
STATUTORY INSTRUMENTS

2008 No. 2566

CONSUMER PROTECTION

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

Made - - - - *30th September 2008*
Laid before Parliament *2nd October 2008*
Coming into force - - *4th April 2009*

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 11 of the Consumer Protection Act 1987⁽¹⁾.

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⁽²⁾.

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,

(1) 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.

(2) S.I. 2008/1284, as amended by SI 2008/2173.

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—

“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

Regulation 2(d)(ii)

PART 1

<i>Reference number</i>	<i>Substance</i>	<i>Restrictions Field of application and/or use</i>	<i>Maximum authorised concentration in the finished cosmetic product</i>	<i>Other limitations and requirements</i>	<i>Conditions of use and warnings which must be printed on the label</i>
<i>a</i>	<i>b</i>	<i>c</i>	<i>d</i>	<i>e</i>	<i>f</i>
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 regulation 12(2) 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	

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				ingredients referred to in regulation 12(2) when its concentration exceeds: — 0.001% in leave-on products — 0.01% in rinse-off products
73	Isoeugenol 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 regulation 12(2) when its concentration exceeds: — 0.001% in leave-on products — 0.01% in rinse-off 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

				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	(b) Other products	(b) 0.01% when used alone	The presence of the substance
	Methyl heptine carbonate		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%)	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

(*) As a preservative, see Schedule 6, Part 1, No 34.

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

Regulation 2(d)(iii)

PART 2

<i>Reference number</i>	<i>Substance</i>	<i>Restrictions Field of application and/or use</i>	<i>Maximum authorised concentration in the finished cosmetic product</i>	<i>Other limitations and requirements</i>	<i>Conditions of use and warnings which must be printed on the label</i>
a	b	c	d	e	f
103	Abies alba cone oil and extract			Peroxide value less than 10 mmoles/L (*)	
	CAS No 90028-76-5				
104	Abies alba needle oil and extract			Peroxide value less than 10 mmoles/L (*)	
	CAS No 90028-76-5				
105	Abies pectinata needle oil and extract			Peroxide value less than 10 mmoles/L (*)	
	CAS No 92128-34-2				
106	Abies sibirica needle oil and extract			Peroxide value less than 10 mmoles/L (*)	
	CAS No 91697-89-1				
107	Abies balsamea needle oil and extract			Peroxide value less than 10 mmoles/L (*)	
	CAS No 85085-34-3				

108	Pinus mugo pumilio leaf and twig oil and extract	Peroxide value less than 10 mmoles/L (*)
	CAS No 90082-73-8	
109	Pinus mugo leaf and twig oil and extract	Peroxide value less than 10 mmoles/L (*)
	CAS No 90082-72-7	
110	Pinus sylvestris leaf and twig oil and extract	Peroxide value less than 10 mmoles/L (*)
	CAS No 84012-35-1	
111	Pinus nigra leaf and twig oil and extract	Peroxide value less than 10 mmoles/L (*)
	CAS No 90082-74-9	
112	Pinus palustris leaf and twig oil and extract	Peroxide value less than 10 mmoles/L (*)
	CAS No 97435-14-8	
113	Pinus pinaster leaf and twig oil and extract	Peroxide value less than 10 mmoles/L (*)
	CAS No 90082-75-0	
114	Pinus pumila leaf and twig oil and extract	Peroxide value less than 10 mmoles/L (*)
	CAS No 97676-05-6	
115	Pinus species leaf and twig oil and extract	Peroxide value less than 10 mmoles/L (*)

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116	CAS No 94266-48-5 Pinus cembra leaf and twig oil and extract	Peroxide value less than 10 mmoles/L (*)
117	CAS No 92202-04-5 Pinus cembra leaf and twig extract acetylated	Peroxide value less than 10 mmoles/L (*)
118	CAS No 94334-26-6 Picea Mariana Leaf Oil and Extract	Peroxide value less than 10 mmoles/L (*)
119	CAS No 91722-19-9 Thuja Occidentalis Leaf Oil and Extract	Peroxide value less than 10 mmoles/L (*)
120	CAS No 90131-58-1 Thuja Occidentalis Stem Oil	Peroxide value less than 10 mmoles/L (*)
121	CAS No 90131-58-1 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	Peroxide value less than 10 mmoles/L (*)
	CAS No 92201-55-3	
123	Cupressus sempervirens leaf oil and extract	Peroxide value less than 10 mmoles/L (*)
	CAS No 84696-07-1	
124	Turpentine gum (<i>Pinus</i> spp.)	Peroxide value less than 10 mmoles/L (*)
	CAS No 9005-90-7	
125	Turpentine oil and rectified oil	Peroxide value less than 10 mmoles/L (*)
	CAS No 8006-64-2	
126	Turpentine, steam distilled (<i>Pinus</i> spp.)	Peroxide value less than 10 mmoles/L (*)
	CAS No 8006-64-2	
127	Terpene alcohols acetates	Peroxide value less than 10 mmoles/L (*)
	CAS No 69103-01-1	
128	Terpene hydrocarbons	Peroxide value less than 10 mmoles/L (*)
	CAS No 68956-56-9	
129	Terpenes and terpenoids with the exception of limonene	Peroxide value less than 10 mmoles/L (*)

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	(d-, l-, and dl-isomers) listed under reference numbers 88, 167 and 168 of Part 1 of this Schedule		
	CAS No 65996-98-7		
130	Terpene terpenoids sinpine		Peroxide value less than 10 mmoles/L (*)
	CAS No 68917-63-5		
131	α -Terpinene		Peroxide value less than 10 mmoles/L (*)
	CAS No 99-86-5		
	p-Mentha-1,3-diene		
132	γ -Terpinene		Peroxide value less than 10 mmoles/L (*)
	CAS No 99-85-4		
	p-Mentha-1,4-diene		
133	Terpinolene		Peroxide value less than 10 mmoles/L (*)
	CAS No 586-62-9		
	p-Mentha-1,4(8)-diene		
134	Acetyl hexamethyl indan	(a) Leave-on products (b) Rinse-off products	(a) 2%
	CAS No 15323-35-0		
	1,1,2,3,3,6-Hexamethylindan-5-yl methyl ketone		

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- Cyclohexanepropanoate	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	Level of free allyl alcohol

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	CAS No 2835-39-4	in the ester should be less than 0.1%
	2-Propenyl 3- Methylbutanoate	
142	Allyl octanoate	Level of free allyl alcohol in the ester should be less than 0.1%
	CAS No 4230-97-1	
	2-Allyl caprylate	
143	Allyl phenoxyacetate	Level of free allyl alcohol in the ester should be less than 0.1%
	CAS No 7493-74-5	
	2-Propenyl Phenoxyacetate	
144	Allyl phenylacetate	Level of free allyl alcohol in the ester should be less than 0.1%
	CAS No 1797-74-6	
	2-Propenyl Benzeneacetate	
145	Allyl 3,5,5- trimethylhexanoate	Level of free allyl alcohol in the ester should be less than 0.1%
	CAS No 71500-37-3	
146	Allyl cyclohexyloxyacetate	Level of free allyl alcohol in the ester should be less than 0.1%
	CAS No 68901-15-5	
147	Allyl isoamyloxyacetate	Level of free allyl alcohol in the ester should be less than 0.1%
	CAS No 67634-00-8	
148	Allyl 2- methylbutoxyacetate	Level of free allyl alcohol in the ester should be less than 0.1%
	CAS No 67634-01-9	

149	Allyl nonanoate		Level of free allyl alcohol in the ester should be less than 0.1%
	CAS No 7493-72-3		
150	Allyl propionate		Level of free allyl alcohol in the ester should be less than 0.1%
	CAS No 2408-20-0		
151	Allyl trimethylhexanoate		Level of free allyl alcohol in the ester should be less than 0.1%
	CAS No 68132-80-9		
152	Allyl heptine carbonate	0.002%	This material should not be used in
	CAS No 73157-43-4		
	(allyl oct-2- ynoate)		combination with any other 2-alkynoic acid ester (e.g methyl heptine carbonate)
153	Amylcyclopentenone	0.1%	
	CAS No 25564-22-1		
	2- Pentylcyclopent-2- en-1-one		
154	<i>Myroxylon</i> <i>balsamum var</i>	0.4%	
	<i>pereirae.</i> extracts and <i>distillates</i>		
	CAS No 8007-00-9		
	Balsam Peru oil, absolute and anhydrol		

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	(Balsam Oil Peru)		
155	4- <i>tert.</i> - Butyldihydrocinnamaldehyde		0.6%
	CAS No 18127-01-0		
	3-(4- <i>tert.</i> - Butylphenyl)propionaldehyde		
156	Cuminum cuminum fruit oil and extract	(a) Leave-on products (b) Rinse-off products	(a) 0.4% of Cumin oil
	CAS No 84775-51-9		
157	<i>cis</i> -Rose ketone-1 (**)	(a) Oral products (b) Other products	(b) 0.02%
	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)		
158	<i>trans</i> -Rose ketone-2 (**)	(a) Oral products (b) Other products	(b) 0.02%
	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)		

159	<i>trans</i> -Rose ketone-5 (**)		0.02%
	CAS No 39872-57-6		
	(<i>E</i>)-1-(2,4,4-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one		
	(Isodamascone)		
160	Rose ketone-4 (**)	(a) Oral products	
	CAS No 23696-85-7	(b) Other products	(b) 0.02%
	1-(2,6,6-Trimethylcyclohexa-1,3-dien-1-yl)-2-buten-1-one		
	(Damascenone)		
161	Rose ketone-3 (**)	(a) Oral products	
	CAS No 57378-68-4	(b) Other products	(b) 0.02%
	1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one		
	(Delta-Damascone)		
162	<i>cis</i> -Rose ketone-2 (**)	(a) Oral products	
	CAS No 23726-92-3	(b) Other products	(b) 0.02%

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	1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one (cis- β -Damascone)		
163	<i>trans</i> -Rose ketone-1 (**)	(a) Oral products	
	CAS No 24720-09-0	(b) Other products	(b) 0.02%
	1-(2,6,6-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one (trans- α -Damascone)		
164	Rose ketone-5 (**)		0.02%
	CAS No 33673-71-1		
	1-(2,4,4-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one		
165	<i>trans</i> -Rose ketone-3 (**)	(a) Oral products	
	CAS No 71048-82-3	(b) Other products	(b) 0.02%
	1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-		

	buten-1-one			
	(trans-delta-Damascone)			
166	<i>trans</i> -2-hexenal	(a) Oral products		
	CAS No 6728-26-3	(b) Other products	(b) 0.002%	
167	<i>l</i> -Limonene			Peroxide value less than
	CAS No 5989-54-8			20 mmols/L (*)
	(S)- <i>p</i> -Mentha-1,8-diene			
168	<i>dl</i> -Limonene (racemic)			Peroxide value less than
	CAS No 138-86-3			20 mmols/L (*)
	1,8(9)- <i>p</i> -Menthadiene;			
	<i>p</i> -Mentha-1,8-diene			
	(Dipentene)			
169	Perillaldehyde	(a) Oral products		
	CAS No 2111-75-3	(b) Other products	(b) 0.1%	
	<i>p</i> -Mentha-1,8-dien-7-al			
170	Isobergamate		0.1%	
	CAS No 68683-20-5			
	Menthadiene-7-methyl formate			
171	Methoxy dicyclopentadiene		0.5%	
	carboxaldehyde			

Status: This is the original version (as it was originally made).

	CAS No 86803-90-9		
	Octahydro-5- methoxy-		
	4,7- Methano-1H- indene-		
	2- carboxaldehyde		
172	3- methylnon-2- enenitrile		0.2%
	CAS No 53153-66-5		
173	Methyl octine carbonate	(a) Oral products	
	CAS No 111-80-8	(b) Other products	(b) 0.002% when used alone
	Methyl non-2- ynoate		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	(a) Oral products	(b) 0.3%
	CAS No 2442-10-6	(b) Other products	
	1-Octen-3-yl acetate		
175	Propylidene phthalide	(a) Oral products	(b) 0.01%
	CAS No 17369-59-4	(b) Other products	
	3-Propylidene phthalide		
176	Isocyclogeraniol		0.5%
	CAS No 68527-77-5		
	2,4,6-Trimethyl-3-cyclohexene-1-methanol		
177	2-Hexylidene cyclopentanone	(a) Oral products	(b) 0.06%
	CAS No 17373-89-6	(b) 0.01 %	
178	Methyl heptadienone	(a) Oral products	(b) 0.002%
	CAS No 1604-28-0	(b) Other products	
	6-Methyl-3,5-heptadien-2-one		
179	p-methylhydrocinnamic aldehyde		0.2%
	CAS No 5406-12-2		
	Cresylpropionaldehyde		

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180	<i>p</i> - Methyldihydrocinnamaldehyde		
	Liquidambar orientalis		0.6%
	Balsam oil and extract		
	CAS No 94891-27-7		
181	(styrax) Liquidambar styraciflua		0.6%
	balsam oil and extract		
	CAS No 8046-19-3		
182	(styrax) Acetyl hexamethyl tetralin	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%
	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)		
			(b) rinse-off products: 0.2%
183	<i>Commiphora erythrea</i>		0.6%

	engler var. <i>glabrescens</i> engler gum extract and oil	
	CAS No 93686-00-1	
184	Opopanax chironium resin	0.6%
	CAS No 93384-32-8	

(*) 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.