



STATUTORY INSTRUMENTS

S.I. No. 191 of 2009

EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)
(AMENDMENT) REGULATIONS 2009

(Prn. A9/0705)

EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)
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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 2008/88/EC¹ of 23 September 2008, Commission Directive 2008/123/EC² of 18 December 2008, and Commission Directive 2009/6/EC³ of 4 February 2009, hereby make the following regulations:

1. These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) Regulations 2009.

2. These Regulations shall be construed as one with the European Communities (Cosmetics Products) Regulations 2004 to 2008 and may be cited together with those Regulations as 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 paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

(c) 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 Regulations 6, 7 and 8, Regulation 4(1) of the Principal Regulations is amended by the addition to the definition of “Directive” of references to the following Commission Directives: “2008/88/EC, 2008/123/EC and 2009/6/EC”.

5. Subject to Regulations 6, 7 and 8, the Schedules to the Principal Regulations are amended in the manner set out in the Schedule to these Regulations.

¹OJ No. L256, 24.9.2008, p12 and Corrigendum in OJ No. L263, 2.10.2008, p26

²OJ No. L340, 19.12.2008, p71

³OJ No. L36, 5.2.2009, p15

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 26th May, 2009.*

6. The provisions of these Regulations, insofar as such provisions relate to Commission Directive 2008/88/EC and the requirements of paragraphs 1(*b*), 2(*a*) and (*b*), and 3 of the Schedule, shall come into operation on 14 October 2009.

7. (1) Subject to subparagraph (2), the provisions of these Regulations, insofar as such provisions relate to Commission Directive 2008/123/EC and the requirements of paragraphs 1(*a*), and 4(*a*) of the Schedule, shall come into operation on 8 October 2009.

(2) The provisions of these Regulations, insofar as such provisions relate to Commission Directive 2008/123/EC and the requirements of paragraph 4(*b*) of the Schedule, shall come into operation on 8 July 2009.

8. (1) Subject to subparagraph (2), the provisions of these Regulations, insofar as such provisions relate to Commission Directive 2009/6/EC and the requirements of paragraphs 1(*c*), and 2(*d*) of the Schedule, shall come into operation on 5 November 2009.

(2) The provisions of these Regulations, insofar as such provisions relate to Commission Directive 2009/6/EC and the requirements of paragraph 2(*c*) of the Schedule, shall come into operation on 5 February 2010.

SCHEDULE

1. Schedule 2 to the Principal Regulations is amended as follows:—

(a) the entry under reference number 167 is replaced by the following:

“4-aminobenzoic acid and its esters, with the free amino group”;

(b) the following reference numbers 1329 to 1369 are inserted:

Reference no.	Chemical name/INCI-name
“1329	4-[(4-Aminophenyl)(4-iminocyclohexa-2,5-dien-1-ylidene)methyl]-o-toluidine (CAS 3248-93-9; EINECS 221-832-2) and its hydrochloride salt (Basic Violet 14; CI 42510) (CAS 632 99-5; EINECS 211-189-6) when used as a substance in hair dye products
1330	4-(2,4-Dihydroxyphenylazo)benzenesulphonic acid (CAS 2050-34-2; EINECS 218-087-0) and its sodium salt (Acid Orange 6; CI 14270) (CAS 547-57-9; EINECS 208-924-8) when used as a substance in hair dye products
1331	3-Hydroxy-4-(phenylazo)-2-naphthoic acid (CAS 27757-79-5; EINECS 248-638-0) and its calcium salt (Pigment Red 64:1; CI 15800) (CAS 6371-76-2; EINECS 228-899-7), when used as a substance in hair dye products
1332	2-(6-Hydroxy-3-oxo-(3H)-xanthen-9-yl)benzoic acid; Fluorescein (CAS 2321-07-5; EINECS 219-031-8) and its disodium salt (Acid yellow 73 sodium salt; CI 45350) (CAS 518-47-8; EINECS 208-253-0), when used as a substance in hair dye products
1333	4',5'-Dibromo-3',6'-dihydroxyspiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one; 4',5'-Dibromofluorescein; (Solvent Red 72) (CAS 596-03-2; EINECS 209-876-0) and its disodium salt (CI 45370) (CAS 4372-02-5; EINECS 224-468-2) when used as a substance in hair dye products
1334	2-(3,6-Dihydroxy-2,4,5,7-tetrabromoxanthen-9-yl)-benzoic acid; Fluorescein, 2',4',5',7'-tetrabromo-; (Solvent Red 43) (CAS 15086-94-9; EINECS 239-138-3), its disodium salt (Acid Red 87; CI 45380) (CAS 17372-87-1; EINECS 241-409-6) and its aluminium salt (Pigment Red 90:1 Aluminium lake) (CAS 15876-39-8; EINECS 240-005-7) when used as a substance in hair dye products
1335	Xanthylium, 9-(2-carboxyphenyl)-3-((2-methylphenyl)amino)-6-((2-methyl-4-sulfophenyl)amino)-, inner salt (CAS 10213-95-3); and its sodium salt (Acid Violet 9; CI 45190) (CAS 6252-76-2; EINECS 228-377-9) when used as a substance in hair dye products
1336	3',6'-Dihydroxy-4',5'-diiodospiro(isobenzofuran-1(3H),9'-[9H]xanthene)-3-one; (Solvent Red 73) (CAS 38577-97-8; EINECS 254-010-7) and its sodium salt (Acid Red 95; CI 45425) (CAS 33239-19-9; EINECS 251-419-2) when used as a substance in hair dye products
1337	2',4',5',7'-Tetraiodofluorescein (CAS 15905-32-5; EINECS 240-046-0), its disodium salt (Acid Red 51; CI 45430) (CAS 16423-68-0; EINECS 240-474-8) and its aluminium salt (Pigment Red 172 Aluminium lake)(CAS 12227-78-0; EINECS 235-440-4) when used as a substance in hair dye products

Reference no.	Chemical name/INCI-name
1338	1-Hydroxy-2,4-diaminobenzene (2,4-Diaminophenol) (CAS 95-86-3; EINECS 202-459-4) and its dihydrochloride salt (2,4-Diaminophenol HCl) (CAS 137-09-7; EINECS 205-279-4) when used as a substance in hair dye products
1339	1,4-Dihydroxybenzene (Hydroquinone) (CAS 123-31-9; EINECS 204-617-8) when used as a substance in hair dye products
1340	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (Basic Blue 26; CI 44045) (CAS 2580-56-5; EINECS 219-943-6) when used as a substance in hair dye products
1341	Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]-4-hydroxynaphthalene-1-sulphonate (Ponceau SX; CI 14700) (CAS 4548-53-2; EINECS 224-909-9) when used as a substance in hair dye products
1342	Trisodium tris[5,6-dihydro-5-(hydroxyimino)-6-oxonaphthalene-2-sulphonato(2-)-N5,O6]ferrate(3-) (Acid Green 1; CI 10020) (CAS 19381-50-1; EINECS 243-010-2) when used as a substance in hair dye products
1343	4-(Phenylazo)resorcinol (Solvent Orange 1; CI 11920) (CAS 2051-85-6; EINECS 218-131-9) and its salts, when used as a substance in hair dye products
1344	4-[(4-Ethoxyphenyl)azo]naphthol (Solvent Red 3; CI 12010) (CAS 6535-42-8; EINECS 229-439-8) and its salts, when used as a substance in hair dye products
1345	1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol (Pigment Red 4; CI 12085) (CAS 2814-77-9; EINECS 220-562-2) and its salts when used as a substance in hair dye products
1346	3-Hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide (Pigment Red 112; CI 12370) (CAS 6535-46-2; EINECS 229-440-3) and its salts when used as a substance in hair dye products
1347	N-(5-Chloro-2,4-dimethoxyphenyl)-4-[[5 [(diethylamino)sulphonyl]-2-methoxyphenyl]azo]-3 hydroxynaphthalene-2-carboxamide (Pigment Red 5; CI 12490) (CAS 6410-41-9; EINECS 229-107-2) and its salts when used as a substance in hair dye products
1348	Disodium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3 hydroxy-2-naphthoate (Pigment Red 48; CI 15865) (CAS 3564-21-4; EINECS 222-642-2) when used as a substance in hair dye products
1349	Calcium 3-hydroxy-4-[(1-sulphonato-2-naphthyl)azo]-2 naphthoate (Pigment Red 63:1; CI 15880) (CAS 6417-83-0; EINECS 229-142-3) when used as a substance in hair dye products
1350	Trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene 2,7-disulphonate (Acid Red 27; CI 16185) (CAS 915-67-3; EINECS 213-022-2) when used as a substance in hair dye products
1351	2,2'-[(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide] (Pigment Yellow 13; CI 21100) (CAS 5102-83-0; EINECS 225-822-9) when used as a substance in hair dye products

Reference no.	Chemical name/INCI-name
1352	2,2'-[Cyclohexylidenebis[(2-methyl-4,1-phenylene)azo]]bis[4-cyclohexylphenol] (Solvent Yellow 29; CI 21230) (CAS 6706-82-7; EINECS 229-754-0) when used as a substance in hair dye products
1353	1-((4-Phenylazo)phenylazo)-2-naphthol (Solvent Red 23; CI 26100) (CAS 85-86-9; EINECS 201-638-4) when used as a substance in hair dye products
1354	Tetrasodium 6-amino-4-hydroxy-3-[[7-sulphonato-4-[(4-sulphonatophenyl)azo]-1-naphthyl]azo]naphthalene-2,7-disulphonate (Food Black 2; CI 27755) (CAS 2118-39-0; EINECS 218-326-9) when used as a substance in hair dye products
1355	Ethanaminium, N-(4-((4-(diethylamino)phenyl)(2,4-disulphophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-N-ethyl, hydroxide, inner salt, sodium salt (Acid Blue 1; CI 42045) (CAS 129-17-9; EINECS 204-934-1) when used as a substance in hair dye products
1356	Ethanaminium, N-(4-((4-(diethylamino)phenyl)(5-hydroxy-2,4-disulphophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-N-ethyl, hydroxide, inner salt, calcium salt (2:1) (Acid Blue 3; CI 42051) (CAS 3536-49-0; EINECS 222-573-8) when used as a substance in hair dye products
1357	Benzenemethanaminium, N-ethyl-N-(4-((4-(ethyl((3-sulphophenyl)methyl)amino)phenyl)(4-hydroxy-2-sulphophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-3-sulfo-, hydroxide, inner salt, disodium salt (Fast Green FCF; CI 42053) (CAS 2353-45-9; EINECS 219-091-5) when used as a substance in hair dye products
1358	1,3-Isobenzofurandione, reaction products with methylquinoline and quinoline (Solvent Yellow 33; CI 47000) (CAS 8003-22-3; EINECS 232-318-2) when used as a substance in hair dye products
1359	Nigrosine (CI 50420) (CAS 8005-03-6) when used as a substance in hair dye products
1360	8,18-Dichloro-5,15-diethyl-5,15-dihydrodiindolo[3,2-b:3',2'm]triphenodioxazine (Pigment Violet 23; CI 51319) (CAS 6358-30-1; EINECS 228-767-9) when used as a substance in hair dye products
1361	1,2-Dihydroxyanthraquinone (Pigment Red 83; CI 58000) (CAS 72-48-0; EINECS 200-782-5) when used as a substance in hair dye products
1362	Trisodium 8-hydroxypyrene-1,3,6-trisulphonate (Solvent Green 7; CI 59040) (CAS 6358-69-6; EINECS 228-783-6) when used as a substance in hair dye products
1363	1-Hydroxy-4-(p-toluidino)anthraquinone (Solvent Violet 13; CI 60725) (CAS 81-48-1; EINECS 201-353-5), when used as a substance in hair dye products
1364	1,4-bis(p-Tolylamino)anthraquinone (Solvent Green 3; CI 61565) (CAS 128-80-3; EINECS 204-909-5) when used as a substance in hair dye products
1365	6-Chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)ylidene)-4-methylbenzo[b]thiophene-3(2H)-one (VAT Red 1; CI 73360) (CAS 2379-74-0; EINECS 219-163-6) when used as a substance in hair dye products

Reference no.	Chemical name/INCI-name
1366	5,12-Dihydroquino[2,3-b]acridine-7,14-dione (Pigment Violet 19; CI 73900) (CAS 1047-16-1; EINECS 213-879-2) when used as a substance in hair dye products
1367	(29H,31H-Phthalocyaninato(2-)-N29,N30,N31,N32)copper (Pigment Blue 15; CI 74160) (CAS 147-14- 8; EINECS 205-685-1) when used as a substance in hair dye products
1368	Disodium [29H,31H-phthalocyaninedisulphonato(4-) N29,N30,N31,N32]cuprate(2-) (Direct Blue 86; CI 74180) (CAS 1330-38-7; EINECS 215-537-8) when used as a substance in hair dye products
1369	Polychloro copper phthalocyanine (Pigment Green 7; CI 74260) (CAS 1328-53-6; EINECS 215-524-7) when used as a substance in hair dye products”

(c) the following reference numbers 1370 and 1371 are inserted:

Reference no.	Chemical name/INCI-name	CAS Number EC Number
“1370	Diethylene glycol (DEG), for traces level see Schedule 3 2,2'-Oxydiethanol	CAS No 111-46-6 EC No 203-872-2
1371	Phytonadione [INCI], phytomenadione [INN]	CAS No 84-80-0/81818-54-4; EC No 201-564-2”

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

- (a) the entry under reference number 10 is deleted;
- (b) under reference number 14, item (a) is deleted from column ‘c’ along with related entries in columns ‘d’ and ‘f’;
- (c) the following reference number 185 is inserted:

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
"185	Toluene CAS No 108-88-3 EC No 203-625-9	Nail products	25 %		Keep out of reach of children To be used by adults only"

(d) the following reference numbers 186 to 188 are inserted:

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
"186	Diethylene glycol (DEG) CAS No 111-46-6 EC No 203-872-2 2,2'-Oxydiethanol	Traces in ingredients	0.1 %		
187	Butoxydiglycol CAS No 112-34-5 EC No 203-961-6 diethylene glycol monobutyl ether (DEGBE)	Solvent in hair dye products	9%	No use in aerosol dispensers (sprays)	
188	Butoxyethanol CAS No 111-76-2 EC No 203-905-0 ethylene glycol monobutyl ether (EGBE)	Solvent in oxidative hair dye products Solvent in non-oxidative hair dye products	4.0% 2.0 %	No use in aerosol dispensers (sprays) No use in aerosol dispensers (sprays)"	

3. Part 2 of Schedule 3 to the Principal Regulations is amended by the deletion of the entries under reference numbers 57, 59 and 60.

4. Part 1 of Schedule 7 to the Principal Regulations is amended as follows:—

- (a) the entry under reference number 1 is deleted;
- (b) under reference number 28, the words “in sunscreen products” are deleted from column c.



GIVEN under my Official Seal
21 May 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 2008/88/EC, Commission Directive 2008/123/EC and Commission Directive 2009/6/EC with a view to improving the safety of those products. These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) Regulations 2009.

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