

Annex VI – 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 substances in this ANNEX and which release formaldehyde (Entries 20,21,27,30,31,33,46,49, 51,55) 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 Ammonium benzoate (CAS No.1863-63-4)/ Calcium benzoate (CAS No. 2090-05-3)/ Potassium benzoate (CAS No. 582-25-2)/ Magnesium benzoate (CAS No. 553-70-8)/ MEA- benzoate (CAS No. 4337-66-0)/ Methyl benzoate (CAS No. 93-58-3) / Ethyl benzoate (CAS No. 93-89-0)/ Propyl benzoate (CAS No. 92315-68-6)/ Butyl benzoate (CAS No. 136-60-7) / Isobutyl benzoate (CAS No. 120-50-3)/ Isopropyl benzoate (CAS No. 939-48-0)/ Phenyl benzoate (CAS No. 93-99-2)	0.5 % (acid)		

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2	Propionic acid (CAS No. 79-09-4) and its salts Ammonium propionate (CAS No.17496-08-1) / Calcium propionate (CAS No. 4075-81-4)/ Magnesium propionate (CAS No. 557-27-7)/ Potassium propionate (CAS No. 327-62-8)/ Sodium propionate (CAS No. 137-40-6)	2% (acid)		
3	Salicylic acid (69-72-7) and its salts ⁽¹⁾ : Calcium salicylate (CAS No. 824-35-1), Magnesium salicylate (CAS No. 18917-89-0), MEA-salicylate (CAS No. 59866-70-5), Sodium salicylate (CAS No. 54-21-7), Potassium salicylate (CAS No. 578-36-9), TEA-salicylate (CAS No. 2174-16-5)	0.5% (acid) 0.5% (acid)	Salicylic acid: Not to be used in products for children under three years of age. Not to be used in oral products. Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Salicylic acid salts: Not to be used in preparations for children under three years of age, except for shampoos	Salicylic acid: Not to be used for children under three years of age ^(2.1) Salicylic acid salts: Not to be used for children under three years of age ^(2.2)
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts Sorbic acid (CAS No. 110-44-1), Calcium sorbate (CAS No. 7492-55-9), Sodium sorbate (CAS No.7757-81-5), Potassium sorbate (CAS No. 24634-61-5)	0.6% (acid)		
5	Entry deleted			
6	Entry moved or deleted			

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a	b	c	d	e
7	Biphenyl-2-ol CAS No. 90-43-7	Rinse-off products; 0.2% (as phenol) Leave-on products; 0.15% (as phenol)		Avoid contact with eyes.
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⁾ Sodium Sulfite (CAS No 7757-83-7), Ammonium bisulfite (CAS No. 10192-30-0) Ammonium sulfite (CAS No. 10196-04-0), Potassium sulfite (CAS No.10117-38-1), Potassium hydrogen sulfite (CAS No.7773-03-07), Sodium sulfite (CAS No. 7631-90-5), sodium Metabisulfite (CAS No.7681-57-4) potassium Metabisulfite (CAS No.16731-55-8)	0.2% expressed as free SO ₂		
10	Entry moved or deleted			
11	Chlorobutanol (INN) CAS No. 57-15-8	0.5%	Prohibited in aerosol dispensers (sprays)	- Contains chlorobutanol

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12	<p>4-Hydroxybenzoic acid and its Methyl- and Ethyl- esters, and their salts (INCI)</p> <p>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;</p>	<p>0.4% (as acid) for single ester</p> <p>0.8% (as acid) for mixtures of esters</p>		

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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 Dehydroacetic acid (CAS No. 520-45-6, 16807-48-0), Sodium dehydroacetate (CAS No. 4418-26-2)	0.6% (acid)	Prohibited in aerosol dispensers (sprays)	
14	Formic acid (CAS No. 64-18-6) and its sodium salt (CAS No. 141-53-7)	0.5% (expressed as acid)		
15	3,3'-Dibromo-4,4'-hexamethylenedioxydi-benzamidine (Dibromohexamidine) and its salts (including isethionate) (CAS No. 93856-83-8)	0.1%		
16	Entry deleted			
17	Entry deleted			

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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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18	Undec-10-enoic acid and its salts (+) Undecylenic acid (CAS No. 112-38-9) /Potassium undecylenate (CAS No. 6159-61-47)/ Sodium undecylenate (CAS No. 3398-33-2)/Calcium undecylenate (CAS No. 1322-14-1) / TEA- undecylenate (CAS No. 84471-25-0)/ MEA- undecylenate (CAS No. 56532-40-2)	0.2% (acid)		
19	Hexetidine (INN) CAS No. 141-94-6	0.1%		
20	5-Bromo-5-nitro-1,3 dioxane CAS No. 30007-47-7	0.1%	Rinse-off products only Avoid formation of nitrosamines	
21	Bronopol (INN) CAS No. 52-51-7	0.1%	Avoid formation of nitrosamines	
22	2,4-Dichlorobenzyl alcohol CAS No. 1777-82-8	0.15%		
23	Triclocarban (INN) ⁽⁶⁾ CAS No. 101-20-2	0.2%	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene < 1 ppm; 3,3',4,4'-Tetrachloroazoxybenzene < 1 ppm	
24	4-Chloro-m-cresol CAS No. 59-50-7	0.2%	Prohibited in products intended to come into contact with mucous membranes	

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30	Hexamethylenetetramine (methenamine) (INN) CAS No. 100-97-0	0.15%		
31	Entry deleted			
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one) ¹⁵ Climbazole CAS No. 38083-17-9	Hair lotions; 0.2% Face creams; 0.2% Rinse-off shampoo; 0.5% Rinse-off hair conditioner : 0.5%		
33	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione) CAS No. 6440-58-0	0.6%		
34	Benzyl alcohol ⁽⁸⁾ CAS No. 100-51-6	1%		
35	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-pyridon and its monoethanolamine salt (+) 1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-pyridon (CAS No. 50650-76-5), piroctone Olamine (CAS No. 68890-66-4)	1% 0.5%	Rinse-off products For other products	
36	Entry deleted			

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37	6,6-Dibromo-4,4-dichloro-2,2'-methylene-diphenol (Bromochlorophen) CAS No. 15435-29-7	0.1%		
38	4-Isopropyl-m-cresol CAS No. 3228-02-2	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	
	Entry 40 deleted			
	Entry 41 deleted			
42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+) Chlorhexidine (CAS No. 55-56-1), Chlorhexidine diacetate (CAS No. 56-95-1), Chlorhexidine digluconate, Chlorhexidine dihydrochloride (CAS No. 3697-42-5)	0.3% expressed as chlorhexidine		
43	1-Phenoxypropan-2-ol ⁽¹⁰⁾ CAS No. 770-35-4	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), stearrimonium bromide (CAS No. 1120-02-1), stearrimonium chloride ⁽¹²⁾ (CAS No. 112-03-8)	0.1%		
45	4,4-Dimethyl-1,3-oxazolidine CAS No. 51200-87-4	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) CAS No. 78491-02-8	0.5%		
47	1,6-Di(4-amidinophenoxy)-n-hexane (Hexamidine) and its salts (including isethionate and p-hydroxybenzoate (+) Hexamidine (CAS No. 3811-75-4), Hexamidine diisethionate (CAS No. 659-40-5), Hexamidine paraben(CAS No. 93841-83-9),	0.1%		
48	Glutaraldehyde (Pentane-1,5-dial) CAS No. 111-30-8	0.1%	Prohibited in aerosols (sprays)	- Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0.05%)

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49	5-Ethyl-3,7-dioxa-1-azabicyclo [3.3.0] octane CAS No. 7747-35-5	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) CAS No. 104-29-0	0.3%		
51	Sodium N-(hydroxymethyl) glycinate (Sodium Hydroxymethylglycinate) CAS No. 70161-44-3	0.5%	Not to be used unless it can be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is < 0.1 % w/w.	
52	Silver chloride deposited on titanium dioxide CAS No. 7783-90-6	0.004% calculated as AgCl	20% AgCl (w/w) on TiO ₂ Prohibited in products for children under three years of age	
53	Benzethonium Chloride (INCI)	0.1%	(a) Rinse-off products (b) Leave on products other than eye cosmetics	
54	Benzalkonium chloride, bromide and saccharinate ⁽¹³⁾ Benzalkonium chloride (CAS No. 8001-54-5, 63449-41-2, 68424-85-1, 68391-01-5, 61789-71-7, 85409-22-9), Benzalkonium bromide (CAS No. 91080-29-4), Benzalkonium saccharinate (CAS No. 68989-01-5)	0.1% calculated as Benzalkonium chloride		- Avoid contact with the eyes
55	Benzylhemiformal CAS No. 14548-60-8	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	0.0015%	Rinse-off products only	
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	
60	4-(3-ethoxy-4-hydroxyphenyl)butan-2-one Hydroxyethoxyphenyl Butanone CAS No. 569646-79-3	0.7 %		

- (1) For non-preservative usage see Annex III. Part 1, entry 98
 - (2.1) Solely for products which might be used for children under three years of age
 - (2.2) 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
 - (15) For use other than as a preservative, see Annex III, Part 1, entry 326
- (*) 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

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