

Annex VI – Part 1 – List of preservatives allowed for use in cosmetic products

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%.

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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)		

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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 Methyl- and Ethyl- esters, and their salts (INCI) 4-Hydroxybenzoic acid; CAS No. 99-96-7; Methylparaben; CAS No. 99-76-3; potassium ethylparaben; CAS No. 36457-19-9; potassium paraben; CAS No. 16782-08-4 sodium methylparaben; CAS No. 5026-62-0; sodium ethylparaben; CAS No. 35285-68-8; ethylparaben; CAS No. 120-47-8; sodium paraben; CAS No. 114-63-6; potassium methylparaben; CAS No. 26112-07-2; calcium paraben; CAS No. 69959-44-0;	0.4% (as acid) for single ester 0.8% (as acid) for mixtures of esters		

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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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12a	Butyl 4-hydroxybenzoate and its salts Propyl 4- hydroxybenzoate and its salts Butylparaben; CAS No. 94-26-8; Propylparaben; CAS No. 94-13-3 sodium propylparaben; CAS No. 35285-69-9 sodium butylparaben; CAS No. 36457-20-2 ; potassium butylparaben; CAS No. 38566-94-8; potassium propylparaben; CAS No. 84930-16-5;	0.14 % (as acid) for the sum of the individual concentrations 0.8 % (as acid) for mixtures of substances mentioned in entry 12 and 12a, where the sum of the individual concentrations of butyl- and propylparaben and their salts does not exceed 0.14 %	Not to be used in leave-on products designed for application on the nappy area of children under three years of age.	For leave-on products designed for children under three years of age: "Do not use on the nappy area"
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'-hexamethylenedioxydibenzamidine (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
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

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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	

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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%		
39	Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-Methylisothiazol-3(2H)-one (INCI) Methylchloroisothiazolinone (and) Methylisothiazolinone ⁽⁹⁾ CAS No. 26172-55-4, 2682-20-4, 55965-84-9	0,0015 % (of a mixture in the ratio 3:1 of 5-chloro- 2-methylisothiazol 3(2H)-one and 2-methylisothiazol-3 (2H)-one)	Rinse-off products	
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(+) ⁽¹⁰⁾	1.0%	Only for rinse-off products	

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44	Alkyl (C ₁₂₋₂₂) trimethyl ammonium bromide and chloride) (+) Behentrimonium chloride ⁽¹¹⁾ , CAS No. 17301-53-0, cetrimonium bromide, CAS No. 57-09-0, cetrimonium chloride ⁽¹²⁾ , CAS No. 112-02-7, laurrimonium bromide, CAS No. 1119-94-4, laurrimonium chloride, CAS No. 112-00-5, steartrimonium bromide, CAS No. 1120-02-1, steartrimonium chloride ⁽¹²⁾ CAS No. 112-03-8,	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%)
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	

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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	Benzethonium Chloride (INCI)	0.1%	(a) Rinse-off products (b) Leave on products other than for oral care use.	
54	Benzalkonium chloride, bromide and saccharinate(+) ⁽¹³⁾	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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56	Iodopropynyl butylcarbamate (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	2-Methyl-2H-isothiazol-3-one (INCI) Methylisothiazolinone ⁽¹⁴⁾ CAS No.2682-20-4	0.01% (In Indonesia the maximum authorized concentration is 0.0015%) (Note: At the 26 th ACSB Meeting a future maximum authorized concentration of 0.0015% was proposed – to be considered at a future ACSB Meeting.)	Rinse-off products only	

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58	Ethyl Lauroyl Arginate HCl (INCI) (+) ⁽⁶⁾ Ethyl-N α -dodecanoyl- L-arginate hydrochloride CAS No 60372-77-2	(a) mouthwashes: 0.15% (b) other products: 0.4 %	(a) Not to be used in preparations for children under 10 years of age. (b) Not to be used in lip products, oral products and spray products.	(a) Not to be used for children under 10 years of age.
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59	1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate and 1,2,3-Propanetricarboxylic acid, 2-hydroxy-,silver(1+) salt, monohydrate (INCI) Citric acid (and) Silver citrate	0.2 %, corresponding to 0.0024 % of silver	Not to be used in oral products and eye products	

- (1) For non-preservative usage 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 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, entry 207
 - (7) For non-preservative usage see Annex III. Part 1, entry 13
 - (8) For non-preservative usage see Annex III. Part 1, entry 45
 - (9) Methylisothiazolinone is also regulated in entry 57. The two entries are mutually exclusive: the use of the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone is incompatible with the use of Methylisothiazolinone alone in the same product.
 - (10) For non-preservative usage see Annex III. Part 1, entry 54
 - (11) For use other than as a preservative, see Annex III, No 287
 - (12) For use other than as a preservative, see Annex III, No 286
 - (13) For non-preservative usage see Annex III. Part 1, entry 65
 - (14) Methylisothiazolinone is also regulated in entry 39 in a mixture with Methylchloroisothiazolinone. The two entries are mutually exclusive: the use of the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone is incompatible with the use of Methylisothiazolinone alone in the same product
- (*) 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