

ANNEX VI

LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS MAY CONTAIN

Preamble

1. Preservatives are substances which may be added to cosmetic products for the primary purpose of inhibiting the development of micro-organisms in such products.
2. The substances marked with the symbol (+) may also be added to cosmetic products in concentration 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.
3. Other substances used in the formulation of cosmetic products may also have anti-microbial properties and thus help in the preservation of the products, as, for instance, many essential oils and some alcohols. These substances are not included in the ANNEX.
4. 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.
5. 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%.

ANNEX VI – PART 1**LIST OF PRESERVATIVES ALLOWED**

Colipa Number	Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
	a	b	c	d	e
P 2	1	Benzoic acid, its salts and esters(+)	0.5% (acid)		
P 13	2	Propionic acid and its salts (+)	2% (acid)		
P 14	3	Salicylic acid and its salts (+)	0.5% (acid)		
P 15	4	Sorbic acid (hexa-2,4-dienoic acid) and its salts (+)	0.6% (acid)	Not to be used in preparations for children under 3 years of age, except for shampoos	- Not to be used for children under 3 years of age (1)
P 39	5	Formaldehyde and paraformaldehyde (+)	0.2% (except for products for oral hygiene) 0.1% (products for oral hygiene) expressed as free formaldehyde	Prohibited in aerosol dispensers (sprays)	
P 47	7	Biphenyl-2-ol (o-phenylphenol) and its salts (+)	0.2% expressed as phenol		
P 81	8	Pyrithione zinc (INN) (+)	0.5%	Authorized in products rinsed off, forbidden in products for oral hygiene	
P 51	9	Inorganic sulphites and hydrogensulphites (+)	0.2% expressed as free SO ₂		
P 66	10	Sodium iodate	0.1%	Rinse-off products only	
P 68	11	Chlorobutanol (INN)	0.5%	Prohibited in aerosol	- Contains chlorobutanol

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	a	b	c	d	e
				dispensers (sprays)	
P 82	12	4-Hydroxybenzoic acid its salts and esters (+)	0.4% (acid) for 1 ester; 0.8% (acid) for mixtures of esters		
P 5	13	3-Acetyl-6-methylpyran-2,4 (3H)-dione (Dehydroacetic acid) and its salts	0.6% (acid)	Prohibited in aerosol dispensers (sprays)	
P 6	14	Formic acid and its sodium salt (+)	0.5% (expressed as acid)		
P 9	15	3,3'-Dibromo-4,4'-hexamethylene-dioxydibenzamidine (Dibromohexamidine) and its salts (including isethionate)	0.1%		
P 12	16	Thiomersal (INN)	0.007% (of Hg) If mixed with other mercurial compounds authorized by this Directive, the maximum concentration of Hg remains fixed at 0.007%	For eye make-up and eye make-up remover only	- Contains thiomersal
P 48	17	Phenylmercuric salts (including borate)	Ditto	Ditto	- Contains phenylmercuric compounds
P 16	18	Undec-10-enoic acid and salts (+)	0.2% (acid)		
P20	19	Hexetidine (INN) (+)	0.1%		
P 23	20	5-Bromo-5-nitro-1,3 dioxane	0.1%	Rinse-off products only Avoid formation of nitrosamines	
P 24	21	Bronopol (INN) (+)	0.1%	Avoid formation of	

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	a	b	c	d	e
				nitrosamines	
P 74	22	2,4-Dichlorobenzyl alcohol (+)	0.15%		
P 29	23	Triclocarban (INN) (+)	0.2%	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene less than 1 ppm; 3,3',4,4'-Tetrachloroazoxybenzene less than 1 ppm	
P 30	24	4-Chloro-m-cresol (+)	0.2%	Prohibited in products intended to come into contact with mucous membranes	
P 32	25	Triclosan (INN) (+)	0.3%		
P 37	26	4-Chloro-3,5-xyleneol (+)	0.5%		
P 43	27	3,3'-Bis(1-hydroxymethyl-2,5-dioxoimidazolidin-4-yl)-1,1'-methyleneurea ("Imidazolidinyl urea") (+)	0.6%		
P 52	28	Poly(1-hexamethylenebiguanide hydrochloride) (+)	0.3%		
P 53	29	2-Phenoxyethanol (+)	1.0%		
P 55	30	Hexamethylenetetramine (+) (methenamine) (INN)	0.15%		
P 63	31	Methenamine 3-chloroallylochloride (INN)	0.2%		
P 64	32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl) 3,3-dimethylbutan-2-one (+)	0.5%		

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P 65	33	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (+)	0.6%		
P 67	34	Benzyl alcohol (+)	1%		
P 59	35	1-Hydroxy-4-methyl-6(2,4,4-trimethylpentyl)2-pyridon and its monoethanolamine salt(+)	1% 0.5%	Products rinsed-off For other products	
P 77	36	1,2-Dibromo-2,4-dicyanobutane	0.1%	Not to be used in cosmetic sunscreen products at a concentration exceeding 0.025%	
P 25	37	6,6-Dibromo-4,4-dichloro-2,2'-methylene-diphenol:Bromochlorophen) (+)	0.1%		
P 44	38	4-Isopropyl-m-cresol	0.1%		
P 56	39	Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate	0.0015% (of a mixture in the ratio 3:1 of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one)		
P 22	40	2-Benzyl-4-chlorophenol (Chlorophene)	0.2%		
P 27	41	2-Chloroacetamide	0.3%		- Contains chloroacetamide
P 35	42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+)	0.3% expressed as chlorhexidine		
P 54	43	1-Phenoxypropan-2-ol	1.0%	Only for rinse-off products	

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	a	b	c	d	e
P 72	44	Alkyl (C12-C22) trimethyl ammonium, bromide and chloride (+)	0.1%		
P 75	45	4,4-Dimethyl-1,3-oxazolidine	0.1%	The pH of the finished product must not be lower than 6	
P 79	46	N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolinidyl-4)-N'-(hydroxymethyl) urea	0.5%		
P 8	47	1,6-Di(4-amidinophenoxy)-n-hexane (Hexamidine) and its salts (including isethionate and p-hydroxy- benzoate (+)	0.1%		
P 76	48	Glutaraldehyde (Pentane-1,5-dial)	0.1%	Prohibited in aerosols (sprays)	- Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0.05%)
P 90	49	5-Ethyl-3,7-dioxa-1-azabicyclo [3.3.0] octane	0.3%	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes	
P 4	50	3-(p-Chlorophenoxy)-propane-1,2-diol (chlorphenesin)	0.3%		
P 84	51	Sodium hydroxymethylamino acetate (Sodium hydroxymethylglycinate)	0.5%		
P 93	52	Silver chloride deposited on Titanium dioxide	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	

Colipa Number	Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
	a	b	c	d	e
				products and in products intended for application around the eyes and on the lips	
P 70	53	Benzethonium chloride	0.1%	Rinse-off products only	
P 71	54	Benzalkonium chloride, bromide and saccharinate	0.1% calculated as Benzalkonium chloride		- Avoid contact with the eyes
	55	Benzylhemiformal	0.15%	Only for products to be removed by rinsing	
	56	3-Iodo-2-propynylbutylcarbamate	0.05%	1. Not to be used for oral hygiene and lipcare products 2. If the concentration in products intended to remain on the skin exceeds 0.02% add the phrase: Contains iodine	- Contains iodine

ANNEX VI – PART 2**LIST OF PRESERVATIVES PROVISIONALLY ALLOWED**

Colipa Number	Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
	a	b	c	d	e

Note: no preservative is listed in this section for the present time.