

A.L. 266 ta' l-2009

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

Cosmetic Products (Amendment) (No. 3) 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) (No. 3) Regulations, 2009 and they shall be read and construed as one with the Cosmetic Products Regulations, hereinafter in these regulations referred to as "the principal regulations".

Citation.

S.L. 427.58

2. (1) These regulations shall apply as from 15th May, 2010.

Commencement and scope.

(2) These regulations implement the provisions of Commission Directive 2009/36/EC of 16 April 2009 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress.

3. (1) In Part 1 of the Third Schedule to the principal regulations the following reference numbers 189 to 205 shall be added immediately after entry 188:

Amends the Third Schedule to the principal regulations.

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
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 %		
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-disulphonato-phenyl) 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-dioxoanthracene-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 nitrosating 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 nitrosating systems - Maximum nitrosamine content: 50 µg/kg - Keep in nitrite-free containers	
197	1,5-Di-(8-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 nitrosating 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 products	0.15 %	- Do not use with nitrosating systems - Maximum nitrosamine content: 50 µg/kg - Keep in nitrite-free containers	

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 nitrosating 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 nitrosating systems - Maximum nitrosamine content: 50 µg/kg - Keep in nitrite-free containers	Can cause allergic reaction
201	Phenol, 2-chloro-6-(ethylamino)-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 nitrosating systems - Maximum nitrosamine content: 50 µg/kg - Keep in nitrite-free containers Can cause allergic reaction	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).	(a) The mixing ratio must be printed on the label. For (a) and (b): Can cause allergic reaction

203	<p>6-Methoxy-N2-methyl-2,3-pyridinediamine hydrochloride and dihydrochloride salt ⁽¹⁵⁾</p> <p>6-Methoxy-2-methylamino-3-aminopyridine HCl CAS 90817-34-8 (HCl) CAS 83732-72-3 (2HCl) EINECS 280-622-9 (2HCl)</p>	<p>(a) Hair dye substance in oxidative hair dye products</p> <p>(b) Hair dye substance in non-oxidative hair dye</p>	<p>(b) 0.68 % as free base (1.0% as dihydrochloride)</p>	<p>(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 nitrosating systems - Maximum nitrosamine content: 50µg/kg - Keep in nitrite-free containers</p>	<p>(a) The mixing ratio must be printed on the label.</p> <p>For (a) and (b): Can cause allergic reaction</p>
204	<p>2,3-Dihydro-1H-indole-5,6-diol and its hydrobromide salt⁽¹⁵⁾</p> <p>Dihydroxyindoline CAS 29539-03-5 Dihydroxyindoline HBr CAS 138937-28-7 EINECS 421-170-6</p>	<p>Hair dye substance in non-oxidative hair dye products</p>	<p>2.0 %</p>		<p>Can cause allergic reaction</p>

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	(a) The mixing ratio must be printed on the label.
(15) The free base and salts of this hair colouring ingredient, unless prohibited under Annex II, are permitted for use."					

(2) In columns 'c' and 'd' of entry 55 of Part 2 of the Third Schedule, section b shall be deleted.

(3) In Part 2 of the Third Schedule, reference numbers 7, 9, 14, 18, 24, 28, 47 and 58 shall be deleted.