

L.N. 16 of 2006**PRODUCT SAFETY ACT
(CAP. 427)****Cosmetic Products (Amendment) Regulations, 2006**

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, 2006, and they shall be read and construed as one with the Cosmetic Products Regulations, 2004 hereinafter referred to as “the principal regulations”. Citation and coming into force. L.N. 424 of 2004.

2. As from the 20th January, 2006, cosmetic products that fail to comply with the provisions of these regulations shall not be placed on the market by manufacturers or importers.

3. These regulations implement the provisions of Commission Directive 2005/52/EC of the 9th September, 2005. Scope.

4. For Part 2 of the Third Schedule to the principal regulations, there shall be substituted the following:— Amends the Third Schedule to the principal regulations.

“PART 2

List of Substances provisionally allowed

Reference Number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements		
A	B	C	D	E	F	G
1	Basic Blue 7 (CAS No 2390-60-5)	Non-oxidising colouring agents for hair dyeing	0.2 %		Can cause allergic reaction	31.08.2006
2	2-Amino-3-nitrophenol (CAS No 603-85-0) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3.0 % (b) 3.0 % 50	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %	(a) (b) Can cause allergic reaction	31.08.2006
3	4-Amino-3-nitrophenol (CAS No 610-81-1) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3.0 % (b) 3.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %	(a) (b) Can cause allergic reaction	31.12.2006
4	2,7-Naphthalenediol (CAS no 582-17-2) and its salts	Oxidising colouring agents for hair dyeing	1.0 %	In combination with hydrogen peroxide the maximum use concentration upon		31.12.2006

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A	B	C	D	E	F	G
				application is 0.5 %		
5	m-Aminophenol (CAS no 591-27-5) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %	Can cause allergic reaction	31.12.2006
6	2,6-Dihydroxy-3,4-dimethylpyridine (CAS No 84540-47-6) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %	Can cause allergic reaction	31.12.2006
7	4-Hydroxypropylamino-3-nitrophenol (CAS No 92952-81-3) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 5.2 % (b) 2.6 %	In combination with hydrogen peroxide the maximum use concentration upon application is 2.6 %	(a) (b) Can cause allergic reaction	31.12.2006
8	6-Nitro-2,5-pyridinediamine (CAS No 69825-83-8) and its salts	Non-oxidising colouring agent for hair dyeing	3.0 %		Can cause allergic reaction	31.08.2006
9	HC Blue No 11 (CAS No 23920-15-2) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3.0 % (b) 2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %	(a) (b) Can cause allergic reaction	31.12.2006

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A	B	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	F	G
		C	D	E		
10	Hydroxyethyl-2-nitro-p-toluidine (CAS No 100418-33-5) and its salts	hair dyeing (a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 1.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %	(a) (b) Can cause allergic reaction	31.12.2006
11	2-Hydroxyethylpicramic acid (CAS No 99610-72-7) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3.0% (b) 2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %	(a) (b) Can cause allergic reaction	31.12.2006
12	p-Methylaminophenol (CAS No 150-75-4) and its salts	Oxidising colouring agent for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %	Can cause allergic reaction	31.12.2006
13	2,4-Diamino-5-methylphenoxyethanol (CAS No 141614-05-3) and its salts	Oxidising colouring agent for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %	Can cause allergic reaction	31.08.2006
14	HC Violet No 2 (CAS No 104226-19-9) and its salts	Non-oxidising colouring agent for hair dyeing	2.0 %			31.12.2006

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15	Hydroxyethyl-2,6-dinitro-p-anisidine (CAS No 122252-11-3) and its salts	Non-oxidising colouring agent for hair dyeing	3.0 %		Can cause allergic reaction	31.08.2006
16	HC Blue No 12 (CAS No 104516-93-0) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 1.5 % (b) 1.5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0.75 %	(a) (b) Can cause allergic reaction	31.12.2006
17	2,4-Diamino-5-methylphenetol (CAS No 113715-25-6) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %	Can cause allergic reaction	31.08.2006
18	1,3-Bis-(2,4-diaminophenoxy) propane (CAS No 81892-72-0) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %	Can cause allergic reaction	31.12.2006
19	3-Amino-2,4-dichlorophenol (CAS No 61693-43-4) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %	Can cause allergic reaction	31.12.2006
20	Phenyl methyl pyrazolone (CAS No 89-25-8) and its salts	Oxidising colouring agents for hair dyeing	0.5 %	In combination with hydrogen peroxide the maximum use		31.12.2006

Reference Number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
A	B	C	D	E	F	G
21	2-Methyl-5-hydroxyethylaminophenol (CAS No 55302-96-0) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %	Can cause allergic reaction	31.12.2006
22	Hydroxybenzomorpholine (CAS No 26021-57-8) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %	Can cause allergic reaction	31.12.2006
23	1,7-Naphthalenediol (CAS No 575-38-2) and its salts	Oxidising colouring agents for hair dyeing	1.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0.5 %	Can cause allergic reaction	31.08.2006
24	HC Yellow No 10 (CAS No 109023-83-8) and its salts	Non-oxidising colouring agents for hair dyeing	0.2 %			31.12.2006
25	2,6-Dimethoxy-3,5-pyridinediamine (CAS No 85679-78-3) and its salts	Oxidising colouring agents for hair dyeing	0.5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0.25 %	Can cause allergic reaction	31.12.2006
26	HC Orange No 2 (CAS No 85765-48-6) and its salts	Non-oxidising colouring agents for hair dyeing	1.0 %			31.12.2006
27	HC Violet No 1 (CAS No	(a) Oxidising	(a) 0.5 %	In combination with		31.12.2006

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		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements		
A	B	C	D	E	F	G
	82576-75-8) and its salts	colouring agents for hair dyeing		hydrogen peroxide the maximum use concentration upon application is 0.25 %		
		(b) Non-oxidising colouring agents for hair dyeing	(b) 0.5 %			
28	3-Methylamino-4-nitro-phenoxyethanol (CAS No 59820-63-2) and its salts	Non-oxidising colouring agents for hair dyeing	1.0 %			31.12.2006
29	2-Hydroxy-ethylamino-5-nitroanisole (CAS No 66095-81-6) and its salts	Non-oxidising colouring agents for hair dyeing	1.0 %			31.12.2006
30	2-Chloro-5-nitro-N-hydroxyethyl-p-phenylene-diamine (CAS No 50610-28-1) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 1.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %		31.08.2006
31	HC Red No 13 (CAS No 94158-13-1) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2.5 % (b) 2.5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.25 %		31.12.2006
32	1,5-Naphthalenediol	Oxidising colouring	1.0 %	In combination with		31.12.2006

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		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements		
A	B (CAS No 83-56-7) and its salts	C	D	E	F	G
		agents for hair dyeing		hydrogen peroxide the maximum use concentration upon application is 0.5 %		
33	Hydroxypropyl bis N-hydroxyethyl-pphenylenediamine) CAS No 128729-30-6) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %	Can cause allergic reaction	31.12.2006
34	o-Aminophenol (CAS No 95-55-6) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %		31.08.2006
35	4-Amino-2-hydroxytoluene (CAS No 2835-95-2) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %		31.12.2006
36	2,4-Diaminophenoxyethanol (CAS No 66422-95-5) and its salts	Oxidising colouring agents for hair dyeing	4.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 2.0 %		31.12.2006
37	2-Methylresorcinol (CAS No 608-25-3) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum use		31.12.2006

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A	B	C	D	E	F	G
38	4-Amino-m-cresol (CAS No 2835-99-6) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %		31.12.2006
39	2-Amino-4-hydroxyethylaminoaniline (CAS No 83763-47-7) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %		31.12.2006
40	3,4-Diaminobenzoic acid (CAS No 619-05-6) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %		31.08.2006
41	6-Amino-o-cresol (CAS No 17672-22-9) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %		31.08.2006
42	2-Aminomethyl-paminophenol (CAS No 79352-72-0) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %		31.08.2006
43	Hydroxyethylamino-methyl-paminophenol	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the		31.08.2006

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A	B (CAS No 110952-46-0) and its salts	C	D	E	F	G
				maximum use concentration upon application is 1.5 %		
44	Hydroxyethyl-3,4-methylenedioxyaniline (CAS No 81329-90-0) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %		31.12.2006
45	Acid Black 52 (CAS No 3618-58-4) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %		31.08.2006
46	2-Nitro-p-phenylenediamine (CAS No 5307-14-2) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0.3 % (b) 0.3 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0.15 %		31.08.2006
47	HC Blue No 2 (CAS No 33229-34-4) and its salts	Non-oxidising colouring agents for hair dyeing	2.8 %			31.12.2006
48	3-Nitro-p-hydroxyethylaminophenol (CAS No 65235-31-6) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising	(a) 6.0 % (b) 6.0 %	In combination with hydrogen peroxide the maximum use concentration upon application		31.12.2006

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49	4-Nitrophenyl aminoethylurea (CAS No 27080-42-8) and its salts	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements		31.12.2006
		C	D	E		
		colouring agents for hair dyeing		is 3.0 %		
50	HC Red No 10 + HC Red No 11 (CAS No 95576-89-9 + 95576-92-4) and its salts	(a) Oxidising colouring agents for hair dyeing	(a) 0.5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0.25 %		31.12.2006
		(b) Non-oxidising colouring agents for hair dyeing	(b) 0.5 %			
51	Yellow No 6 (CAS No 104333-00-8) and its salts	(a) Oxidising colouring agents for hair dyeing	(a) 2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %		31.08.2006
		(b) Non-oxidising colouring agents for hair dyeing	(b) 1.0 %			
52	HC Yellow No 12 (CAS No 59320-13-7) and its salts	(a) Oxidising colouring agents for hair dyeing	(a) 1.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0.5 %		31.08.2006
		(b) Non-oxidising colouring agents for hair dyeing	(b) 0.5 %			

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53	B HC Blue No 10 (CAS No 102767-27-1) and its salts	C	D	E	F	G
		Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %		31.08.2006
54	HC Blue No 9 (CAS No 114087-47-1) and its salts	(a) Oxidising colouring agents for hair dyeing	(a) 2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %		31.08.2006
		(b) Non-oxidising colouring agents for hair dyeing	(b) 1.0 %			
55	2-Chloro-6-ethylamino-4-nitrophenol (CAS No 131657-78-8) and its salts	(a) Oxidising colouring agents for hair dyeing	(a) 3.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 %		31.12.2006
		(b) Non-oxidising colouring agents for hair dyeing	(b) 3.0 %			
56	2-Amino-6-chloro-4-nitrophenol (CAS No 6358-09-4) and its salts	(a) Oxidising colouring agents for hair dyeing	(a) 2.0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0 %		31.12.2006
		(b) Non-oxidising colouring agents for hair dyeing	(b) 2.0 %			
57	Basic Blue 26 (CAS No 2580-56-5) (CI 44045) and its salts	(a) Oxidising colouring agents for hair dyeing	(a) 0.5 %	In combination with hydrogen peroxide the maximum use concentration upon		31.08.2006

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A	B	C	D	E	F	G
		(b) Non-oxidising colouring agents for hair dyeing	(b) 0.5 %	application is 0.25 %		
58	Acid Red 33 (CAS No 3567-66-6) (CI 17200) and its salts	Non-oxidising colouring agents for hair dyeing	2.0 %			31.12.2006
59	Ponceau SX (CAS No 4548-53-2) (CI 14700) and its salts	Non-oxidising colouring agents for hair dyeing	2.0 %			31.08.2006
60	Basic Violet 14 (CAS No 632-99-5) (CI 42510) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0.3 % (b) 0.3 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0.15 %		31.08.2006

