



STATUTORY INSTRUMENTS

S.I. No. 370 of 2008

EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)
(AMENDMENT) (No. 2) REGULATIONS 2008

(Prn. A8/1455)

EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)
(AMENDMENT) (No. 2) REGULATIONS 2008

I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972), and for the purpose of giving effect to Commission Directive 2008/14/EC¹ of 15 February 2008 and Commission Directive 2008/42/EC² of 3 April 2008, hereby make the following regulations:

1. These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) (No. 2) Regulations 2008.

2. The collective citation “the European Communities (Cosmetic Products) Regulations 2004 to 2008” includes these Regulations.

3. (1) In these Regulations, “Principal Regulations” mean the European Communities (Cosmetic Products) Regulations 2004 (S.I. No. 870 of 2004), as amended.

(2) (a) A reference in these Regulations to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other Regulations is intended.

(b) A reference in these Regulations to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

(c) A reference in these Regulations to a Schedule is to a Schedule to these Regulations, unless it is indicated that reference to some other Regulations is intended.

4. Subject to Regulations 6 and 7, Regulation 4(1) of the Principal Regulations is amended by the addition to the definition of “Directive” of references to the following Commission Directives:

“2008/14/EC and 2008/42/EC”.

5. Subject to Regulations 6 and 7, the Schedules to the Principal Regulations are amended in the manner set out in the Schedules to these Regulations.

6. (1) Subject to paragraph (2), the provisions of these Regulations, insofar as such provisions relate to Commission Directive 2008/14/EC and the requirements of Schedule 1, shall come into operation on 16 November 2008.

¹OJ L 42, 16.2.2008, p. 43.

²OJ L 93, 4.4.2008, p. 13.

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 23rd September, 2008.*

(2) Insofar as cosmetic products fail to comply with the provisions and requirements referred to in paragraph (1), the prohibition on sales and disposals to the final consumer shall not come into operation until 16 February 2009.

7. (1) Subject to paragraph (2), the provisions of these Regulations, insofar as such provisions relate to Commission Directive 2008/42/EC and the requirements of Schedule 2, shall come into operation on 4 April 2009.

(2) Insofar as cosmetic products fail to comply with the provisions and requirements referred to in paragraph (1), the prohibition on sales and disposals to the final consumer shall not come into operation until 4 October 2009.

8. The European Communities (Cosmetic Products) (Amendment) Regulations 2008 (S.I. No. 6 of 2008) are amended by substituting for Regulation 2 the following Regulation:

“2. These Regulations shall be construed as one with the European Communities (Cosmetic Products) Regulations 2004 to 2007 and may be cited together with those Regulations as the European Communities (Cosmetic Products) Regulations 2004 to 2008.”

9. The European Communities (Cosmetic Products) (Amendment) Regulations 2008 are amended in Regulation 10 by substituting “March” for “January”.

SCHEDULE 1

In Part 1 of Schedule 3 to the Principal Regulations, the following entry for glyoxal is added:

Reference No	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		100mg/kg'		

SCHEDULE 2

1. In Schedule 2, substance reference number 1136 is replaced by the following:

‘Exudation of *Myroxylon pereirae* (Royle) Klotzch (Peru balsam, crude); (CAS No 8007-00-9) when used as fragrance ingredient’.

2. Part 1 of schedule 3 is amended as follows:

(a) reference number 68 is deleted;

(b) reference numbers 45, 72, 73, 88 and 89 are replaced by the following:

Reference No	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	Hydroxy citronellal 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	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	

Reference No	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
				ingredients referred to in Article 6(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> — 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 Article 6(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> — 0,001 % in leave-on products — 0,01 % in rinse-off products Peroxide value less than 20 mmoles/L (**) (**)	

Reference No	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
89	Methyl 2-octynoate CAS No 111-12-6 Methyl heptine carbonate	(a) Oral products (b) Other products	(b) 0,01 % when used alone When present in combination with methyl octane carbonate, the combined level in the finished product should not exceed 0,01 % (of which methyl octane 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 Schedule 6, Part 1, No 34.					
(**) This limit applies to the substance and not to the finished cosmetic product.*					

(c) the following reference numbers 103 to 184 are added:

Reference No	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 (*)	

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

Reference No	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
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-3-ene (Isodiprene)			Peroxide value less than 10 mmoles/L (*)	

Reference No	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
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 Schedule 3, Part 1 CAS No 65996-98-7			Peroxide value less than 10 mmoles/L (*)	
130	Terpene terpenoids sinpine CAS No 68917-63-5			Peroxide value less than 10 mmoles/L (*)	

Reference No	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
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 cyclohexyl acetate CAS No 4728-82-9 2-Propenyl Cyclohexyl acetate			Level of free allyl alcohol in the ester should be less than 0,1 %	

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		Field of Application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
138	Allyl cyclohexyl propionate CAS No 2705-87-5 2-Propenyl 3-Cyclohexane propanoate			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 2835-39-4 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 %	

Reference No	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
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	Allylcyclohexyloxyacetate CAS No 68901-15-5			Level of free allyl alcohol in the ester should be less than 0,1 %	
147	Allyl isoamyloxyacetate 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 %	

Reference No	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
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 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.-Butyldihydrocinna maldehyde CAS No 18127-01-0 3-(4-tert-Butylphenyl) propionaldehyde		0,6 %		

Reference No	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
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 %		

Reference No	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
160	Rose ketone-4 (**) CAS No 23696-85-7 1-(2,6,6-Trimethylcyclohexa-1,3-dien-1-yl)-2-buten-1-one (Damascenone)	(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-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-Trimethylcyclohexen-1-yl)-2-buten-1-one (<i>cis</i> - β -Damascone)	(a) Oral products (b) Other products	(b) 0,02 %		

Reference No	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
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 -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 (<i>trans</i> - δ -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 %		

Reference No	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
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>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 %		

Reference No	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
171	Methoxy dicyclopentadiene carboxaldehyde CAS No 86803-90-9 Octahydro-5-methoxy-4,7-Methano-1H-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 %)		

Reference No	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
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-Propylidene phthalide	(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-methylhydrocinnamic aldehyde CAS No 5406-12-2 Cresylpropionaldehyde p-Methyldihydrocinnamaldehyde		0,2 %		

Reference No	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
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.					



GIVEN under my Official Seal
18 September 2008

MARY HARNEY
Minister for Health and Children.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation).

These Regulations further amend the European Communities (Cosmetic Products) Regulations 2004, as amended.

The purpose of these Regulations is to update the law in relation to the manufacture, marketing and sale of cosmetic products by the implementation of Commission Directive 2008/14/EC³ and Commission Directive 2008/42/EC⁴ with a view to improving the safety of those products.

These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) (No. 2) Regulations 2008.

³OJ L 42, 16.2.2008, p. 43.

⁴OJ L 93, 4.4.2008, p. 13.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
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TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
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