

Draft

COMMISSION DIRECTIVE ../.../EC

of [...]

amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and III thereto to technical progress

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products¹, and in particular Article 8(2) thereof,

Whereas:

- (1) On the basis of the IFRA (International Fragrance Association) Code of Practice, the Scientific Committee on Consumer Products (SCCP)², identified substances used as fragrance compounds in cosmetic products for which some restrictions should be provided.
- (2) Considering that whatever the function of these substances in cosmetic products is, it is the exposure to these substances which should be considered. Therefore the restrictions should not be limited to the use of the identified substances as fragrance compounds in cosmetic products.
- (3) However, sensitisation would not exist when the substance is used in oral products. Therefore, in order to ensure consistency, as some of these substances are authorised as flavouring substances by Commission Decision No 1999/217/EC of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996³, these restrictions should not apply to substances listed under this register.
- (4) In the light of the opinions of the SCCP, it is necessary to amend the restrictions related to the identified substances which are already listed in Annex III to Directive 76/768/EEC under entries 45, 72, 73, 88 and 89. Furthermore it is appropriate to

¹ OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive [reference should be introduced at the time of publication].

² OJ L 66, 04.03.2004, p. 45. Decision as amended by Decision 2007/263/EC (OJ L 114, 1.5.2007, p. 14).

³ OJ L 84, 27.03.1999, p. 1. Decision as last amended by Decision 2006/252/EC (OJ L 91, 29.3.2006, p. 48).

include in that Annex those identified substances which are not yet listed with their respective restrictions, as well as, for consistency, substances belonging to the same family identified in Commission Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products⁴.

- (5) Benzyl alcohol being listed twice in Annex III part 1, under reference numbers 45 and 68, the content of entry 68 as well as the new restrictions should be included in entry 45.
- (6) Following clarification by the SCCP regarding Peru balsam, entry 1136 of Annex II should be amended.
- (7) Directive 76/768/EEC should therefore be amended accordingly.
- (8) In order to ensure a smooth progression from the existing formulae of cosmetic products to formulae which comply with the requirements laid down in this Directive, it is necessary to provide for appropriate transitional periods.
- (9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II and III of Directive 76/768/EEC are amended in accordance with the Annex to this Directive.

Article 2

Member States shall take all necessary measures to ensure that products which fail to comply with this Directive are not sold or disposed of to the final consumer after [Day, Month, Year = 18 months after the publication of the Directive⁵].

Article 3

1. Member States shall adopt and publish, by [Day, Month, Year = Six months after the publication of the Directive⁶] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

⁴ OJ L 132, 1.06.1996, p.1. Decision as amended by Commission Decision 2006/257/EC (OJ L 97, 5.4.2006, p. 1).

⁵ Date to be included.

⁶ Date to be included.

They shall apply those provisions from [Day, Month, Year = twelve months after the publication of the Directive⁷].

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 4

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, [...]

For the Commission

[...]

Member of the Commission

⁷ Date to be included.

ANNEX

Directive 76/768/EEC is amended as follows:

- (1) In Annex II, 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 Annex III 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 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 ⁽⁸⁾ 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 it is used as perfume and aromatic compositions and when its concentration	

⁸ As a preservative, see Annex VI, Part 1, No 34.

				<p>exceeds:</p> <ul style="list-style-type: none"> – 0.001% in leave-on products – 0.01% in rinse-off products 	
72	<p>Hydroxycitronellal</p> <p>CAS no 107-75-5</p>	<p>a) Oral products</p> <p>b) Other products</p>	b) 1.0%	<p>a) b)</p> <p>The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g):</p> <ul style="list-style-type: none"> – when it is used as perfume and aromatic compositions and when its concentration exceeds: – 0.001% in leave-on products – 0.01% in rinse-off products 	
73	<p>Isoeugenol</p> <p>CAS no 97-54-1</p>	<p>a) Oral products</p> <p>b) Other products</p>	b) 0.02%	<p>a) b)</p> <p>The presence of the substance must be indicated in the list of</p>	

				<p>ingredients referred to in Article 6(1)(g):</p> <ul style="list-style-type: none"> – when it is used as perfume and aromatic compositions and 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			<p>The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g):</p> <ul style="list-style-type: none"> – when it is used as perfume and aromatic compositions and when its concentration exceeds: – 0.001% in leave-on 	

				products – 0.01% in rinse-off products Peroxide value less than 20 mmoles/L ¹¹	
89	Methyl oct-2-ynoate 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 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 it is used as perfume and aromatic compositi ons and when its concentrat ion exceeds: – 0.001% in leave-on products – 0.01% in rinse-off products”	

(c) The following reference numbers X⁹ to Y¹⁰ are added:

Reference	Substance	Restrictions	Conditio
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⁹ Number to be added at the time of publication

¹⁰ Number to be added at the time of publication

number		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	ns of use and warnings which must be printed on the label
a	b	C	d	e	f
“X	Abies Alba Cone Oil and Extract CAS no 90028-76-5			Peroxide value less than 10 mmoles/L ¹¹	
	Abies Alba Needle Oil and Extract CAS no 90028-76-5			Peroxide value less than 10 mmoles/L ¹¹	
	Abies Pectinata Needle Oil and Extract CAS no 92128-34-2			Peroxide value less than 10 mmoles/L ¹¹	
	Abies Sibirica Needle Oil and Extract CAS no 91697-89-1			Peroxide value less than 10 mmoles/L ¹¹	
	Abies Balsamea Needle Oil and Extract CAS no 85085-34-3			Peroxide value less than 10 mmoles/L ¹¹	
	Pinus Mugo Pumilio Leaf and Twig Oil and Extract CAS no 90082-73-8			Peroxide value less than 10 mmoles/L ¹¹	
	Pinus Mugo Leaf and Twig Oil and Extract CAS no 90082-72-7			Peroxide value less than 10 mmoles/L ¹¹	

¹¹ This limit applies to the substance and not to the finished cosmetic product.

	Pinus Sylvestris Leaf and Twig Oil and Extract CAS no 84012-35-1			Peroxide value less than 10 mmoles/L ¹¹	
	Pinus Nigra Leaf and Twig Oil and Extract CAS no 90082-74-9			Peroxide value less than 10 mmoles/L ¹¹	
	Pinus Palustris Leaf and Twig Oil and Extract CAS no 97435-14-8			Peroxide value less than 10 mmoles/L ¹¹	
	Pinus Pinaster Leaf and Twig Oil and Extract CAS no 90082-75-0			Peroxide value less than 10 mmoles/L ¹¹	
	Pinus Pumila Leaf and Twig Oil and Extract CAS no 97676-05-6			Peroxide value less than 10 mmoles/L ¹¹	
	Pinus Species Leaf and Twig Oil and Extract CAS no 94266-48-5			Peroxide value less than 10 mmoles/L ¹¹	
	Pinus Cembra Leaf and Twig Oil and Extract CAS no 92202-04-5			Peroxide value less than 10 mmoles/L ¹¹	
	Pinus Cembra Leaf and Twig Extract Acetylated CAS no 94334-26-6			Peroxide value less than 10 mmoles/L ¹¹	
	Picea Mariana Leaf Oil and Extract			Peroxide value less than 10 mmoles/L ¹¹	

	CAS no 91722-19-9				
	Thuja Occidentalis Leaf Oil and Extract CAS no 90131-58-1				Peroxide value less than 10 mmoles/L ¹¹
	Thuja Occidentalis Stem Oil CAS no 90131-58-1				Peroxide value less than 10 mmoles/L ¹¹
	3-Carene CAS no 13466-78-9 3,7,7- Trimethylbicyclo[4.1.0]h ept-3-ene (isodiprene)				Peroxide value less than 10 mmoles/L ¹¹
	Cedrus Atlantica Wood Oil and Extract CAS no 92201-55-3				Peroxide value less than 10 mmoles/L ¹¹
	Cupressus Sempervirens Leaf Oil and Extract CAS no 84696-07-1				Peroxide value less than 10 mmoles/L ¹¹
	Turpentine gum (<i>Pinus</i> spp.) CAS no 9005-90-7				Peroxide value less than 10 mmoles/L ¹¹
	Turpentine Oil and rectified oil CAS no 8006-64-2				Peroxide value less than 10 mmoles/L ¹¹
	Turpentine, steam distilled (<i>Pinus</i> spp.) CAS no 8006-64-2				Peroxide value less than 10 mmoles/L ¹¹
	Terpene alcohols acetates				Peroxide value less

	CAS no 69103-01-1			than 10 mmoles/L ¹¹	
	Terpene hydrocarbons CAS no 68956-56-9			Peroxide value less than 10 mmoles/L ¹¹	
	Terpenes and Terpenoids with the exception of limonene (d-, l-, and dl-isomers) listed under reference numbers a ¹² , b ¹³ and 88 of this Annex III, part 1 CAS no 65996-98-7			Peroxide value less than 10 mmoles/L ¹¹	
	Terpene Terpenoids Sinpine CAS no 68917-63-5			Peroxide value less than 10 mmoles/L ¹¹	
	•-Terpinene CAS no 99-86-5 p-Mentha-1,3-diene			Peroxide value less than 10 mmoles/L ¹¹	
	•-Terpinene CAS no 99-85-4 p-Mentha-1,4-diene			Peroxide value less than 10 mmoles/L ¹¹	
	Terpinolene CAS no 586-62-9 p-Mentha-1,4(8)-diene			Peroxide value less than 10 mmoles/L ¹¹	
	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%		

¹² Cross reference to be specified when number attributed for a and b below.

¹³ Cross reference to be specified when number attributed for a and b below.

	<p>Allyl butyrate</p> <p>CAS no 2051-78-7</p> <p>2-Propenyl Butanoate</p>			<p>Level of free allyl alcohol in the ester should be less than 0.1%</p>	
	<p>Allyl cinnamate</p> <p>CAS no 1866-31-5</p> <p>2-Propenyl 3-Phenyl-2-propenoate</p>			<p>Level of free allyl alcohol in the ester should be less than 0.1%.</p>	
	<p>Allyl cyclohexylacetate</p> <p>CAS no 4728-82-9</p> <p>2-Propenyl Cyclohexaneacetate</p>			<p>Level of free allyl alcohol in the ester should be less than 0.1%.</p>	
	<p>Allyl cyclohexylpropionate</p> <p>CAS no 2705-87-5</p> <p>2-Propenyl 3-Cyclohexanepropanoate</p>			<p>Level of free allyl alcohol in the ester should be less than 0.1%.</p>	
	<p>Allyl heptanoate</p> <p>CAS no 142-19-8</p> <p>2-Propenyl Heptanoate</p>			<p>Level of free allyl alcohol in the ester should be less than 0.1%.</p>	
	<p>Allyl caproate</p> <p>CAS no 123-68-2</p> <p>Allyl hexanoate</p>			<p>Level of free allyl alcohol in the ester should be less than 0.1%.</p>	
	<p>Allyl isovalerate</p> <p>CAS no 2835-39-4</p> <p>2-Propenyl 3-Methyl-</p>			<p>Level of free allyl alcohol in the ester should be less than 0.1%.</p>	

	butanoate				
	Allyl octanoate CAS no 4230-97-1 2-Allyl Caprylate			Level of free allyl alcohol in the ester should be less than 0.1%.	
	Allyl phenoxyacetate CAS no 7493-74-5 2-Propenyl Phenoxyacetate			Level of free allyl alcohol in the ester should be less than 0.1%.	
	Allyl phenylacetate CAS no 1797-74-6 2-Propenyl Benzeneacetate			Level of free allyl alcohol in the ester should be less than 0.1%.	
	Allyl 3,5,5-trimethylhexanoate CAS no 71500-37-3			Level of free allyl alcohol in the ester should be less than 0.1%.	
	Allyl cyclohexyloxyacetate CAS no 68901-15-5			Level of free allyl alcohol in the ester should be less than 0.1%	
	Allyl isoamyloxyacetate CAS no 67634-00-8			Level of free allyl alcohol in the ester should be less than 0.1%	
	Allyl 2-methylbutoxyacetate CAS no 67634-01-9			Level of free allyl alcohol in the ester should be less than 0.1%	
	Allyl nonanoate			Level of free allyl alcohol	

	CAS no 7493-72-3			in the ester should be less than 0.1%	
	Allyl propionate CAS no 2408-20-0			Level of free allyl alcohol in the ester should be less than 0.1%	
	Allyl trimethylhexanoate CAS no 68132-80-9			Level of free allyl alcohol in the ester should be less than 0.1%	
	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)	
	Amylcyclopentenone CAS no 25564-22-1 2-Pentylcyclopent-2-en-1-one		0.1%		
	<i>Myroxylon balsamum</i> var. <i>pereirae</i> extracts and distillates CAS no 8007-00-9 Balsam Peru oil, absolute and anhydrol (Balsam Oil Peru)		0.4%		
	4-tert.- Butyldihydrocinnamaldehyde CAS no 18127-01-0		0.6%		

	3-(4- <i>tert</i> -Butylphenyl)propion-aldehyde				
	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		
	<i>cis</i> -Rose ketone-1 ⁽¹⁴⁾ CAS no 23726-94-5 (<i>Z</i>)-1-(2,6,6-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one (<i>cis</i> -•-Damascone)	a) Oral products b) Other products	b) 0.02%		
	<i>trans</i> -Rose ketone-2 ⁽¹⁴⁾ CAS no 23726-91-2 (<i>E</i>)-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one (<i>trans</i> -•-Damascone)	a) Oral products b) Other products	b) 0.02%		
	<i>trans</i> -Rose ketone-5 ⁽¹⁴⁾ CAS no 39872-57-6 (<i>E</i>)-1-(2,4,4-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one		0.02%		

¹⁴ The sum of those substances used in combination should not exceed the limits given in column d.

	(Isodamascone)				
	Rose ketone-4 ⁽¹⁴⁾ 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%		
	Rose ketone-3 ⁽¹⁴⁾ 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%		
	<i>cis</i> -Rose ketone-2 ⁽¹⁴⁾ CAS no 23726-92-3 1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one (<i>cis</i> -•-Damascone)	a) Oral products b) Other products	b) 0.02%		
	<i>trans</i> -Rose ketone-1 ⁽¹⁴⁾ CAS no 24720-09-0 1-(2,6,6-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one (<i>trans</i> -•-Damascone)	a) Oral products b) Other products	b) 0.02%		

	Rose ketone-5 ⁽¹⁴⁾ CAS no 33673-71-1 1-(2,4,4-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one		0.02%		
	<i>trans</i> -Rose ketone-3 ⁽¹⁴⁾ CAS no 71048-82-3 1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one (<i>trans</i> -delta-Damascone)	a) Oral products b) Other products	b) 0.02%		
	<i>trans</i> -2-hexenal CAS no 6728-26-3	a) Oral products b) Other products	b) 0.002%		
a ¹⁵	<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 ¹¹	
b ¹⁶	<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 ¹¹	

¹⁵ When mention of the reference number, specify the cross reference above under “Terpenes and Terpenoids”

¹⁶ When mention of the reference number, specify the cross reference above under “Terpenes and Terpenoids”

	<p>Perillaldehyde</p> <p>CAS no 2111-75-3</p> <p>p-Mentha-1,8-dien-7-al</p>	<p>a) Oral products</p> <p>b) Other products</p>	<p>b) 0.1%</p>		
	<p>Isobergamate</p> <p>CAS no 68683-20-5</p> <p>Menthadiene-7-methyl formate</p>		<p>0.1%</p>		
	<p>Methoxy dicyclopentadiene carboxaldehyde</p> <p>CAS no 86803-90-9</p> <p>Octahydro-5-methoxy-4,7-Methano-1H-indene-2-carboxaldehyde</p>		<p>0.5%</p>		
	<p>3-methylnon-2-enenitrile</p> <p>CAS no 53153-66-5</p>		<p>0.2%</p>		
	<p>Methyl octine carbonate</p> <p>CAS no 111-80-8</p> <p>Methyl non-2-ynoate</p>	<p>a) Oral products</p> <p>b) Other products</p>	<p>b) 0.002% when used alone</p> <p>When present in combination with methyl heptine carbonate, the combined level in the finished product should not</p>		

			exceed 0.01% (of which methyl octine carbonate should not be more than 0.002%)		
	<p>Amylvinylcarbinyl acetate</p> <p>CAS no 2442-10-6</p> <p>1-Octen-3-yl acetate</p>	<p>a) Oral products</p> <p>b) Other products</p>	<p>b) 0.3%</p>		
	<p>Propylidenephthalide</p> <p>CAS no 17369-59-4</p> <p>3-Propylidenephthalide</p>	<p>a) Oral products</p> <p>b) Other products</p>	<p>b) 0.01%</p>		
	<p>Isocyclogeraniol</p> <p>CAS no 68527-77-5</p> <p>2,4,6-Trimethyl-3-cyclohexene-1-methanol</p>		<p>0.5%</p>		
	<p>2-Hexylidene cyclopentanone</p> <p>CAS no 17373-89-6</p>	<p>a) Oral products</p> <p>b) Other products</p>	<p>b) 0.06%</p>		
	<p>Methyl heptadienone</p> <p>CAS no 1604-28-0</p>	<p>a) Oral products</p>			

	6-Methyl-3,5-heptadien-2-one	b) Other products	b) 0.002%		
	p-methylhydrocinnamic aldehyde CAS no 5406-12-2 Cresylpropionaldehyde <i>p</i> -Methyldihydrocinnamaldehyde		0.2%		
	Liquidambar Orientalis Balsam Oil and Extract CAS no 94891-27-7 (styrax)		0.6%		
	Liquidambar Styraciflua Balsam Oil and Extract CAS no 8046-19-3 (styrax)		0.6%		
	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%		
	<i>Commiphora Erythrea</i> Engler var. <i>glabrescens</i> Engler Gum Extract and Oil CAS no 93686-00-1		0.6%		
Y	Opopanax Chironium Resin CAS no 93384-32-8		0.6%”		