

Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 19,028, 8 ta' Frar, 2013

Taqsim B

L.N. 57 of 2013

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

Cosmetic Products (Amendment) Regulations, 2013

IN exercise of the powers conferred by article 39 of the Product Safety Act, the Minister for Fair Competition, Small Business and Consumers, 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, 2013, and they shall be read and construed as one with the Cosmetic Products Regulations, hereinafter referred to as "the principal regulations".

Citation.

S.L. 427.58.

2. (a) These regulations shall come into force on 1st September 2013.

Commencement and scope.

(b) These regulations implement the provisions of Commission Implementing Directive 2012/21/EU of 2 August 2012 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 the following entry shall be added:

Amends the Second Schedule to the principal regulations.

Ref no.	Chemical Name	CAS No./EC No.
"1373	N-(2-Nitro-4-aminophenyl)-allylamine (HC Red No 16) and its salts	CAS No 160219-76-1".

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

Amends the Third Schedule to the principal regulations.

(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	
"253	2,2'-(4-Aminophenyl)iminobis (ethanol) sulphate N,N-bis(2-Hydroxyethyl)- p-Phenylenediamine Sulfate CAS No 54381-16-7 EC No 259-134-5	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,5% (calculated 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)
254	1,3-Benzenediol, 4-chloro- 4-Chlororesorcinol CAS No 95-88-5 EC No 202-462-0	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,5%	As mentioned in reference number 205, column f (a)
255	2,4,5,6-Tetraaminopyrimidine sulphate Tetraaminopyrimidine Sulfate CAS No 5392-28-9 EC No 226-393-0	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 3,4% (calculated as sulphate)	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 3,4% (calculated as sulphate)	(a) As mentioned in reference number 205, column f (a)
256	3-(2-Hydroxyethyl)-p-phenylenediammonium sulphate Hydroxyethyl-p-Phenylenediamine Sulfate CAS No 93841-25-9 EC No 298-995-1	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0% (calculated as sulphate)	As mentioned in reference number 205, column f (a)
257	1H-Indole-5,6-diol Dihydroxyindole CAS No 3131-52-0 EC No 412-130-9	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 0,5%	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,5%	(a) As mentioned in reference number 205, column f (a) (b) As mentioned in reference number 208, column f

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258	5-Amino-4-chloro-2-methylphenol hydrochloride 5-Amino-4-Chloro-o-Cresol HCl CAS No 110102-85-7	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5% (calculated as hydrochloride)	As mentioned in reference number 205, column f (a)
259	1H-Indol-6-ol 6-Hydroxyindole CAS No 2380-86-1 EC No 417-020-4	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,5%	As mentioned in reference number 205, column f (a)
260	1H-Indole-2,3-Dione Isatin CAS No 91-56-5 EC No 202-077-8	Hair dye substance in non-oxidative hair dye products	1,6%		As mentioned in reference number 208, column f
261	2-Aminopyridin-3-ol 2-Amino-3-Hydroxypyridine CAS No 16867-03-1 EC No 240-886-8	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)
262	2-Methyl-1-naphthyl acetate 1-Acetoxy-2-Methylnaphthalene CAS No 5697-02-9 EC No 454-690-7	Hair dye substance in oxidative hair dye products			As mentioned in reference number 205, column f (a)

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263	1-Hydroxy-2-methylnaphthalene 2-Methyl-1-Naphthol CAS No 7469-77-4 EC No 231-265-2	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0% (When both 2-Methyl-1-Naphthol and 1-Acetoxy-2-Methylnaphthalene are present in a hair dye formulation, the maximum concentration on the head of 2-Methyl-1-Naphthol should not exceed 2,0%.)	As mentioned in reference number 205, column f (a)
264	Disodium 5,7-dinitro-8-oxido-2-naphthalenesulfonate Acid Yellow 1 CAS No 846-70-8 EC No 212-690-2 CI 10316	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 0,2%	(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) (b) As mentioned in reference number 208, column f
265	4-Nitro-1,2-phenylenediamine 4-Nitro-o-Phenylenediamine CAS No 99-56-9 EC No 202-766-3	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,5%	As mentioned in reference number 205, column f (a)
266	2-(4-Amino-3-nitroanilino)ethanol HC Red No 7 CAS No 24905-87-1 EC No 246-521-9	Hair dye substance in non-oxidative hair dye products	1,0%	-Do not use with nitrosating agents -Maximum nitrosamine content: 50 µg/kg -Keep in nitrite-free containers	As mentioned in reference number 208, column f
267	2-[bis(2-Hydroxyethyl)amino]-5-nitrophenol HC Yellow No 4 CAS No 59820-43-8 EC No 428-840-7	Hair dye substance in non-oxidative hair dye products	1,5%	-Do not use with nitrosating agents -Maximum nitrosamine content: 50 µg/kg -Keep in nitrite-free containers	

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268	2-[(2-Nitrophenyl)-amino] ethanol HC Yellow No 2 CAS No 4926-55-0 EC No 225-555-8	(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 0,75% 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)
269	4-[(2-Nitrophenyl)amino]phenol HC Orange No 1 CAS No 54381-08-7 EC No 259-132-4	Hair dye substance in non-oxidative hair dye products	1,0%		
270	2-Nitro-N1-phenyl-benzene-1,4- diamine HC Red No 1 CAS No 2784-89-6 EC No 220-494-3	Hair dye substance in non-oxidative hair dye products	1,0%		As mentioned in reference number 208, column f
271	1-Methoxy-3-(β-aminoethyl) amino-4-nitrobenzene, hydrochloride HC Yellow No 9 CAS No 86419-69-4 EC No 415-480-1	Hair dye substance in non-oxidative hair dye products	0,5% (calculated as hydrochl- oride)	- Do not use with nitrosating agents - Maximum nitrosamine content: 50 µg/kg - Keep in nitrite-free containers	
272	1-(4'-Aminophenylazo)-2-methyl- 4-(bis-2-hydroxyethyl) aminobenzene HC Yellow No 7 CAS No 104226-21-3 EC No 146-420-6	Hair dye substance in non-oxidative hair dye products	0,25%		

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273	N-(2-Hydroxyethyl)-2-nitro-4-trifluormethyl-aniline HC Yellow No 13 CAS No 10442-83-8 EC No 443-760-2	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 2,5%	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,5% 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)
274	Benzenaminium, 3-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]-N,N,N-trimethyl-, chloride Basic Yellow 57 CAS No 68391-31-1 EC No 269-943-5	Hair dye substance in non-oxidative hair dye products	2,0%		
275	Ethanol, 2,2'-[[4-[(4-aminophenyl)azo]phenyl]imino]bis- Disperse Black 9 CAS No 20721-50-0 EC No 243-987-5	Hair dye substance in non-oxidative hair dye products	0,3% (of the mixture in the ratio 1:1 of 2,2'-[4-(4-aminophenylazo)phenylimino] diethanol and lignosulfate)		
276	9,10-Anthracenedione, 1,4-bis [(2,3-dihydroxypropyl)amino]- HC Blue No 14 CAS No 99788-75-7 EC No 421-470-7	Hair dye substance in non-oxidative hair dye products	0,3%	-Do not use with nitrosating agents -Maximum nitrosamine content: 50 µg/kg -Keep in nitrite-free containers	

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277	2-(4-Methyl-2-nitroanilino)ethanol 1-Hydroxyethyl-2-Nitro-p-Toluidine CAS No 100418-33-5 EC No 408-090-7	(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% 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)
278	1-Amino-2-nitro-4-(2',3'-dihydroxypropyl)amino-5-chlorobenzene + 1,4-bis-(2',3'-dihydroxypropyl)amino-2-nitro-5-chlorobenzene HC Red No 10 + HC Red No 11 CAS No 95576-89-9 + 95576-92-4	(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 1,0% 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)"

(ii) the entries with reference numbers 16 and 22 shall be substituted with the following:

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	
"16	1-Naphthalenol 1-Naphthol CAS No 90-15-3 EC No 201-969-4	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 mentioned in reference number 205, column f (a)

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		Field of application and/or use	Max. authorised concentration in the finished cosmetic product	Other limitations and requirements	
22	1,3-benzenediol Resorcinol CAS No 108-46-3 EC No 203-585-2	(a) Hair dye substance in oxidative hair dye products 1. general use (b) Hair lotions and shampoos	(b) 0,5%	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,25%	(a) 1. Contains resorcinol Rinse hair well after application. Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them. As mentioned in reference number 205, column f (a). (b) Contains resorcinol."

(b) in Part 2 the entries with reference numbers 10 and 50 shall be deleted.

