-nitrobenzene, hydrochloride HC Yellow No 9 CAS No 86419-69-4 EC No 415-480-1	Hair dye substance in non-oxidative hair dye products	0.5 % (calculated as hydrochloride)	— Do not use with nitrosating agents — Maximum nitrosamine content: 50 μ g/kg — Keep in nitrite-free containers	
272	1-(4'-Aminophenylazo)-2-methyl-4-(bis-2-hydroxyethyl) aminobenzene HC Yellow No 7 CAS No 104226-21-3 EC No 146-420-6	Hair dye substance in non-oxidative hair dye products	0.25 %		

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
273	N-(2-Hydroxyethyl)-2-nitro-4-trifluoromethyl-aniline HC Yellow No 13 CAS No 10442-83-8 EC No 443-760-2	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 2.5 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.5 % For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)
274	Benzenaminium, 3-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]-N,N,N-trimethyl-, chloride Basic Yellow 57 CAS No 68391-31-1 EC No 269-943-5	Hair dye substance in non-oxidative hair dye products	2.0 %		
275	Ethanol, 2,2'-[[4-[(4-aminophenyl)azo]phenyl]imino]bis- Disperse Black 9 CAS No 20721-50-0 EC No 243-987-5	Hair dye substance in non-oxidative hair dye products	0.3 % (of the mixture in the ratio 1:1 of 2,2'-[4-(4-amino phenylazo) phenylimino] diethanol and lignosulfate)		

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
276	9,10-Anthracenedione, 1,4-bis [(2,3-dihydroxypropyl) amino]- HC Blue No 14 CAS No 99788-75-7 EC No 421-470-7	Hair dye substance in non-oxidative hair dye products	0.3 %	— Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
277	2-(4-Methyl-2-nitroanilino) ethanol Hydroxyethyl-2-Nitro-p-Toluidine CAS No 100418-33-5 EC No 408-090-7	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 1.0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.0 % For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)

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
278	<p>1-Amino-2-nitro-4-(2',3'-dihydroxypropyl) amino-5-chlorobenzene + 1,4-bis-(2',3'-dihydroxypropyl) amino-2-nitro-5-chlorobenzene</p> <p>HC Red No 10 + HC Red No 11 CAS No 95576-89-9 + 95576-92-4</p>	<p>(a) Hair dye substance in oxidative hair dye products</p> <p>(b) Hair dye substance in non-oxidative hair dye products</p>	(b) 2.0 %	<p>(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.0 %</p> <p>For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers</p>	(a) As mentioned in reference number 205, column f (a)'

(b) by substituting for the entries at reference numbers 16 and 22 the following:

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
16	1-Naphthalenol 1-Naphthol CAS No 90-15-3 EC No 201-969-4	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0 %	As mentioned in reference number 205, column f (a)
22	1,3-benzenediol Resorcinol CAS No 108-46-3 EC No 203-585-2	(a) Hair dye substance in oxidative hair dye products 1. general use 2. professional use (b) Hair lotions and shampoos	(b) 0.5 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.25 %	(a) 1. Contains resorcinol Rinse hair well after application. Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them. As mentioned in reference number 205, column f (a). 2. For professional use only Contains resorcinol. Rinse eyes immediately if product comes into contact with them. As mentioned in reference number 205, column f (a) (b) Contains resorcinol.

2. Part 2 of Schedule 3 to the Principal Regulations is amended by deleting the entries at reference numbers 10 and 50.



GIVEN under my Official Seal,
16 May 2013.

JAMES REILLY,
Minister for Health.

EXPLANATORY NOTE

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

These Regulations amend the European Communities (Cosmetic Products) Regulations 2004. They update the law in relation to the manufacture, marketing and sale of cosmetic products by the implementation of Council Directive 2012/21/EU of 2 August 2012.

These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) Regulations 2013.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2
(Teil: 01 - 6476834 nó 1890 213434; Fax: 01 - 6476843)
nó trí aon díoltóir leabhar.

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2.
(Tel: 01 - 6476834 or 1890 213434; Fax: 01 - 6476843)
or through any bookseller.

€4.06

