

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 for use in cosmetic products

ANNEX VI – PART 1

LIST OF PRESERVATIVES ALLOWED

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
1	Benzoic acid (CAS No. 65-85-0), and its sodium salt (CAS No 532-32-1)	Rinse off products, except oral care products; 2.5 % (acid) Oral care products; 1.7 % (acid) Leave-on products; 0.5 % (acid)		
1a	Salts of benzoic acid other than that listed under reference number 1 and esters of benzoic acid	0.5 % (acid)		
2	Propionic acid and its salts	2% (acid)		
3	Salicylic acid and its salts (+) ⁽¹⁾	0.5% (acid)	Not to be used in preparations for children under three years of age, except for shampoos	- Not to be used for children under three years of age ⁽²⁾
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts	0.6% (acid)		
5	Formaldehyde and paraformaldehyde(+) ⁽⁷⁾	0.2% (except for products for oral hygiene) 0.1% (for oral hygiene) expressed as free formaldehyde	Prohibited in aerosol dispensers(sprays)	
6	Entry moved or deleted			

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a	b	c	d	e
7	Biphenyl-2-ol (o-phenylphenol) and its salts	0.2% expressed as phenol		
8	Zinc pyrithione (+) ⁽³⁾ (CAS No 13463-41-7)	Hair products; 1.0 % Other products; 0.5%	Rinse off products only. Not for use in products for oral hygiene	
9	Inorganic sulphites and hydrogensulphites(+) ⁽⁴⁾	0.2% expressed as free SO ₂		
10	Entry moved or deleted			
11	Chlorobutanol(INN)	0.5%	Prohibited in aerosol dispensers (sprays)	- Contains chlorobutanol
12	4-Hydroxybenzoic acid and its salts and esters	0.4% (acid) for 1 ester; 0.8% (acid) for mixtures of esters		
13	3-Acetyl-6-methylpyran-2,4 (3H)-dione (Dehydroacetic acid) and its salts	0.6% (acid)	Prohibited in aerosol dispensers (sprays)	
14	Formic acid and its sodium salt	0.5% (expressed as acid)		
15	3,3'-Dibromo-4,4'-hexamethylenedioxydi-benzamidine (Dibromohexamidine) and its salts (including isethionate)	0.1%		
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

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17	Phenylmercuric salts (including borate)	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 phenylmercuric compounds
18	Undec-10-enoic acid and its salts(+)	0.2% (acid)		
19	Hexetidine(INN)	0.1%		
20	5-Bromo-5-nitro-1,3 dioxane	0.1%	Rinse-off products only Avoid formation of nitrosamines	
21	Bronopol(INN)	0.1%	Avoid formation of nitrosamines	
22	2,4-Dichlorobenzyl alcohol	0.15%		
23	Triclocarban(INN) (+) ⁽⁵⁾	0.2%	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene <1 ppm; 3,3',4,4'-Tetrachloroazoxybenzene < 1 ppm	
24	4-Chloro-m-cresol	0.2%	Prohibited in products intended to come into contact with mucous membranes	
25	Triclosan(INN) (+)	0.3%		

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26	4-Chloro-3,5-xyleneol	0.5%		
27	3,3'-Bis(1-hydroxymethyl-2,5-dioximidazolidin-4-yl)-1,1'-methylenediurea ("Imidazolidinyl urea")	0.6%		
28	Poly(1-hexamethylenebiguanide hydrochloride)	0.3%		
29	2-Phenoxyethanol	1.0%		
30	Hexamethylenetetramine (methenamine) (INN)	0.15%		
31	Methenamine 3-chloroallylochloride (INN)	0.2%		
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one (+)	0.5%		
33	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione)	0.6%		
34	Benzyl alcohol(+) ⁽⁸⁾	1%		
35	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2 pyridon and its monoethanolamine salt(+)	1% 0.5%	Rinse-off products For other products	
36	Entry deleted			
37	6,6-Dibromo-4,4-dichloro-2,2'-methylene-diphenol (Bromochlorophen)	0.1%		
38	4-Isopropyl-m-cresol	0.1%		

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Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
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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)		
40	2-Benzyl-4-chlorophenol (chlorophene)	0.2%		
41	2-Chloroacetamide	0.3%		- Contains chloroacetamide
42	Chlorhexidine(INN) and its digluconate, diacetate and dihydrochloride(+)	0.3% expressed as chlorhexidine		
43	1-Phenoxypropan-2-ol(+) ⁽⁹⁾	1.0%	Only for rinse-off products	
44	Alkyl (C12-C22) trimethyl ammonium, bromide and chloride) (+)	0.1%		
45	4,4-Dimethyl-1,3-oxazolidine	0.1%	The pH of the finished product must not be lower than 6	
46	N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolidinidyl-4)-N'-(hydroxymethyl) urea)	0.5%		
47	1,6-Di(4-amidinophenoxy)-n-hexane (Hexamidine) and its salts (including isethionate and p-hydroxybenzoate(+)	0.1%		
48	Glutaraldehyde (Pentane-1,5-dial)	0.1%	Prohibited in aerosols (sprays)	- Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0.05%)

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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
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	
50	3-(p-Chlorophenoxy)-propane-1,2-diol (chlorphenesin)	0.3%		
51	Sodium hydroxymethylamino acetate (Sodium hydroxymethylglycinate)	0.5%		
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 products and in products intended for application around the eyes and on the lips	
53	BenzethoniumChloride (INCI)	0.1%	(a) Rinse-off products (b) Leave on products other than for oral care use.	
54	Benzalkonium chloride, bromide and saccharinate(+) ⁽¹⁰⁾	0.1% calculated as Benzalkonium chloride		- Avoid contact with the eyes
55	Benzylhemiformal	0.15%	Only for products to be removed by rinsing	

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a	b	c	d	e
56	Iodopropynylbutylcarbamate (IPBC); 3-Iodo-2-propynylbutylcarbamate CAS No: 55406-53-6	(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 shampoos. (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 (***)
57	Methylisothiazolinone(INCI)	0.01 %		
58	Ethyl LauroylArginateHCl (INCI) (+) ⁽⁶⁾ Ethyl-N α -dodecanoyl- L-arginate hydrochloride CAS No 60372-77-2 EC No 434-630-6	0.4%	Not to be used in lip products, oral products and spray products.	

(1) For non-preservative usage see Annex III. Part 1, entry98

(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 usage see Annex III. Part 1, entry 101

(4) For non-preservative usage see Annex III. Part 1, entry 99

(5)For non-preservative usage see Annex III. Part 1, entry 100

(6) For non-preservative usage see Annex III. Part 1, entry207

(7) For non-preservative usage see Annex III. Part 1, entry13

(8) For non-preservative usage see Annex III. Part 1, entry 45

(9) For non-preservative usage see Annex III. Part 1, entry54

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(10) For non-preservative usage see Annex III. Part 1, entry 65

(*) Concerns any products aimed to be applied on a large part of the body

(**) Solely for products, other than bath products/shower gels and shampoo, 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

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.