

Schedule 7

Preservatives Cosmetic Products May Contain With Restrictions

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 Schedule for other specific 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 this Schedule.
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 Schedule and which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0.05%.

TABLE 1: LIST OF PRESERVATIVES ALLOWED

Reference No.	Substance	Maximum authorised concentration	Other 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 (*)	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 ⁽¹⁾
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts	0.6% (acid)		
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)	
7	Biphenyl-2-ol (o-phenylphenol) and its salts	0.2% expressed as the phenol		
8	Zinc pyrithione (*) (CAS No 13463-41-7)	Hair products: 1.0% Other products: 0.5%	Rinse-off products only. No use in products for oral hygiene	
9	Inorganic sulphites and hydrogen sulphites (*)	0.2% expressed as free SO ₂		
11	Chlorobutanol (INN)	0.5%	Prohibited in aerosol dispensers (sprays)	Contains chlorobutanol

Schedule 7 – Preservatives Cosmetic Products May Contain with Restrictions

Reference No.	Substance	Maximum authorised concentration	Other limitations and Requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
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 (Dehydracetic 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
18	Undec-10-enoic acid and 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%		

Schedule 7 – Preservatives Cosmetic Products May Contain with Restrictions

Reference No.	Substance	Maximum authorised concentration	Other limitations and Requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
23	Triclocarban (INN) (*)	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 the products intended to come into contact with mucous membranes	
25	Tricolosan (INN)	0.3%		
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 (INNM)	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 (*)	1.0%		
35	1-Hydroxy-4-methyl-6(2,4,4-trimethylpentyl) 2-pyridon and its monoethanolamine salt	1.0% 0.5%	Products rinsed off For other products	
37	6,6-Dibromo-4,4-dichloro2,2'-methylenediphenol (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 with magnesium chloride and magnesium nitrate	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	2-Benzyl-4-chlorophenol (clorophene)	0.2%		

Schedule 7 – Preservatives Cosmetic Products May Contain with Restrictions

Reference No.	Substance	Maximum authorised concentration	Other limitations and Requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
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 (*)	1.0%	Only for rinse-off products	
44	Alkyl (C12-C22) trimethyl ammonium, bromide and chloride (*)	0.1%		
45	4,4-dimethyl-1,3-oxizalidine	0.1%	The pH of the finished product must not be lower than 6	
46	N-(Hydroxymethyl)-N-(dihydroxymethyl- 1,3-dioxo-2,5-imidazolidinyl-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	
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	

Schedule 7 – Preservatives Cosmetic Products May Contain with Restrictions

Reference No.	Substance	Maximum authorised concentration	Other limitations and Requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
53	Benzethonium chloride	0.1%	(a) Rinse-off products only (b) Leave-on products other than for oral care use	
54	Benzalkonium chloride, bromide and saccharinate (+)	0.1% calculated as benzalkonium chloride		Avoid contact with eyes
55	Benzylhemiformal	0.15%	Only for products to be removed by rinsing	
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 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)	0.01%		

(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 shampoo, 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.

TABLE 2: LIST OF ADDITIONAL PRESERVATIVES ALLOWED IN NEW ZEALAND

Reference No.	Substance	Maximum authorised concentration	Other limitations and Requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	Quaternium-15 (Dowicil 200)		See preamble item 5	Contains formaldehyde if free formaldehyde exceeds 0.05%