L.N. 22 of 2008

PRODUCT SAFETY ACT
(CAP. 427)

The Cosmetic Products (Amendment) Regulations, 2008

IN exercise of the powers conferred by article 39 of the Product Safety Act, the Minister for Competitiveness and Communications 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, 2008, 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) Regulations 3 and 4 of these principal regulations shall enter into force on 18th June 2008. These regulations implement the provisions of Commission Directive 2007/54/EC of the 29th August, 2007 (OJ L 226, 30.8.2007, p. 21 - 27 and OJ L 258, 4.10.2007, p. 44 - 44). Commencement and scope.

(2) Regulation 5 of these regulations shall enter into force on 19th January 2009. This regulation implements the provisions of Commission Directive 2007/53/EC of the 29th August, 2007 (OJ L 226, 30.8.2007, p. 19 - 20).

3. In the Second Schedule to the principal regulations, the following reference numbers 1244 to 1328 are added: Amends the Second Schedule to the principal regulations.

Ref. No	*Chemical name/INCI-name*
“1244	1-Methyl-2,4,5-trihydroxybenzene (CAS No 1124-09-0) and its salts, when used as a substance in hair dye products
1245	2,6-Dihydroxy-4-methylpyridine (CAS No 4664-16-8) and its salts, when used as a substance in hair dye products
1246	5-Hydroxy-1,4-benzodioxane (CAS No 10288-36-5) and its salts, when used as a substance in hair dye products
1247	3,4-Methylenedioxyphenol (CAS No 533-31-3) and its salts, when used as a substance in hair dye products
1248	3,4-Methylenedioxyaniline (CAS No 14268-66-7) and its salts, when used as a substance in hair dye products
1249	Hydroxypyridinone (CAS No 822-89-9) and its salts, when used as a substance in hair dye products
1250	3-Nitro-4-aminophenoxyethanol (CAS No 50982-74-6) and its salts, when used as a substance in hair dye products
1251	2-methoxy-4-nitrophenol (CAS No 3251-56-7) (4-Nitroguaiacol) and its salts, when used as a substance in hair dye products
1252	C.I. Acid Black 131 (CAS No 12219-01-1) and its salts, when used as a substance in hair dye products
1253	1,3,5-Trihydroxybenzene (CAS No 108-73-6) (Phloroglucinol) and its salts, when used as a substance in hair dye products
1254	1,2,4-Benzenetriacetate (CAS No 613-03-6) and its salts, when used as a substance in hair dye products
1255	Ethanol, 2,2'-iminobis-, reaction products with epichlorohydrin and 2-nitro-1,4-benzenediamine (CAS No 68478-64-8) (CAS 158571-58-5) (HC Blue No 5) and its salts, when used as a substance in hair dye products
1256	N-Methyl-1,4-diaminoanthraquinone, reaction products with epichlorohydrin and monoethanolamine (CAS No 158571-57-4) (HC Blue No 4) and its salts, when used as a substance in hair dye products
1257	4-Aminobenzenesulfonic acid (CAS No 121-57-3) and its salts, when used as a substance in hair dye products
1258	3,3'-(Sulfonylbis(2-nitro-4,1-phenylene)imino)bis(6-(phenylamino)) benzenesulfonic acid and its salts, when used as a substance in hair dye products
1259	3(or5)-((4-(Benzylmethylamino)phenyl)azo)-1,2-(or1,4)-dimethyl-1H-1,2,4-triazolium and its salts, when used as a substance in hair dye products
1260	2,2'-((3-Chloro-4-((2,6-dichloro-4-nitrophenyl)azo)phenyl)imino)bisethanol (CAS No 23355-64-8) (Disperse Brown 1) and its salts, when used as a substance in hair dye products
1261	Benzothiazolium, 2-[[4-[ethyl(2-hydroxyethyl)amino]phenyl]azo]-6-methoxy-3-methyl-and its salts, when used as a substance in hair dye products
1262	2-[(4-Chloro-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutanamide (CAS No 13515-40-7) (Pigment Yellow 73) and its salts, when used as a substance in hair dye products
1263	2,2'-[(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-N-phenylbutanamide] (CAS No 6358-85-6) (Pigment Yellow 12) and its salts, when used as a substance in hair dye products
1264	2,2'-(1,2-Ethenediyl)bis[5-((4-ethoxyphenyl)azo]benzenesulfonic acid) and its salts, when used as a substance in hair dye products
1265	2,3-Dihydro-2,2-dimethyl-6-[(4-(phenylazo)-1-naphthalenyl)azo]-1H-pyrimidine (CAS No 4197-25-5) (Solvent Black 3) and its salts, when used as a substance in hair dye products
1266	3(or5)-[[4-[(7-amino-1-hydroxy-3-sulphonato-2-naphthyl)azo]-1-naphthyl]azo]salicylic acid and its salts, when used as a substance in hair dye products

Ref. No	*Chemical name/INCI-name*
1267	2-Naphthalenesulfonic acid, 7-(benzoylamino)-4-hydroxy-3-[[4-[(4-sulfophenyl)azo]phenyl]azo]- and its salts, when used as a substance in hair dye products
1268	(μ-((7,7'-Iminobis(4-hydroxy-3-((2-hydroxy-5-(N-methylsulphamoyl)phenyl)azo)naphthalene-2-sulphonato))(6-)))dicuprate(2-) and its salts, when used as a substance in hair dye products
1269	3-[(4-(Acetylamino)phenyl)azo]-4-hydroxy-7-[[[[5-hydroxy-6-(phenylazo)-7-sulfo-2-naphthalenyl]amino]carbonyl]amino]-2-naphthalenesulfonic acid and its salts, when used as a substance in hair dye products
1270	2-Naphthalenesulfonic acid, 7,7'-(carbonyldiimino)bis(4-hydroxy-3-[[2-sulfo-4-[(4-sulfophenyl)azo]phenyl]azo]-, (CAS No 25188-41-4) and its salts, when used as a substance in hair dye products
1271	Ethanaminium, N-(4-[bis[4-(diethylamino)phenyl]methylene]-2,5-cyclohexadien-1-ylidene)-Nethyl-and its salts, when used as a substance in hair dye products
1272	3H-Indolium, 2-[[(4-methoxyphenyl)methylhydrazono]methyl]-1,3,3-trimethyl- and its salts, when used as a substance in hair dye products
1273	3H-Indolium, 2-(2-((2,4-dimethoxyphenyl)amino)ethenyl)-1,3,3-trimethyl- and its salts, when used as a substance in hair dye products
1274	Nigrosine spirit soluble (CAS No 11099-03-9) (Solvent Black 5), when used as a substance in hair dye products
1275	Phenoxazin-5-ium, 3,7-bis(diethylamino)-, (CAS No 47367-75-9) and its salts, when used as a substance in hair dye products
1276	Benzo[a]phenoxazin-7-ium, 9-(dimethylamino)-, and its salts, when used as a substance in hair dye products
1277	6-Amino-2-(2,4-dimethylphenyl)-1H-benz[de]isoquinoline-1,3(2H)-dione (CAS No 2478-20-8) (Solvent Yellow 44) and its salts, when used as a substance in hair dye products
1278	1-Amino-4-[[4-[(dimethylamino)methyl]phenyl]amino]anthraquinone (CAS No 12217-43-5) and its salts, when used as a substance in hair dye products
1279	Laccaic Acid (CI Natural Red 25) (CAS No 60687-93-6) and its salts, when used as a substance in hair dye products
1280	Benzenesulfonic acid, 5-[(2,4-dinitrophenyl)amino]-2-(phenylamino)-, (CAS No 15347-52-1) and its salts, when used as a substance in hair dye products
1281	4-[(4-Nitrophenyl)azo]aniline (CAS No 730-40-5) (Disperse Orange 3) and its salts, when used as a substance in hair dye products
1282	4-Nitro-m-phenylenediamine (CAS No 5131-58-8) and its salts, when used as a substance in hair dye products
1283	1-Amino-4-(methylamino)-9,10-anthracenedione (CAS No 1220-94-6) (Disperse Violet 4) and its salts, when used as a substance in hair dye products
1284	N-Methyl-3-nitro-p-phenylenediamine (CAS No 2973-21-9) and its salts, when used as a substance in hair dye products
1285	N1-(2-Hydroxyethyl)-4-nitro-o-phenylenediamine (CAS No 56932-44-6) (HC Yellow No 5) and its salts, when used as a substance in hair dye products
1286	N1-(Tris(hydroxymethyl))methyl-4-nitro-1,2-phenylenediamine (CAS No 56932-45-7) (HC Yellow No 3) and its salts, when used as a substance in hair dye products
1287	2-Nitro-N-hydroxyethyl-p-anisidine (CAS No 57524-53-5) and its salts, when used as a substance in hair dye products
1288	N,N'-Dimethyl-N-Hydroxyethyl-3-nitro-p-phenylenediamine (CAS No 10228-03-2) and its salts, when used as a substance in hair dye products
1289	3-(N-Methyl-N-(4-methylamino-3-nitrophenyl)amino)propane-1,2-diol (CAS No 93633-79-5) and its salts, when used as a substance in hair dye products

Ref. No	*Chemical name/INCI-name*
1290	4-Ethylamino-3-nitrobenzoic acid (CAS No 2788-74-1) (N-Ethyl-3-Nitro PABA) and its salts, when used as a substance in hair dye products
1291	(8-[(4-Amino-2-nitrophenyl)azo]-7-hydroxy-2-naphthyl)trimethylammonium and its salts, except Basic Red 118 (CAS 71134-97-9) as impurity in Basic Brown 17), when used as a substance in hair dye products
1292	5-((4-(Dimethylamino)phenyl)azo)-1,4-dimethyl-1H-1,2,4-triazolium and its salts, when used as a substance in hair dye products
1293	m-Phenylenediamine, 4-(phenylazo)-, (CAS No 495-54-5) and its salts, when used as a substance in hair dye products
1294	1,3-Benzenediamine, 4-methyl-6-(phenylazo)- and its salts, when used as a substance in hair dye Products
1295	2,7-Naphthalenedisulfonic acid, 5-(acetylamino)-4-hydroxy-3-((2-methylphenyl)azo)- and its salts, when used as a substance in hair dye products
1296	4,4'-[(4-Methyl-1,3-phenylene)bis(azo)]bis[6-methyl-1,3-benzenediamine] (CAS No 4482-25-1) (Basic Brown 4) and its salts, when used as a substance in hair dye products
1297	Benzenaminium, 3-[[4-[[diamino(phenylazo)phenyl]azo]-2-methylphenyl]azo]-N,N,N-trimethyl and its salts, when used as a substance in hair dye products
1298	Benzenaminium, 3-[[4-[[diamino(phenylazo)phenyl]azo]-1-naphthalenyl]azo]-N,N,N-trimethyl and its salts, when used as a substance in hair dye products
1299	Ethanaminium, N-[4-[(4-(diethylamino)phenyl)phenylmethylene]-2,5-cyclohexadien-1-ylidene]-Nethyl- and its salts, when used as a substance in hair dye products
1300	9,10-Anthracenedione, 1-[(2-hydroxyethyl)amino]-4-(methylamino)- (CAS No 86722-66-9) and its derivatives and salts, when used as a substance in hair dye products
1301	1,4-Diamino-2-methoxy-9,10-anthracenedione (CAS No 2872-48-2) (Disperse Red 11) and its salts, when used as a substance in hair dye products
1302	1,4-Dihydroxy-5,8-bis[(2-hydroxyethyl)amino]anthraquinone (CAS No 3179-90-6) (Disperse Blue 7) and its salts, when used as a substance in hair dye products
1303	1-[(3-Aminopropyl)amino]-4-(methylamino)anthraquinone and its salts, when used as a substance in hair dye products
1304	N-[6-[(2-Chloro-4-hydroxyphenyl)imino]-4-methoxy-3-oxo-1,4-cyclohexadien-1-yl]acetamide (CAS No 66612-11-1) (HC Yellow No 8) and its salts, when used as a substance in hair dye Products
1305	[6-[[3-Chloro-4-(methylamino)phenyl]imino]-4-methyl-3-oxocyclohexa-1,4-dien-1-yl]urea (CAS No 56330-88-2) (HC Red No 9) and its salts, when used as a substance in hair dye products
1306	Phenothiazin-5-ium, 3,7-bis(dimethylamino)- and its salts, when used as a substance in hair dye Products
1307	4,6-Bis(2-Hydroxyethoxy)-m-Phenylenediamine and its salts, when used as a substance in hair dye Products
1308	5-Amino-2,6-Dimethoxy-3-Hydroxypyridine (CAS No 104333-03-1) and its salts, when used as a substance in hair dye products
1309	4,4'-Diaminodiphenylamine (CAS No 537-65-5) and its salts, when used as a substance in hair dye products
1310	4-Diethylamino-o-toluidine (CAS No 148-71-0) and its salts, when used as a substance in hair dye products
1311	N,N-Diethyl-p-phenylenediamine (CAS No 93-05-0) and its salts, when used as a substance in hair dye products
1312	N,N-Dimethyl-p-phenylenediamine (CAS No 99-98-9) and its salts, when used as a substance in hair dye products

Ref. No	*Chemical name/INCI-name*
1313	Toluene-3,4-Diamine (CAS No 496-72-0) and its salts, when used as a substance in hair dye products
1314	2,4-Diamino-5-methylphenoxyethanol (CAS No 141614-05-3) and its salts, when used as a substance in hair dye products
1315	6-Amino-o-cresol (CAS No 17672-22-9) and its salts, when used as a substance in hair dye Products
1316	Hydroxyethylaminomethyl-p-aminophenol (CAS No 110952-46-0) and its salts, when used as a substance in hair dye products
1317	2-Amino-3-nitrophenol (CAS No 603-85-0) and its salts, when used as a substance in hair dye Products
1318	2-Chloro-5-nitro-N-hydroxyethyl-p-phenylenediamine (CAS No 50610-28-1) and its salts, when used as a substance in hair dye products
1319	2-Nitro-p-phenylenediamine (CAS No 5307-14-2) and its salts, when used as a substance in hair dye products
1320	Hydroxyethyl-2,6-dinitro-p-anisidine (CAS No 122252-11-3) and its salts, when used as a substance in hair dye products
1321	6-Nitro-2,5-pyridinediamine (CAS No 69825-83-8) and its salts, when used as a substance in hair dye products
1322	Phenazinium, 3,7-diamino-2,8-dimethyl-5-phenyl- and its salts, when used as a substance in hair dye products
1323	3-Hydroxy-4-[(2-hydroxynaphthyl)azo]-7-nitronaphthalene-1-sulphonic acid (CAS No 16279-54-2) and its salts, when used as a substance in hair dye products
1324	3-[(2-nitro-4-(trifluoromethyl)phenyl)amino]propane-1,2-diol (CAS No 104333-00-8) (HC Yellow No 6) and its salts, when used as a substance in hair dye products
1325	2-[(4-chloro-2-nitrophenyl)amino]ethanol (CAS No 59320-13-7) (HC Yellow No 12) and its salts, when used as a substance in hair dye products
1326	3-[[4-[(2-Hydroxyethyl)Methylamino]-2-Nitrophenyl]Amino]-1,2-Propanediol (CAS No 173994-75-7) and its salts, when used as a substance in hair dye products
1327	3-[[4-[Ethyl(2-Hydroxyethyl)Amino]-2-Nitrophenyl]Amino]-1,2-Propanediol (CAS No 114087-41-1) and its salts, when used as a substance in hair dye products
1328	Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl- and its salts, when used as a substance in hair dye products”

Amends the Third Schedule to the principal regulations.

4. Part 1 of the Third Schedule to the principal regulations is amended as follows:

(a) in column b of reference number 8, the words "p-Phenylenediamine, its N-substituted derivatives and its salts; N-substituted derivatives of o-Phenylenediamine, with exception of those derivatives listed elsewhere in this Annex" are replaced by the following "p-Phenylenediamine, its N-substituted derivatives and its salts; N-substituted derivatives of o-Phenylenediamine, with the exception of those derivatives listed elsewhere in this Annex and under reference numbers 1309, 1311, and 1312 in Annex II"; and

(b) in column b of reference number 9, the words "Methylphenylenediamines, their N-substituted derivatives and their salts with the exception of substance No 364 in Annex II" are replaced by the following "Methylphenylenediamines, their N-substituted derivatives and their salts with the exception of substances under reference numbers 364, 1310 and 1313 in Annex II"; and

Further amends the Third Schedule to the principal regulations.

5. In reference numbers 26 to 43, and reference numbers 47 and 56 of Part 1 of the Third Schedule to the principal regulations, the following text is added after each entry in column f:

"For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. "for adult use only") the following labelling is obligatory:

"Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor." ".

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