

2008 No. 2566

CONSUMER PROTECTION

**The Cosmetic Products (Safety) (Amendment No. 2)
Regulations 2008**

<i>Made</i> - - - -	<i>30th September 2008</i>
<i>Laid before Parliament</i>	<i>2nd October 2008</i>
<i>Coming into force</i> - -	<i>4th April 2009</i>

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 11 of the Consumer Protection Act 1987(a).

In accordance with section 11(5) of that Act he has consulted such organisations as appear to him to be representative of interests substantially affected by the following Regulations, such other persons as he considered appropriate and the Health and Safety Executive.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Cosmetic Products (Safety) (Amendment No. 2) Regulations 2008 and shall come into force on 4th April 2009.

(2) In these Regulations “the Principal Regulations” means the Cosmetic Products (Safety) Regulations 2008(b).

Amendment to the Principal Regulations

2. The Principal Regulations are amended as follows—

(a) in regulation 2, after paragraph (1A), insert—

“(1B) Cosmetic products which fail to comply with the restrictions on the substances specified in—

- (a) column d of the entries relating to reference numbers 72, 73 and 89 in Part 1 of Schedule 4; and
- (b) the final sentence in column e of the entry relating to reference number 88 in Part 1 of Schedule 4,

may not be placed on the market by EEA manufacturers or by importers established within the EEA after 3rd April 2009, and cosmetic products which fail to comply with this restriction may not be disposed of to the final consumer after 4th October 2009.”;

(b) in Schedule 2 (list of Directives implemented by the Principal Regulations) insert at the end—

(a) 1987 c.43. Section 11(1) has been amended by S.I. 2005/1803, and section 11(5) has been amended by S.I. 2008/960.
(b) S.I. 2008/1284, as amended by SI 2008/2173.

“55. Commission Directive 2008/42/EC (O.J. No. L93, 4.4.2008, p.13).”;

- (c) in Schedule 3 (list of substances which must not form part of the composition of cosmetic products (unless otherwise specified)), the name of the substance in the second column in relation to reference number 1136 is replaced by the following—

“Exudation of *Myroxylon pereirae* (Royle) Klozsch (Peru balsam, crude), when used as a fragrance ingredient”; and

- (d) in Part 1 of Schedule 4 (list of substances which cosmetic products must not contain except subject to restrictions and conditions)—

- (i) the entry relating to reference number 68 is deleted;
- (ii) the entries relating to reference numbers 45, 72, 73, 88 and 89 are replaced by the corresponding entries in Part 1 of the Schedule to these Regulations; and
- (iii) after the entry relating to reference number 102, the entries relating to reference numbers 103 to 184, as set out in Part 2 of the Schedule to these Regulations, are added.

Gareth Thomas

Minister of State for Trade and Consumer Affairs
Department for Business, Enterprise & Regulatory Reform

30th September 2008

SCHEDULE

PART 1

Regulation 2(d)(ii)

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	
45	Benzyl alcohol (*) CAS No 100-51-6	<i>c</i>	<i>d</i>	<i>e</i>	<i>f</i>
		(a) Solvent			
72	Hydroxycitronellal CAS No 107-75-5	(b) fragrance/aromatic compositions/their raw materials		(b) The presence of the substance must be indicated in the list of ingredients referred to in regulation 12(2) when its concentration exceeds: — 0.001% in leave-on products — 0.01% in rinse-off products	
		(a) Oral products		(a) (b) The presence of the substance must be indicated in the list of ingredients referred to in regulation 12(2) when its concentration exceeds: — 0.001% in leave-on products	
		(b) Other products	(b) 1.0%		

					— 0.01% in rinse-off products	
73	Isoeugenol CAS No 97-54-1	(a) Oral products		(a) (b) The presence of the substance must be indicated in the list of ingredients referred to in regulation 12(2) when its concentration exceeds: — 0.001% in leave-on products — 0.01% in rinse-off products		
		(b) Other products	(b) 0.02%			
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 regulation 12(2) when its concentration exceeds: — 0.001% in leave-on products — 0.01% in rinse-off products Peroxide value less than 20 mmoles/L (**)		
89	Methyl 2-octynoate	(a) Oral products		(a) (b)		

CAS No 111-12-6 Methyl heptine carbonate	(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%)	The presence of the substance must be indicated in the list of ingredients referred to in regulation 12(2) when its concentration exceeds: — 0.001% in leave-on products — 0.01% in rinse-off products	
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(*) As a preservative, see Schedule 6, Part 1, No 34.

(**) This limit applies to the substance and not to the finished cosmetic product

PART 2

Regulation 2(d)(iii)

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
103	Abies alba cone oil and extract CAS No 90028-76-5			Peroxide value less than 10 mmoles/L (*)	
104	Abies alba needle oil and extract CAS No 90028-76-5			Peroxide value less than 10 mmoles/L (*)	
105	Abies pectinata needle			Peroxide value less than 10	

106	oil and extract CAS No 92128-34-2 Abies sibirica needle oil and extract CAS No 91697-89-1				mmoles/L (*) Peroxide value less than 10 mmoles/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				Peroxide value less than 10 mmoles/L (*)	

115	CAS No 97676-05-6 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-Trimethylbicyclo[4.1.0]hept-3-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				Peroxide value less than 10 mmoles/L (*)	

124	CAS No 84696-07-1 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 88, 167 and 168 of Part 1 of this Schedule CAS No 65996-98-7				Peroxide value less than 10 mmoles/L (*)	
130	Terpene terpenoids sinalbin 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				Peroxide value less than 10	

	CAS No 99-85-4 p-Mentha-1,4-diene				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 Cyclohexaneacetate				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- Cyclohexanepropanoa te				Level of free allyl alcohol in the ester should be less than 0.1%	
139	Allyl heptanoate CAS No 142-19-8				Level of free allyl alcohol in the ester should be less than 0.1%	

140	2-Propenyl heptanoate 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 2835-39-4 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 isoamylacetate 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 heptine 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 heptine carbonate)	
153	Amylcyclopentenone CAS No 25564-22-1 2-Pentylcyclopent-2-en-1-one		0.1%		
154	<i>Myroxylon balsamum</i> <i>var</i> <i>pereirae</i> . extracts and <i>distillates</i> CAS No 8007-00-9 Balsam Peru oil, absolute and anhydrol (Balsam Oil Peru)		0.4%		
155	4- <i>tert</i> -Butyldihydrocinnamaldehyde CAS No 18127-01-0 3-(4- <i>tert</i> -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	<i>cis</i> -Rose ketone-1 (**) CAS No 23726-94-5 (<i>Z</i>)-1-(2,6,6- Trimethyl- 2-cyclohexen-1-yl)-2- buten-1-one (<i>cis</i> - α -Damascone)	(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 -Damascone)	(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 (Isodamascone)		0.02%		
160	Rose ketone-4 (**) CAS No 23696-85-7 1-(2,6,6-	(a) Oral products			

	Trimethylcyclohexa-1,3-dien-1-yl)-2-buten-1-one (Damascone)	(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-Damascone)	(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 (cis-β-Damascone)	(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 (trans-α-Damascone)	(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		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 (trans-delta-Damascone)	(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 (S)- <i>p</i> -Mentha-1,8-diene			Peroxide value less than 20 mmoles/L (*)	
168	<i>dl</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 products	(b) 0.1%		
170	Isobergamate CAS No 68683-20-5 Menthadiene-7-methyl formate		0.1%		
171	Methoxy dicyclopentadiene carboxaldehyde		0.5%		

	CAS No 86803-90-9 Octahydro-5-methoxy-4,7-Methano-1H-indene-2-carboxaldehyde					
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 heptene 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	Amylvinylcarbonyl acetate CAS No 2442-10-6 1-Octen-3-yl acetate	(a) Oral products (b) Other products				
175	Propylideneephthalide	(a) Oral products				

	CAS No 17369-59-4 3-Propylidenephthalide	(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) 0.01 %	(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	<i>p</i> -methylhydrocinnamic aldehyde CAS No 5406-12-2 Cresylpropionaldehyde <i>p</i> -Methylidihydrocinnamaldehyde		0.2%		
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		0.6%		

182	(styrax) 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% 0.6%		
183	<i>Commiphora erythrea</i> engler var. <i>glabrescens</i> engler gum extract and oil CAS No 93686-00-1				
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.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Cosmetic Products (Safety) Regulations 2008 (S.I. 2008/1284) (“the Principal Regulations”) to give effect to Commission Directive 2008/42/EC (O.J. No. L93, 4.4.08, p.13) (“the Directive”). The Directive amends Council Directive 76/768/EEC (O.J. L262, 27.9.76, p.169) on the approximation of the laws of the Member States on cosmetic products (the Principal Directive). The Principal Directive has been implemented by the Principal Regulations.

The Directive amends the Principal Directive by inserting an entry into Annex II relating to Exudation of *Myroxylon pereirae* and inserting, amending or deleting entries in Annex III. These entries relate to substances used as fragrance compounds in cosmetic products. Paragraphs (b) and (c) of regulation 2 amend Schedules 3 and 4 of the Principal Regulations accordingly. Paragraph (a) of Regulation 2 provides that products in entries 72, 73, 88 and 89 in Part 1 of Schedule 4 to the Principal Regulations which fail to comply with the restrictions in those entries, as amended, may not be placed on the market after 3rd April 2009 by EEA manufacturers or importers established in the EEA, and may not be sold or otherwise disposed of to a final consumer after 4th October 2009.

A regulatory impact assessment of the effect that these Regulations will have on costs to businesses is available from the Consumer and Competition Policy Directorate of the Department for Business, Enterprise and Regulatory Reform, 1 Victoria Street, London SW1H 0ET and on the BERR website (www.berr.gov.uk). Copies of a transposition note relating to these Regulations have been placed in the libraries of both Houses of Parliament. Copies are also available to the public from the Consumer and Competition Policy Directorate of the Department for Business, Enterprise and Regulatory Reform, 1 Victoria Street, London SW1H 0ET.

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STATUTORY INSTRUMENTS

2008 No. 2566

CONSUMER PROTECTION

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

£5.00