

L.N. 273 of 2008

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

The Cosmetic Products (Amendment) (No. 2) Regulations, 2008

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. 2) 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) Reference item 102 in regulation 4(c) shall come into force on 16th November, 2008, provided that cosmetic products which fail to comply with this regulation are not sold or disposed of to the final consumer after 16th February 2009. This regulation implements the provisions of Commission Directive 2008/14/EC of 15 February 2008 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress (*OJ L 42, 16.2.2008, p. 43–44*). Commencement and scope.

(2) Regulations 3, 4(a), 4(b), and reference items 103 to 184 in regulation 4(c) shall come into force on 4th April, 2009, provided that cosmetic products which fail to comply with these regulations are not sold or disposed of to the final consumer after 4th October 2009. These regulations implement the provisions of Commission Directive 2008/42/EC of 3 April 2008 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and III thereto to technical progress (*OJ L 93, 4.4.2008, p. 13–23*).

3. In the Second Schedule, for reference item 1136 there shall be substituted the following: Amends the Second Schedule to the principal regulations.

“1136. Exudation of *Myroxylon pereirae* (Royle) Klotzch (Peru balsam, crude):

CAS No 8007-00-9) when used as fragrance ingredient”.

Amends the Third
Schedule to the
principal
regulations.

4. Part 1 of the Third Schedule to the principal regulations, shall be amended as follows:

(a) the item under reference number 68 is deleted;

(b) for items under reference numbers 45, 72, 73, 88 and 89 there shall be substituted the following, respectively:

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
45	Benzyl alcohol (*) CAS No 100-51-6	(a) Solvent (b) fragrance / aromatic compositions / their raw materials		(b) The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products”;	
72	Hydroxycitronellal CAS No 107-75-5	(a) Oral products (b) Other products	(b) 1,0 %	(a) (b) The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products”;	
73	Isogeraniol CAS No 97-54-1	(a) Oral products (b) Other products	(b) 0,02 %	(a) (b) The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products”;	

				products”;	
“88	<i>d</i> -Limonene CAS No 5989-27-5			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products Peroxide value less than 20 mmol/L. (**);	
“89	Methyl 2-octynoate CAS No 111-12-6 Methyl heptene carbonate	(a) Oral products (b) Other products	(b) 0,01 % when used alone When present in combination with methyl octine carbonate, the combined level in the finished product should not exceed 0,01 % (of which methyl octine carbonate should not be more than 0,002 %)	(a) (b) The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products”;	
(*) As a preservative, see the Fifth Schedule, Part 1, No 34.					
(**) This limit applies to the substance and not to the finished cosmetic product.”					

(c) immediately after item 101 thereof, there shall be added the following new items:

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
“102	Glyoxal Glyoxal (INCI) CAS No 107-22-2 EINECS No 203-474-9		100 mg/kg		
103	<i>Abies alba</i> cone oil and extract CAS No 90028-76-5			Peroxide value less than 10 mmol/L. (*)	
104	<i>Abies alba</i> needle oil and extract CAS No 90028-76-5			Peroxide value less than 10 mmol/L. (*)	
105	<i>Abies pectinata</i> needle oil and extract CAS No 92128-34-2			Peroxide value less than 10 mmol/L. (*)	
106	<i>Abies sibirica</i> needle oil and extract CAS No 91707-89-1			Peroxide value less than 10 mmol/L. (*)	

107	Abies balsamea needle oil and extract CAS No 85085-34-3			Peroxide value less than 10 mmoles/L (*)	
108	Pinus mugo pumilio leaf and twig oil and extract CAS No 90082-73-8			Peroxide value less than 10 mmoles/L (*)	
109	Pinus mugo leaf and twig oil and extract CAS No 90082-72-7			Peroxide value less than 10 mmoles/L (*)	
110	Pinus sylvestris leaf and twig oil and extract CAS No 84012-35-1			Peroxide value less than 10 mmoles/L (*)	
111	Pinus nigra leaf and twig oil and extract CAS No 90082-74-9			Peroxide value less than 10 mmoles/L (*)	
112	Pinus palustris leaf and twig oil and extract CAS No 97435-14-8			Peroxide value less than 10 mmoles/L (*)	
113	Pinus pinaster leaf and twig oil and extract CAS No 90082-75-0			Peroxide value less than 10 mmoles/L (*)	
114	Pinus pumila leaf and twig oil and extract CAS No 97676-05-6			Peroxide value less than 10 mmoles/L (*)	
115	Pinus species leaf and twig oil and extract CAS No 94266-48-5			Peroxide value less than 10 mmoles/L (*)	
116	Pinus cembra leaf and twig oil and extract CAS No 92202-04-5			Peroxide value less than 10 mmoles/L (*)	
117	Pinus cembra leaf and twig extract acetylated CAS No 94334-26-6			Peroxide value less than 10 mmoles/L (*)	
118	Picea Mariana Leaf Oil and Extract CAS No 91722-19-9			Peroxide value less than 10 mmoles/L (*)	
119	Thuja Occidentalis Leaf Oil and Extract CAS No 90131-58-1			Peroxide value less than 10 mmoles/L (*)	
120	Thuja Occidentalis Stem Oil CAS No 90131-58-1			Peroxide value less than 10 mmoles/L (*)	
121	3-Carene CAS No 13466-78-9 3,7,7-Trimethyl-bicyclo[4.1.0]hept-5-ene (isodiprene)			Peroxide value less than 10 mmoles/L (*)	
122	Cedrus atlantica wood oil and extract CAS No 92201-55-3			Peroxide value less than 10 mmoles/L (*)	
123	Cupressus sempervirens leaf oil and extract CAS No 84696-07-1			Peroxide value less than 10 mmoles/L (*)	
124	Turpentine gum (<i>Pinus</i> spp.) CAS No 9005-90-7			Peroxide value less than 10 mmoles/L (*)	
125	Turpentine oil and rectified oil CAS No 8006-64-2			Peroxide value less than 10 mmoles/L (*)	

126	Turpentine, steam distilled (<i>Pinus</i> spp.) CAS No 8006-64-2			Peroxide value less than 10 mmoles/l. (*)	
127	Terpene alcohols acetates CAS No 69103-01-1			Peroxide value less than 10 mmoles/l. (*)	
128	Terpene hydrocarbons CAS No 68956-56-9			Peroxide value less than 10 mmoles/l. (*)	
129	Terpenes and terpenoids with the exception of limonene (d-, l-, and dl-isomers) listed under reference numbers 167, 168 and 88 of this Annex III, part I CAS No 65996-98-7			Peroxide value less than 10 mmoles/l. (*)	
130	Terpene terpenoids sabinene CAS No 68917-63-5			Peroxide value less than 10 mmoles/l. (*)	
131	α -Terpinene CAS No 99-86-5 p-Mentha-1,3-diene			Peroxide value less than 10 mmoles/l. (*)	
132	γ -Terpinene CAS No 99-85-4 p-Mentha-1,4-diene			Peroxide value less than 10 mmoles/l. (*)	
133	Terpinolene CAS No 586-62-9 p-Mentha-1,4(8)-diene			Peroxide value less than 10 mmoles/l. (*)	
134	Acetyl hexamethyl indan CAS No 15323-35-0 1,1,2,3,3,6-Hexamethylindan-5-yl methyl ketone	(a) Leave-on products (b) Rinse-off products	(a) 2 %		
135	Allyl butyrate CAS No 2051-78-7 2-Propenyl Butanoate			Level of free allyl alcohol in the ester should be less than 0.1 %	
136	Allyl cinnamate CAS No 1866-31-5 2-Propenyl 3-Phenyl-2-propenoate			Level of free allyl alcohol in the ester should be less than 0.1 %	
137	Allyl cyclohexylacetate CAS No 4728-82-9 2-Propenyl Cyclohexanecarboxylate			Level of free allyl alcohol in the ester should be less than 0.1 %	
138	Allyl cyclohexylpropionate CAS No 2705-87-5 2-Propenyl 3-Cyclohexanecarboxylate			Level of free allyl alcohol in the ester should be less than 0.1 %	
139	Allyl heptanoate CAS No 142-19-8 2-Propenyl heptanoate			Level of free allyl alcohol in the ester should be less than 0.1 %	
140	Allyl caproate CAS No 123-68-2 Allyl hexanoate			Level of free allyl alcohol in the ester should be less than 0.1 %	
141	Allyl isovalerate CAS No 2835-39-1 2-Propenyl 3-Methylbutanoate			Level of free allyl alcohol in the ester should be less than 0.1 %	

142	Allyl octanoate CAS No 4230-97-1 2-Allyl caprylate			Level of free allyl alcohol in the ester should be less than 0.1 %	
143	Allyl phenoxyacetate CAS No 7493-74-5 2-Propenyl Phenoxyacetate			Level of free allyl alcohol in the ester should be less than 0.1 %	
144	Allyl phenylacetate CAS No 1797-74-6 2-Propenyl Benzeneacetate			Level of free allyl alcohol in the ester should be less than 0.1 %	
145	Allyl 3,5,5-trimethylhexanoate CAS No 71500-37-3			Level of free allyl alcohol in the ester should be less than 0.1 %	
146	Allyl cyclohexyloxyacetate CAS No 68901-15-5			Level of free allyl alcohol in the ester should be less than 0.1 %	
147	Allyl isoamyl oxyacetate CAS No 67634-00-8			Level of free allyl alcohol in the ester should be less than 0.1 %	
148	Allyl 2-methylbutoxyacetate CAS No 67634-01-9			Level of free allyl alcohol in the ester should be less than 0.1 %	
149	Allyl nonanoate CAS No 7493-72-3			Level of free allyl alcohol in the ester should be less than 0.1 %	
150	Allyl propionate CAS No 2408-20-0			Level of free allyl alcohol in the ester should be less than 0.1 %	
151	Allyl trimethylhexanoate CAS No 68132-80-9			Level of free allyl alcohol in the ester should be less than 0.1 %	
152	Allyl heptene carbonate CAS No 73157-43-4 (allyl oct-2-ynoate)		0.002 %	This material should not be used in combination with any other 2-alkynoic acid ester (e.g methyl heptene carbonate)	
153	Amyleyclopentenone CAS No 25564-22-1 2-Pentyleyclopent-2-en-1-one		0.1 %		
154	<i>Myroxylon balsamum var pereirae</i> , extracts and distillates CAS No 8007-00-9 Balsam Peru oil, absolute and anhydrol (Balsam Oil Peru)		0.4 %		
155	4-tert-Butylidihydrocinnamaldehyde CAS No 18127-01-0 3-(4-tert-Butylphenyl)propionaldehyde		0.6 %		
156	Cuminum cyminum fruit oil and extract CAS No 84775-51-9	(a) Leave-on products (b) Rinse-off products	(a) 0.4 % of Cumin oil		
157	cis-Rose ketone-I (**) CAS No 23726-94-5 (Z)-1-(2,6,6-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one (cis- α -Damascenone)	(a) Oral products (b) Other products	(b) 0.02 %		

158	<i>trans</i> -Rose ketone-2 (**) CAS No 23726-91-2 (<i>E</i>)-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one (<i>trans</i> - β -Damascenone)	(a) Oral products (b) Other products	(b) 0.02 %		
159	<i>trans</i> -Rose ketone-5 (**) CAS No 39872-57-6 (<i>E</i>)-1-(2,4,4-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one (Isodamascenone)		0.02 %		
160	Rose ketone-4 (**) CAS No 23696-85-7 1-(2,6,6-Trimethylcyclohexa-1,3-dien-1-yl)-2-buten-1-one (Jdamascenone)	(a) Oral products (b) Other products	(b) 0.02 %		
161	Rose ketone-3 (**) CAS No 57378-68-4 1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one (Delta-Damascenone)	(a) Oral products (b) Other products	(b) 0.02 %		
162	<i>cis</i> -Rose ketone-2 (**) CAS No 23726-92-3 1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one (<i>cis</i> - β -Damascenone)	(a) Oral products (b) Other products	(b) 0.02 %		
163	<i>trans</i> -Rose ketone-1 (**) CAS No 24720-09-0 1-(2,6,6-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one (<i>trans</i> - α -Damascenone)	(a) Oral products (b) Other products	(b) 0.02 %		
164	Rose ketone-5 (**) CAS No 33673-71-1 1-(2,4,4-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one		(b) 0.02 %		
165	<i>trans</i> -Rose ketone-3 (**) CAS No 71048-82-3 1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one (<i>trans</i> -delta-Damascenone)	(a) Oral products (b) Other products	(b) 0.02 %		
166	<i>trans</i> -2-hexenal CAS No 6728-26-3	(a) Oral products (b) Other products	(b) 0.002 %		
167	<i>l</i> -Limonene CAS No 5989-54-8 (<i>S</i>)- <i>p</i> -Mentha-1,8-diene			Peroxide value less than 20 mmoles/l. (*)	
168	<i>d,l</i> -Limonene (racemic) CAS No 138-86-3 1,8(9)- <i>p</i> -Menthadiene, <i>p</i> -Mentha-1,8-diene (Dipentene)			Peroxide value less than 20 mmoles/l. (*)	
169	Perillaldehyde CAS No 2111-75-3 <i>p</i> -Mentha-1,8-dien-7-al	(a) Oral products (b) Other	(b) 0.1 %		

		products			
170	Isobergamate CAS No 68683-20-5 Menthadiene-7-methyl formate		0.1 %		
171	Methoxy dicyclopentadiene carboxaldehyde CAS No 86803-90-9 Octahydro-5-methoxy- 4,7-Methano-111-indene- 2-carboxaldehyde		0.5 %		
172	3-methylnon-2-enenitrile CAS No 53153-66-5		0.2 %		
173	Methyl octine carbonate CAS No 111-80-8 Methyl non-2-ynoate	(a) Oral products (b) Other products	(b) 0.002 % when used alone When present in combination with methyl heptine carbonate, the combined level in the finished product should not exceed 0.01 % (of which methyl octine carbonate should not be more than 0.002 %)		
174	Amylvinylcarbinyl acetate CAS No 2442-10-6 1-Octen-3-yl acetate	(a) Oral products (b) Other products	(b) 0.3 %		
175	Propylidenephthalide CAS No 17369-59-4 3-Propylidenephthalide	(a) Oral products (b) Other products	(b) 0.01 %		
176	Isocyclogeraniol CAS No 68527-77-5 2,4,6-Trimethyl-3- cyclohexene-1-methanol		0.5 %		
177	2-Hexylidene cyclopentanone CAS No 17373-89-6	(a) Oral products (b) Other products	(b) 0.06 %		
178	Methyl heptadienone CAS No 1604-28-0 6- Methyl-3,5-heptadien-2- one	(a) Oral products (b) Other products	(b) 0.002 %		
179	p-methylhydrocinamic		0.2 %		

	aldehyde CAS No 5406-12-2 Cresylpropionalde-hyde <i>p</i> - Methyldihydrocinnamal- dehyde				
180	Liquidambar orientalis Balsam oil and extract CAS No 94891-27-7 (styrax)		0.6 %		
181	Liquidambar styraciflua balsam oil and extract CAS No 8046-19-3 (styrax)		0.6 %		
182	Acetyl hexamethyl tetralin CAS No 21145-77-7 CAS No 1506-02-1 1- (5,6,7,8-Tetrahydro- 3,5,5,6,8,8-hexamethyl-2- naphthyl)ethan-1-one (AHTN)	All cosmetic products, with the exception of oral products	(a) leave-on products: 0.1 % except: hydro alcoholic products: 1% fine fragrance: 2.5 % fragrance cream: 0.5 % (b) rinse-off products: 0.2 %		
183	<i>Commiphora erythrea</i> engler var. <i>glabrescens</i> engler gum extract and oil CAS No 93686-00-1		0.6 %		
184	Opopanax chironium resin CAS No 93384-32-8		0.6 %		
(*) This limit applies to the substance and not to the finished cosmetic product.					
(**) The sum of those substances used in combination should not exceed the limits given in column d.°.					

