

L.N. 446 of 2011

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

**Cosmetic Products (Amendment) Regulations, 2011**

IN exercise of the powers conferred by article 39 of the Product Safety Act, the Prime Minister, on the advice of the Malta Competition and Consumer Affairs Authority, has made the following regulations:

**1.** The title of these regulations is the Cosmetic Products (Amendment) Regulations, 2011, 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. (a)** These regulations shall come into force on 3 January 2012.

Commencement and scope.

**(b)** These regulations implement the provisions of Commission Directive 2011/59/EU of 13 May 2011, amending for the purpose of adaptation to technical progress, Annexes II and III to Council Directive 76/768/EEC relating to cosmetic products.

**3.** In the Second Schedule to the principal regulations immediately after the entry “1371 Phytotonadione [INCI], phytomenadione [INN] CAS No 84-80-0/81818-54-4; EC No 201-564-2.” there shall be added the following entry:

Amends the Second Schedule to the principal regulations.

Ref no.	Chemical Name	CAS No./EC No.
“1372	2-Aminophenol (o-Aminophenol; CI 76520) and its salts	CAS No 95-55-6/67845-79-8/51-19-4 EC No 202-431-1/267-335-4”

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Amends the Third Schedule to the principal regulations.

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

(a) Part I shall be amended as follows:-

(i) the following entries shall be added:

Ref No.	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Max. authorised concentration in the finished cosmetic product	Other limitations and requirements	
“215	4-amino-3-nitrophenol (CAS No 610-81-1) (EC No 210-236-8)	(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 1,5 %	(a) As mentioned in reference number 205, column f
216	2,7-Naphthalenediol (CAS No 582-17-2) (EC No 209-478-7)	(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 %	(a) As mentioned in reference number 205, column f (a)
217	m-Aminophenol (CAS No 591-27-5) (EC No 209-711-2) and its salts m-Aminophenol HCl (CAS No 51-81-0) (EC No 200-125-2) m-Aminophenol sulphate (CAS No 68239-81-	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,2 %	As mentioned in reference number 205, column f (a)

	6) (EC No 269-475-1) sodium m-Amino-phenol (CAS No 38171-54-9)				
218	2,6-Dihydroxy-3,4-dimethylpyridine (CAS No 84540-47-6) (EC No 283-141-2)	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)
222	2-Hydroxyethyl picramic acid (CAS No 99610-72-7) (EC No 412-520-9)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 2,0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 % 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)
223	p-Methylaminophenol (CAS No 150-75-4) (EC No 205-768-2) and its sulphate p-Methylaminophenol sulphate (CAS No 55-55-0/ 1936-57-8) (EC No 200-237-1/ 217-706-1)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,68 % (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)

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225	Ethanol, 2-[4-[Ethyl[(2-Hydroxyethyl) Amino]-2-Nitrophenyl]-Amino]-, (CAS No 104516-93-0) and its hydrochloride HC Blue No 12 (CAS No 132885-85-9) (EC No 407-020-2)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 1,5 % (as hydrochloride)	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,75 % (as hydrochloride) 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)
227	3-Amino-2,4-dichlorophenol (CAS No 61693-42-3) (EC No 262-909-0) and its hydrochloride 3-Amino-2,4-dichlorophenol HCl (CAS No 61693-43-4)	(a) Hair dye substance in oxidative hair dye products  b) Hair dye substance in non-oxidative hair dye products	(b) 1,5 % (as hydrochloride)	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 % (as hydrochloride)	(a) As mentioned in reference number 205, column f (a)
230	Phenyl methyl pyrazolone (CAS No 89-25-8) (EC No 201-891-0)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,25 %	As mentioned in reference number 205, column f (a)
232	2-Methyl-5-hydroxyethylamino-phenol (CAS No 55302-96-0) (EC No 259-583-7)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 % — Do not use with	As mentioned in reference number 205, column f (a)

				<p>nitrosating agents                      — Maximum nitrosamine content: 50 µg/kg                      — Keep in nitrite-free containers</p>	
234	<p>Hydroxybenzo morpholine                      (CAS No 26021-57-8)                      (EC No 247-415-5)</p>	<p>Hair dye substance in oxidative hair dye products</p>		<p>After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 %                      — Do not use with nitrosating agents                      — Maximum nitrosamine content: 50 µg/kg                      — Keep in nitrite-free containers</p>	<p>As mentioned in reference number 205, column f (a)</p>
237	<p>2,2'-[(4-Amino-3-nitrophenyl)imino]bisethanol                      (CAS No 29705-39-3) and its hydrochloride                      HC Red No 13                      (CAS No 94158-13-1)                      (EC No 303-083-4)</p>	<p>(a) Hair dye substance in oxidative hair dye products                       (b) Hair dye substance in non-oxidative hair dye products</p>	<p>(b) 2,5 % (as hydrochloride)</p>	<p>(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,25 % (as hydrochloride)</p>	<p>(a) As mentioned in reference number 205, column f (a)</p>
238	<p>2,6-Dimethoxy-3,5-pyridinediamine                      (CAS No 85679-78-3 (free base)) and its hydrochloride                      2,6-Dimethoxy-3,5-pyridinediamine HCl                      (CAS No</p>	<p>Hair dye substance in oxidative hair dye products</p>		<p>After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,25 % (as hydrochloride)</p>	<p>As mentioned in reference number 205, column f (a)</p>

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	56216-28-5) (EC No 260-062-1)				
239	HC Violet No 1 (CAS No 82576-75-8) (EC No 417-600-7)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 0,28 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,25 % 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)  (b) As mentioned in reference number 208, column f
241	1,5-Naphthalenedio 1 (CAS No 83-56-7) (EC No 201-487-4	(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 %	(a) As mentioned in reference number 205, column f (a)
242	Hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) (CAS No 128729-30-6) and its tetrahydrochloride Hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) HCl (CAS No 128729-28-2) (EC No 416-320-2)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,4 % (as tetrahydrochloride)	As mentioned in reference number 205, column f (a)
243	4-Amino-2-hydroxytoluene	Hair dye substance in		After mixing under	As mentioned in

	(CAS No 2835-95-2) (EC No 220-618-6)	oxidative hair dye products		oxidative conditions the maximum concentration applied to hair must not exceed 1,5 %	reference number 205, column f (a)
244	2,4-Diaminophenoxyethanol (CAS No 70643-19-5), its hydrochloride and its sulphate 2,4-Diaminophenoxyethanol HCl (CAS No 66422-95-5) (EC No 266-357-1) 2,4-Diaminophenoxyethanol sulphate (CAS No 70643-20-8) (EC No 274-713-2)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0 % (as hydrochloride)	As mentioned in reference number 205, column f (a)
245	2-Methylresorcinol (CAS No 608-25-3) (EC No 210-155-8)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 1,8 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,8 %	(a) As mentioned in reference number 205, column f (a)
246	4-Amino-m-cresol (CAS No 2835-99-6) (EC No 220-621-2)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 %	As mentioned in reference number 205, column f (a)
248	2-Amino-4-hydroxyethylaminoanisol (CAS No 83763-47-7) (EC No 280-733-2) and its sulphate 2-	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not	As mentioned in reference number 205, column f (a)

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	Amino-4-hydroxyethylaminoanisole sulphate (CAS No 83763-48-8) (EC No 280-734-8)			exceed 1,5 % (as sulphate) — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
249	Hydroxyethyl-3,4-methylenedioxyaniline and its hydrochloride Hydroxyethyl-3,4-methylenedioxyaniline HCl (CAS No 94158-14-2) (EC No 303-085-5)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 % — 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)
250	3-Nitro-p-hydroxyethylamino-phenol (CAS No 65235-31-6) (EC No 265-648-0)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 1,85 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 3,0 % For (a) and (b): — Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)  (b) As mentioned in reference number 208, column f
251	4-Nitrophenyl aminoethylurea (CAS No 27080-42-8) (EC No 410-700-1)	(a) Hair dye substance in oxidative hair dye products		(a) After mixing under oxidative conditions the maximum concentration	(a) As mentioned in reference number 205, column f (a)

		(b) Hair dye substance in non-oxidative hair dye products	(b) 0,5 %	applied to hair must not exceed 0,25 % For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
252	2-Amino-6-chloro- 4-nitrophenol (CAS No 6358-09- 4) (EC No 228- 762-1)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 2,0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0 %	(a) As mentioned in reference number 205, column f (a)  (b) As mentioned in reference number 208, column f”

(ii) the following entry with reference number 201 shall be substituted with the following:

“210	2-Chloro-6-ethylamino-4-nitrophenol (CAS No 131657-78-8) (EC No 411-440-1)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 3,0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 % (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)”
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(b) Part 2 shall be amended as follows:

(i) the entries with reference numbers 3 to 6, 11, 12, 16, 19 to 22, 25, 27, 31 to 39, 44, 48, 49, 55 and 56 shall be deleted;

(ii) in column g of the entries with reference numbers 10 and 50, for the words “31.12.2010” there shall be substituted the words “31.12.2011”.



