

Preservative regulations: a global overview



Detailed in the following pages are preservative regulations applying in Europe, China (including Hong Kong), the ASEAN countries, Taiwan, Japan, the United States and Australia.

The first part of this overview was published in the November 2008 issue of *Personal Care*.

The topic of preservatives is complex and, unlike other elements of the personal care sector, the area concerning preservatives seems subject to frequent change.

It was decided that as the European regulations feature a positive list that is fairly well accepted around the world, this would be the best anchor for the comparison and would also make it easier for the formulator seeking a “universal” preservative system. “Natural” preservatives are not legal as such unless they appear in Council Directive 76/768/EEC Annex VI (i.e. the approved preservative section of the law). The natural preservative can only be used legally if it is used as part of the perfume (i.e. parfum), for its marketing claim (e.g. honeysuckle) or as an effect (e.g. hinokitiol is listed as a hair conditioner). *Personal Care* published an update on natural preservatives in September 2005 and so these are not included in this section.

The following notes include elements taken from Council Directive 76/768/EEC, Annex VI, All Cosmetic Products (Safety) Regulations 2104 SI No 2152 Schedule 6.

Substances

The substances marked with the symbol⁺ may also be added to cosmetic products in concentrations other than those laid down in this Annex for other purposes apparent from the presentation of the products, e.g. as deodorants in soaps or as anti-dandruff agents in shampoos.

For the purposes of this list:

- “Salts” is taken to mean: salts of the cations sodium, potassium, calcium, magnesium, ammonium, and ethanolamines; salts of the anions chloride, bromide, sulphate, acetate.

- “Esters” is taken to mean: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl, phenyl.

All finished products containing formaldehyde or substances in this Annex and which release formaldehyde must be labelled with the warning “contains formaldehyde” where the concentration of formaldehyde in the finished product exceeds 0.05%.

- ¹ For non-preservative use see Annex III, Part 1, entry 98.
- ³ For non-preservative use see Annex III, Part 1, entry 101.
- ⁴ For non-preservative use see Annex III, Part 1, entry 99.
- ⁵ For non-preservative use see Annex III, Part 1, entry 100.

Black type = main listed substances.
Blue type = subsidiary substances.

Europe, China (including Hong Kong)

- ¹ Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin.



- ² Concerns any products aimed to be applied on a large part of the body.
- ³ Solely for products, other than bath products/shower gels and shampoos, which might be used for children under three years of age.
- ⁴ Solely for products which might be used for children under three years of age.

ASEAN countries

- * Concerns any products designed to be applied on a large part of the body.
 - ** Solely for products, other than bath products/shower gels and shampoos, which might be used for children under three years of age.
 - *** Solely for products which might be used for children under three years of age.
- ¹ For non-preservative use. See Annex III, Part 1, entry 98.
 - ² Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin.
 - ³ For non-preservative use. See Annex III, Part 1, entry 101.
 - ⁴ For non-preservative use. See Annex III, Part 1, entry 99.
 - ⁵ For non-preservative use. See Annex III, Part 1, entry 100.

Australia

There is no separate list of preservatives.

Japan

Column 1: Not applied on mucous membrane and rinsed off.

Column 2: Not applied on mucous membrane and not rinsed off.

Column 3: Mucous membrane.

Note 1: Empty columns indicate no combinations allowed.

Note 2: Cosmetics which are used on mucous membranes and which can be combined are limited to use in mouth.

Note 3: Refers to aqueous solutions which include 1.0% to 1.3% 5-chloro-2-methyl-4-isothiazoline-3-one and 0.3% to 0.42% of 2-methyl-4-isothiazolinone-3-one.

							Europe, China (including Hong Hong)		
EC number	Colipa number	Substances	Other names	CAS number	EINECS number	Formaldehyde donor?	Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
31	P63	Methenamine 3-chloro-allylochloride (INN)	Quaternium-15	4080-31-3 51229-78-8	223-805-0	Yes	0.20%		
32	P64	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one*	Climbazole	38083-17-9	253-775-4	No	0.50%		
33	P65	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione*	DMDM hydantoin	6440-58-0	229-222-8	Yes	0.60%		
34	P67	Benzyl alcohol*	Benzenemethanol	100-51-6	202-859-9	No	1.00%		
35	P59	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-pyridon and its monoethanolamine salt*	Piroctone olamine	68890-66-4	272-574-2	No	1.0% 0.5%	Products rinsed off For other products	
36	P77	1,2-Dibromo-2,4-dicyanobutane (ENTRY DELETED)	Methylbromo glutaronitrile; 2-bromo-2-(bromomethyl) glutaronitrile; 2-bromo-2-(bromomethyl) pentanedinitrile; glutaronitrile, 2-bromo-2-(bromomethyl)-; pentanedinitrile, 2-bromo-2-(bromomethyl)-	35691-65-7	252-681-0	No	Not permitted		
37	P25	6,6-Dibromo-4,4-dichloro-2,2'-methylene-diphenol (bromochlorophen)*	Bromochlorophene; 3,3'-dibromo-5,5'-dichloro-2,2'-dihydroxydiphenylmethane; 2,2'-methylenebis[6-bromo-4-chlorophenol]; phenol, 2,2'-methylenebis [6-bromo-4-chloro-	15435-29-7	239-446-8	No	0.10%		
38	P44	4-Isopropyl-m-cresol	Isopropyl cresols	485076	221-761-7	No	0.10%		
39	P56	Mixture of 5-chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate		26172-55-4	247-500-7	No	0.0015% (of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol 3(2H)-one and 2-methylisothiazol-3 (2H)-one		
40	P22	2-Benzyl-4-chlorophenol (chlorophene)	Chlorophene; 4-chloro-2-benzylphenol; 5-chloro-2-hydroxydiphenylmethane; phenol, 4-chloro-2-benzyl-	120-32-1	204-385-8	No	0.20%		
42	P35	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride*	N,N'-Bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediimidamide; 1,6-di (N-p-chlorophenyldiguanido) hexane; 1,1'-hexamethylene bis(5-(p-chlorophenyl) biguanide); 2,4,11,13-tetraazatetradecanediimidamide, N,N'-bis(chlorophenyl)-3,12-diimino-	55-56-1	200-238-7	No	0.3% expressed as chlorhexidine		
		Chlorhexidine diacetate	N,N'-Bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediimidamide, diacetate; 2,4,11,13-tetraazatetradecanediimidamide, N,N'-bis(chlorophenyl)-3,12-diimino, diacetate	56-95-1	200-302-4	No	0.3% expressed as chlorhexidine		
		Chlorhexidine digluconate	N,N'-Bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediimidamide, compd. with D-gluconic acid; chlorhexidine gluconate; D-gluconic acid, compd. with N,N'-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediimidamide	18472-51-0	242-354-0		0.3% expressed as chlorhexidine		
		Chlorhexidine dihydrochloride	N,N'-Bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediimidamide, dihydrochloride; 2,4,11,13-tetraazatetradecanediimidamide, N,N'-bis(chlorophenyl)-3,12-diimino-, dihydrochloride	Dihydrochloride: 3697-42-5	223-026-6	No	0.3% expressed as chlorhexidine		

Asean countries: Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, The Philippines, Singapore, Thailand, Vietnam			Taiwan	US	Australia	Japan				
Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label	Maximum concentration	Maximum concentration CIR findings table 31 July 2008	Name (AAN) no positive list	Name	All cosmetics	Maximum content per 100 g		
								(1)	(2)	(3)
0.2%				Up to 1%						
0.5%				No CIR available						
0.6%				Up to 1%		DMDM hydantoin		0.300	Note 1	Note 1
1.0%				Considered safe as used up to a maximum concentration of 5%	Benzyl alcohol	Benzyl alcohol	5.0% (some categories no maximum)			
1.0% 0.5%	Products rinsed off For other products		0.50%	No CIR available	Piroctone olamine					
Not permitted				Considered safe as used in rinse off and <0.025% in leave on products			Not permitted			
0.1%				No CIR available			Not permitted			
0.1%				Up to 5%		o-Cymen-5-ol		No limit	0.100	0.100
0.0015 % (of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol 3(2H)-one and 2-methylisothiazol-3 (2H)-one				Methylisothiazolinone/ methylchloroisothiazolinone may be safely used in rinse-off products at a concentration not to exceed 15 ppm and in leave-on cosmetic products at a concentration not to exceed 7.5 ppm. The stated safe use concentration refers to a mixture containing 23.3% methylisothiazolinone and 76.7% methylchloroisothiazolinone		Methylchloroisothiazolinone/ methylisothiazolinone		0.100	Note 1	0.010
0.2%				Insufficient data for CIR			Not permitted			
0.3% expressed as chlorhexidine			0.05%	Up to 0.14%	Chlorhexidine	Chlorhexidine		0.100	0.050	0.050
0.3% expressed as chlorhexidine			0.05%	Up to 0.19%	Chlorhexidine acetate		Not permitted			
0.3% expressed as chlorhexidine			0.05%	Up to 0.2%	Chlorhexidine gluconate	Chlorhexidine digluconate		No limit	0.050	0.050
0.3% expressed as chlorhexidine			0.05%	Up to 0.16%	Chlorhexidine hydrochloride	Chlorhexidine dihydrochloride		0.100	0.100	0.001

							Europe, China (including Hong Hong)			
EC number	Colipa number	Substances	Other names	CAS number	EINECS number	Formaldehyde donor?	Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label	
43	P54	1-Phenoxypropan-2-ol	Phenoxyisopropanol; 1-phenoxy-2-propanol	4169-04-4	224-027-4	No	1.0%	Only for rinse-off products		
44	P72	Alkyl (C12-C22) trimethyl ammonium, bromide and chloride ⁺	Cetrimonium bromide; CETAB; cetyl trimethyl ammonium bromide; 1-hexadecanaminium, N,N,N-trimethyl-, bromide; N,N,N-trimethyl-1-hexadecanaminium bromide	57-09-0	200-311-3	No	0.1%			
			Cetrimonium chloride; cetyl trimethyl ammonium chloride; 1-hexadecanaminium, N,N,N-trimethyl-, chloride; N,N,N-trimethyl-1-hexadecanaminium chloride	112-02-7	203-928-6	No	0.1%			
45	P75	4,4-Dimethyl-1,3-oxazolidine	Oxazolidine, 4,4'-dimethyl-dimethyl oxazolidine	51200-87-4	257-048-2	Yes	0.1%	The pH of the finished product must not be lower than 6		
46	P79	N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl) urea	Diazolidinyl urea	78491-02-8	278-928-2	Yes	0.5%			
47	P8	1,6-Di (4-amidino-phenoxy)-n-hexane (hexamidine) and its salts (including isethionate and p-hydroxybenzoate) ⁺		659-40-5	211-533-5	No	0.1%			
			Dibromohexamidine isethionate	93856-83-8	299-116-4	No	0.1%			
			Hexamidine	3811-75-4		No	0.1%			
			Hexamidine diisethionate	659-40-5	211-533-5	No	0.1%			
			Hexamidine paraben	93841-83-9	299-055-3	No	0.1%			
48	P76	Glutaraldehyde (pentane-1,5-dial)	Glutaral; glutaral dialdehyde; pentanedial	111-30-8	203-856-5	No	0.1%	Prohibited in aerosols (sprays)	Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0.05%)	
49	P90	5-Ethyl-3,7-dioxo-1-azabicyclo [3.3.0] octane	7-Ethylbicyclooxazolidine	7747-35-5	231-810-4	No	0.3%	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes		
50	P4	3-(p-Chlorophenoxy)-propane-1,2-diol (chlorphenesin)	Chlorphenesin	104-29-0	203-192-6	No	0.3%			
51	P84	Sodium hydroxymethyl-amino acetate (sodium hydroxymethylglycinate)	Sodium hydroxymethyl-glycinate	70161-44-3	274-357-8	Yes	0.5%			
52	P93	Silver chloride deposited on titanium dioxide	Silver chloride	7783-90-6	232-033-3	No	0.004% calculated as AgCl	20% AgCl (w/w) on TiO ₂ Prohibited in products for children under three years of age, in oral hygiene products and in products intended for application around the eyes and on the lips		
53	P70	Benzethonium chloride (INCI)	N,N'-Dimethyl-N-[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethyl]-, chloride; diisobutyl phenoxy ethoxy ethyl dimethyl benzyl ammonium chloride; N,N-dimethyl-N-[2-[2-[4-(1,1,3,3-tetramethyl-butyl)phenoxy]ethoxy]ethyl] benzenemethanaminium chloride	121-54-0	204-479-9	No	0.1%	(a) Rinse-off products. (b) Leave-on products other than for oral care use		
54	P71	Benzalkonium chloride, bromide and saccharinate ⁺	Alkyl dimethyl benzyl ammonium chloride	8001-54-5 68391-01-5 68424-85-1 85409-22-9 61789-71-7	263-080-8 269-919-4 270-325-2 287-089-1	No	0.1% calculated as benzalkonium chloride		Avoid contact with eyes	

Asean countries: Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, The Philippines, Singapore, Thailand, Vietnam			Taiwan	USA	Australia	Japan				
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								(1)	(2)	(3)
1.0%	Only for rinse-off products			No CIR available		Phenoxyisopropanol	No maximum (all product categories)			
0.1%				Safe as used in rinse-off products; but < 0.25% in leave-on products	Cetrimonium bromide	Cetyltrimethylammonium bromide (or) cetyl trimethyl ammonium bromide powder	5.0%, 1.0% (depends on product category)			
0.1%				Safe as used in rinse-off products; but < 0.25% in leave-on products	Cetrimide; cetrimonium chloride	Cetyltrimethylammonium chloride	5.0%, 1.0% (depends on product category)			
0.1%	The pH of the finished product must not be lower than 6			No CIR available			Not permitted			
0.5%				Considered safe as used up to a maximum concentration of 0.5%			Not permitted			
0.1%				Safe at concentrations less than or equal to 0.1%	Hexamidine isethionate		Not permitted			
0.1%				No CIR available						
0.1%				Safe at concentrations less than or equal to 0.1%						
0.1%				Safe at concentrations less than or equal to 0.1%						
0.1%				No CIR available						
0.1%	Prohibited in aerosols (sprays)	Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0.05%)		< 0.5% for rinse-off; but should not be used in products intended to be aerosolised (insufficient data to support safety in leave-on products)	Glutaraldehyde		Not permitted			
0.3%	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes			No CIR available						
0.3%				As above		Chlorphenesin		0.300	0.300	Note 1
0.5%				As above						
0.004% calculated as AgCl	20% AgCl (w/w) on TiO ₂ . Prohibited in products for children under three years of age, in oral hygiene products and in products intended for application around the eyes and on the lips			As above						
0.1%	(a) Rinse-off products (b) Leave-on products other than for oral care use		0.1%	0.5% or less, skin; 0.02% or less, eye area	Benzethonium chloride	Benzethonium chloride		0.050	0.200	Note 1
0.1% calculated as benzalkonium chloride		Avoid contact with eyes	0.05%	0.1% or less free active ingredient	Benzalkonium chloride	Benzalkonium chloride		3.000	0.050	0.010

							Europe, China (including Hong Hong)			
EC number	Colipa number	Substances	Other names	CAS number	EINECS number	Formaldehyde donor?	Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label	
55	P21	Benzylhemiformal	Benzylhemiformal	14548-60-8	238-588-8	Yes	0.15%	Only for products to be removed by rinsing		
56	P91	Iodopropynyl butylcarbamate (IPBC) 3-Iodo-2-propynyl-butyl carbamate (iodopropynyl butylcarbamate)	Iodopropynyl butylcarbamate	55406-53-6	259-627-5	No	(a) Rinse-off products: 0.02% (b) Leave-on products: 0.01% except in deodorants/antiperspirants: 0.0075%	Not to be used in oral hygiene and lip care products. (a) Not to be used in preparations for children under three years of age, except in bath products/shower gels and shampoo. (b) Not to be used in body lotion and body cream. ² Not to be used in preparations for children under three years of age	(a) Not to be used for children under three years of age. ³ b) Not to be used for children under three years of age ⁴	
57		Methylisothiazolinone (INCI)	Methylisothiazolinone	2682-20-4	220-239-6	No	0.01%			
		Halocarbon	Cloflucarban	369-77-7	206-724-5	No	Not permitted			
		Isopropylmethylphenol				No	As above			
		Orthophenylphenol				No	As above			
		2,2'[3'-[2-(3-Heptyl-4-methyl-2-thiazolin-2-ylidene)ethylidene]propylene]bis[3-heptyl-4-methyl]thiazolinium iodide				No	As above			
		2-[2-(3-Heptyl-4-methyl-2-thiazolin-2-ylidene)methine]-3-heptyl-4-methylthiazolinium iodide				No	As above			
		6-[2-(5-Bromo-2-pyridyl)amino]vinyl]-1-ethyl-2-picolinium iodide				No	As above			
		2-(2-Anilinovinyl)-3,4-dimethyl-oxazolinium iodide				No	As above			
		Alkylisoquinolinium bromide	Laurylisoquinolinium bromide; 2-dodecylisoquinolinium bromide	93-23-2	202-230-9	No	As above			
		Ammonium silver zinc aluminum silicate					As above			
		Cetylpyridinium chloride					As above			
		Chloramine T					As above			
		p-Chlorophenol					As above			
		Cresol					As above			
		Dimethylaminostyryl heptyl methyl thiazolium iodide					As above			
		Hinokitiol					As above			
		Lauryl diethylene-diaminoglycine HCl					As above			
		Lauryl isoquinolinium bromide					As above			
		Mixed cresols					As above			
		Phenol					As above			
		o-phenylphenol					As above			
		Platonin					As above			
		Quaternium-45				Yes	As above			
		Quaternium-51				Yes	As above			
		Quaternium-73				Yes	As above			
		Resorcinol					As above			
		Sodium lauryl diethylenediaminoglycinate					As above			
		Sodium o-phenylphenate					As above			
		Thianthol					As above			
		Thymol					As above			

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Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label	Maximum concentration	Maximum concentration CIR findings table 31 July 2008	Name (AAN) no positive list	Name	All cosmetics	Maximum content per 100 g		
								(1)	(2)	(3)
0.15%	Only for products to be removed by rinsing			No CIR available						
(a) Rinse-off products: 0.02%. (b) Leave-on products: 0.01% except in deodorants/antiperspirants: 0.0075%	Not to be used in oral hygiene and lip care products. (a) Not to be used in preparations for children under three years of age, except in bath products/shower gels and shampoo. (b) Not to be used in body lotion and body cream. Not to be used in preparations for children under three years of age	(a) Not to be used for children under three years of age** (b) Not to be used for children under three years of age***		Safe for use at up to 0.1%; should not be used in products intended to be aerosolised						
0.01%				Safe at concentrations up to 100 ppm						
Not permitted			0.3%	No CIR available		Cloflucarban	No limit	0.300	Note 1	
As above			0.1%	As above		Isopropylmethylphenol	No limit	0.100	0.100	
As above			0.3%	As above						
As above			0.01%	As above						
As above			0.002%	As above						
As above			0.002%	As above						
As above			0.002%	As above						
As above			0.05%	As above		Alkylisoquinolinium bromide solution	0.5%, 0.05% (Depends on product category)			
As above				As above		Ammonium silver zinc aluminum silicate		1.000	1.000	Note 1
As above				As above		Cetylpyridinium chloride		5.000	1.000	0.010
As above				As above		Chloramine T		0.300	0.100	Note 1
As above				As above		p-Chlorophenol		0.250	0.250	0.300
As above				As above		Cresol		0.010	0.010	Note 1
As above				As above		Dimethylaminostyryl heptyl methyl thiazolium iodide		0.001	0.002	Note 1
As above				As above		Hinokitiol		No limit	0.100	Note 1
As above				As above		Lauryl Diethylene-diaminoglycine HCl	0.088			
As above				As above		Lauryl isoquinolinium bromide		No limit	0.050	0.050
As above				Safe with qualifications		Mixed cresols		0.010	0.010	Note 1
As above				No CIR available		Phenol	0.100			
As above				As above		o-phenylphenol		No limit	0.300	0.300
As above				As above		Platonin	No data			
As above				As above		Quaternium-45	No data			
As above				As above		Quaternium-51	No data			
As above				As above		Quaternium-73	No data			
As above				As above		Resorcinol	0.100			
As above				As above		Sodium lauryl diethylenediaminoglycinate	0.030			
As above				As above		Sodium o-phenylphenate		0.150	0.150	Note 1
As above				As above		Thianthol		0.800	0.800	Note 1
As above				Up to 0.5%		Thymol		0.050	0.050	No limit