

*Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 18,406, 21 ta' April, 2009*

*Taqsimha B*

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**L.N. 131 of 2009**

**PRODUCT SAFETY ACT  
(CAP. 427)**

**The Cosmetic Products (Amendment) Regulations, 2009**

IN exercise of the powers conferred by article 39 of the Product Safety Act, the Minister of Finance, the Economy and Investment has, on the advice of the Malta Standards Authority, made the following regulations:-

**1.** The title of these regulations is the Cosmetic Products (Amendment) Regulations, 2009, and they shall be read and construed as one with the Cosmetic Products Regulations, 2004, hereinafter referred to as “the principal regulations”. Citation.  
L.N. 424 of 2004.

**2.** (1) Regulation 7(1)(b) shall apply from 8 July, 2009 Commencement.

(2) Regulations 5(1)(a) and 7(1)(a) shall apply from 8 October, 2009.

(3) Regulations 5(1)(b) and 6 shall apply as from 14 October, 2009, provided that cosmetic products which fail to comply with these regulations are not sold or disposed of to the final consumer after 14th October, 2009.

**3.** (1) Regulations 4 and 8 implement the provisions of Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Scope.

(2) Regulations 5(1)(b) and 6 implement the provisions of Commission Directive 2008/88/EC of 23 September 2008 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and III thereto to technical progress.

(3) Regulations 5(1)(a), 7(1)(a) and 7(1)(b) implement the provisions of Commission Directive 2008/123/EC

of 18 December 2008 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and VII thereto to technical progress.

Amends regulation 5 of the principal regulations.

**4.** In regulation 5.3(d) of the principal regulations, for the words “Annex V to Council Directive 67/548/EEC of the 27 June, 1967”, there shall be substituted the words “Regulation (EC) No 440/2008”.

Amends the Second Schedule to the principal regulations.

**5.** (1) In the Second Schedule to the principal regulations:

(a) entry 167 “Esters of 4-aminobenzoic acid, with the free amino group, with the exception of that given in Annex VII, Part 2” shall be substituted with the words “4-aminobenzoic acid and its esters, with the free amino group”; and

(b) immediately after entry 1328, there shall be added the following new entries:

- “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-methylphenylamino)-6-((2-methyl-4-sulphophenylamino)-, 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
- 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-)-N5,06]ferrate(3-) (Acid Green 1; CI 10020) (CAS 19381-50-1; EINECS 243-010-2) when a substance in hair dye products
- 1343 4-(Phenylazo)resorcinol (Solvent Orange 1; CI 11920) (CAS 2051-85-6; EINECS 218-131) 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 228) 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 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]; hydroxynaphthalene-2-carboxamide (Pigment Red 5; CI 12490) (CAS 6410-41-9; EINECS 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 Blue 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
- 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 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-disulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene)-N-ethyl-, hydroxide, inner salt, sodium salt (Acid Blue 1; CI 42) (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-disulfophenyl)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-sulfophenyl)methyl)amino)phenyl]hydroxy-2-sulfophenyl)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 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 dye products
- 1361 1,2-Dihydroxyanthraquinone (Pigment Red 83; CI 58000) (CAS 72-48-0; EINECS 200-700-7) when used as a substance in hair dye products
- 1362 Trisodium 8-hydroxypyrene-1,3,6-trisulphonate (Solvent Green 7; CI 59040) (CAS 6358-30-1; 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 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 163-6) when used as a substance in hair dye products
- 1366 5,12-Dihydroquino[2,3-b]acridine-7,14-dione (Pigment Violet 19; CI 73900) (CAS 104-88-1; 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-) (Pigment 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 254-7) when used as a substance in hair dye products".

Amends the Third Schedule to the principal regulations.

**6.** The Third Schedule to the principal regulations shall be amended as follows:

(a) in Part 1, reference number 10 is deleted and the relative indications in columns b, c, d and f, shall be deleted;

(b) in Part 1, reference number 14, there shall be substituted the following:

"14	Hydroquinone <sup>(3)</sup>		0.3 %		<p>(a) 1. — Do not use to dye eyelashes or eyebrows — Rinse the eyes immediately if the product comes into contact with them — Contains hydroquinone</p> <p>2.— For professional use only — Contains hydroquinone — Rinse the eyes immediately if the product comes into contact with them</p> <p>(b) — For professional use only — Avoid skin contact — Read directions for use carefully</p>
		Artificial nail systems	0.02 % (after mixing for use)	Professional use only	

(3) These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorized for each of them does not exceed 2%.

(c) in Part 2, reference numbers 57, 59 and 60 and the relative indications on columns b, c, d, e and f, shall be deleted, and the reference number 58 shall be renumbered as reference number 57 thereof.

Amends the Sixth Schedule to the principal regulations.

**7.** (1) In the Sixth Schedule to the principal regulations:

(a) Reference number 1 shall be deleted, and reference number 2 to 28 shall be renumbered as reference numbers 1 to 27 respectively; and

(b) in entry 27, as renumbered, in column c thereof, the words "in sunscreen products" shall be deleted.

Amends the Tenth Schedule to the principal regulations.

**8.** In the Tenth Schedule to the principal regulations, for the words "Annex V to Council Directive 67/548/EEC of 27 June 1967", there shall be substituted the words "Regulation (EC) No 440/2008".