

Draft for Comments Only

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BUREAU OF INDIAN STANDARDS
Draft Indian Standard

**Classification Of Cosmetic Raw Materials And Adjuncts – List of
Preservatives Allowed In Cosmetics with Restriction**

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ICS 71.100.70

Cosmetics Sectional Committee, PCD 19

FOREWORD

(Formal clauses will be added later)

With the objective of taking effective step in guarding against harmful substances being used in cosmetics, the Cosmetics Sectional Committee prepared a broad-based classification of raw materials as (a) 'Generally Recognized as Safe' (GRAS) and (b) 'Generally Not Recognized as Safe' (GNRAS). In view of the large number of raw materials which were likely to be used for different intended purposes in cosmetics formulations, such as colourants, preservatives, U.V. filters, basic ingredients, adjuncts etc, it was more convenient and practical to prepare GRAS list for 'colourants' and GNRAS list for other raw materials and adjuncts to serve the intended purpose of safeguarding the interest of the consumer and simultaneously leaving enough scope for innovations in formulations. Towards this purpose, this standard (Part 2) was originally published in 1973 for GNRAS list of raw materials and adjuncts other than Dyes, Colour and Pigments and Part 1 was published in 1968 for GRAS list for Dyes, Colour and Pigments (since

retitled as colourants).

This standard, IS 4707 (Part 2) was first revised in 1993 to update the list to align with the provisions of EEC Directive 76/768/EEC - June 1991 and to include the lists of a) substances which the cosmetic products shall not contain, except subject to conditions and restrictions laid down, b) allowed preservatives and c) U.V. filters for use in cosmetics. Substances, which were provisionally allowed by EEC Directive, were also included in the first revision. The second revision of this standard was done in 2001 to update the list, aligning it with the provisions of EEC Directive 76/768/EEC-2001. Further, the raw materials listed in Annex A (substances which are generally not recognized as safe for use in cosmetics) and Annex B (the list of substances which cosmetic products must not contain except subject to restrictions and conditions laid down) were arranged in alphabetical order for easy referencing. The third revision of the standard was carried out in 2009 to further update the list, aligning it with the revised EEC Directive 76/768/EEC-2007 with marginal differences in certain parameters as per the restrictions given in The Drugs and Cosmetics Act and Rules 1945 (such as permissible limits of fluoride in dentifrice and m-, p-phenylene diamines for use in hair dyes). Substances provisionally allowed by EEC Directive were not included in this revision.

The fourth revision was done to further align the standard with the EEC Directive 76/768/EEC-2012. Substances provisionally allowed by EEC Directive continued to be excluded from the Standard.

The current revision (fifth draft revision) is being done to update IS 4707 (Part 2) in line with the latest EC 1223/2009 and to trifurcate it as follows:

1. IS 4707 (Part 2) for GNRAS and restricted ingredients.
2. IS 4707 (Part 3) for preservatives allowed with restrictions
3. IS 4707 (Part 4) for U.V. filters allowed with restrictions

Accordingly, in this revision only preservatives allowed with restrictions are included under IS 4707 Part 3.

It is not the intent of this standard to prescribe any specific composition of finished cosmetic products. The manufacturers are encouraged to develop any composition through innovations and keeping pace with the technological advancements, provided that the provisions of this standard are complied with.

At present, there is no International Standard published by International Organization for Standardization (ISO) on the subject.

1 SCOPE

This standard (Part 3) lists cosmetics raw materials and adjuncts which can be classified as Preservatives which are allowed with restrictions.

2 TERMINOLOGY

For the purpose of this Standard, the following definitions shall apply:

2.1 'GRAS List' — Ingredients which are generally recognized as safe and which when used in the concentration conventionally adopted shall be permissible in cosmetics.

2.2 'GNRAS List' — Ingredients which are generally not recognized as safe and which shall not be permissible either in any amount whatsoever or in amounts exceeding those specifically laid down for cosmetics.

NOTE — An ingredient classified as 'GNRAS' may be present as an impurity when its concentration is less than what can be detected by standard analytical method. It shall not, however, be used as a component of a preparation.

3 GNRAS LISTS FOR RAW MATERIALS AND ADJUNCTS

The raw materials and adjuncts prescribed in this standard have been classified as follows:

3.1 Annex A – List of preservatives, which are allowed with restrictions.

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 specific purposes apparent from the presentation of the products, for example, 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 Annex
4. For the purposes of this list:
 - a) 'Salts' is taken to mean: salts of the cations sodium, potassium, calcium, magnesium, ammonium and ethanolamines; salts of the anions chloride, bromide, sulphate, acetate.
 - b) '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 percent~~

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ANNEX.A

LIST OF PRESERVATIVE ALLOWED WITH RESTRICTIONS – PART 3

S. No.	Chemical Name	Maximum Authorised Concentration	Product Type, Body parts and other conditions	Wordings of conditions of use and warnings which must be printed on the label
1.	Benzoic acid and its sodium salts Benzoic acid (CAS No. 65-85-0) Sodium Benzoate (CAS No. 532-32-1)	a) 2.5 % (acid) b) 1.7 % (acid) c) 0.5 % (acid)	a) Rinse-off products except oral products b) Oral products c) Leave on products	—
2.	Salts of benzoic acid other than listed under reference No.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. 2315-68-6) 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)		

3.	Propionic acid and its salts Propionic acid (CAS No. 79-09-4) 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)		—
4.	Salicylic acid and its salts (*) Salicylic acid (CAS No. 69-72-7) 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)	Not to be used in products for children under 3 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. Not to be used in products for children under 3 years of age, except for shampoos.	Not to be used for children under 3 years of age ¹⁾ Not to be used for children under 3 years of age ²⁾
5	Hexa-2,4-dienoic acid and its salts Sorbic acid (CAS No. 110-44-1) Calcium sorbate (CAS No. 7492-55-9)	0.6 % (acid)		

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	Sodium sorbate (CAS No. 7757-81-5) Potassium sorbate (CAS No. 24634-61-5)			
6	Formaldehyde, paraformaldehyde (*) Formaldehyde (CAS No. 50-00-0) Paraformaldehyde (CAS No. 30525-89-4)	a) 0.1 % (free formaldehyde) b) 0.2 % (free formaldehyde)	a) Oral products b) Other products Not to be used in aerosol dispensers (Sprays)	
7	Biphenyl-2-ol, and its salts o-Phenylphenol (CAS No. 90-43-7) Sodium o-phenylphenate, (CAS No. 132-27-4) Potassium o-phenylphenate (CAS No. 13707-65-8) MEA o-phenylphenate (CAS No. 84145-04-0)	a) 0.2 % (as phenol) b) 0.15 % (as phenol)	a) Rinse-off products b) Leave-on products	Avoid contact with eyes
8	Pyrithione zinc (*) (CAS NO. 13463-41-7) Zinc pyrithione	a) 1.0% b) 0.5%	a) Hair products b) Other products Only in rinse-off products Not to be used in oral products	
9	Inorganic sulphites and hydrogen- sulphites (*) 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. 7773-03-7) Sodium bisulfite	0.2 % (as free SO ₂)		

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	(CAS No. 38566-94-8) Potassium propylparaben (CAS No.84930-16-5)			
12	3-Acetyl-6-methylpyran-2,4 (3H)-dione and its salts Dehydroacetic acid (CAS No. 520-45-6/16807-48-0) Sodium dehydroacetate (CAS No. 4418-26-2)	0.6 % (as acid)	Not to be used in aerosol dispensers (sprays)	
13	Formic acid and its sodium salt Formic acid (CAS No. 64-18-6) Sodium formate (CAS No. 141-53-7)	0.5 % (as acid)		
14	3,3'-Dibromo-4,4'-hexamethylenedioxydibenzamidine and its salts (including isethionate) Dibromohexamidine Isethionate (CAS No. 93856-83-8)	0.1 %		
15	Thiomersal Thimerosal (CAS NO. 54-64-8)	0,007 % (of Hg) If mixed with other mercurial compounds authorised by this Standard, the maximum concentration of Hg remains fixed at 0,007 %	Eye products	Contains Thiomersal
16	Phenylmercuric salts (including borate) Phenyl Mercuric Acetate (CAS No. 62-38-4) Phenyl Mercuric Benzoate (CAS No. 94-43-9)	0,007 % (of Hg) If mixed with other mercurial compounds authorised by this Standard, the maximum concentration of Hg remains fixed at 0.007 %	Eye products	Contains Phenylmercuric compounds
17	Undec-10-enoic acid and its salts Undecylenic acid (CAS No. 112-38-9) potassium undecylenate (CAS No. 6159-41-7) sodium undecylenate (CAS No. 3398-33-2) Calcium undecylenate (CAS No. 1322-14-1) TEA-undecylenate	0.2 % (as acid)		

	(CAS No. 84471-25-0) MEA-undecylenate (CAS No. 56532-40-2)			
18	5-Pyrimidinamine, 1,3-bis (2-ethylhexyl) hexahydro-5-methyl- Hexetidine (CAS No. 141-94-6)	0.1%		
19	5-Bromo-5-nitro-1,3-dioxane (CAS No. 30007-47-7)	0.1 %	Rinse-off products Avoid formation of nitrosamines	
20	Bronopol 2-Bromo-2-nitropropane-1,3-diol (CAS No. 52-51-7)	0.1%	Avoid formation of nitrosamines	
21	2,4-Dichlorobenzyl alcohol Dichlorobenzyl Alcohol (CAS No. 1777-82-8)	0.15 %		
22	1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl) urea (*) Triclocarban (CAS No. 101-20-2)	0.2 %	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene <1 ppm 3,3',4,4'-Tetrachloroazoxybenzene <1 ppm	
23	Chlorocresol p-Chloro-m-Cresol (CAS No. 59-50-60)	0.2%	Not to be used in products applied on mucous membranes	
24	5-Chloro-2- (2,4- dichlorophenoxy) phenol Triclosan (CAS No. 3380-34-5)	a) 0.3 % b) 0.2 %	a) Toothpastes, hand soaps, body soaps/shower gels, deodorants (non-spray), face powders and blemish concealers, nail products for cleaning the fingernails and toenails before the application of artificial nail systems b) Mouthwashes	— —
25	Chloro-xyleneol Chloroxylenol (CAS No. 88-04-0/1321-23-9)	0.5 %		
26	N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioximidazolidin-4-yl]urea] Imidazolidinyl urea (CAS No. 39236-46-9)	0.6 %		

27	<p>Polyhexamethylenbiguanide hydrochloride [1]: poly((iminimidocarbonyl)iminohexamethylene hydrochloride [2]: Poly((aminocarbonimidoyliminocarbonimidoylimino-1,6-hexanediy)) [3]; [4]</p> <p>Polyaminopropyl biguanide (CAS No. 32289-58-0, 27083-27-8, 70170-61-5/ 28757-47-3/133029-32-0)</p>	<p>0.2-4% 0.11%</p>		<p>Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation'</p>
28	<p>2-Phenoxyethanol Phenoxyethanol (CAS No. 122-99-6)</p>	1.0 %		
29	<p>Methenamine (CAS No. 100-97-0)</p>	0.15 %		
30	<p>Methenamine 3-chloroallylochloride Quaternium-15 (CAS No. 4080-31-3)</p>	0.2 %		
31	<p>1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one (*) Climbazole (*) (CAS No. 38083-17-9)</p>	<p>0.5 % (a) 0.2 % (b) 0.2 % (c) 0.2 % (c)(d) 0.5 %</p>	<p>(a) Hair lotions (b) Face creams (c) Foot care products (d) Rinse-off shampoo</p>	
32	<p>1,3-Bis (hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione DMDM Hydantoin (CAS No. 6440-58-0)</p>	0.6 %		
33	<p>Benzyl alcohol (*) (CAS No. 100-51-6)</p>	1.0 %		
34	<p>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)</p>	<p>a) 1.0 % b) 0.5 %</p>	<p>a) Rinse-off products b) Other products</p>	

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	Piroctone Olamine (CAS No. 68890-66-4)			
35	2,2'-methylenebis(6-bromo-4-chlorophenol) Bromochlorophene (CAS No. 15435-29-7)	0.1 %		
36	4-Isopropyl-m-cresol o-Cymen-5-ol (CAS No. 3228-02-2)	0.1 %		
37	Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one Methylchloroisothiazolinone and Methylisothiazolinone ⁽²⁾ (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	
38	2-Benzyl-4-chlorophenol Chlorophene (CAS No. 120-32-1)	0.2 %		
39	Chloroacetamide Chloroacetamide (CAS No. 79-07-2)	0.3 %		Contains chloroacetamide
40	N,N'-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13- tetraazatetradecanediamidine and its digluconate, diacetate and dihydrochloride Chlorhexidine (CAS No. 55-56-1) Chlorhexidine Diacetate (CAS No. 56-95-1) Chlorhexidine Digluconate (CAS No. 18472-51-0) Chlorhexidine Dihydrochloride (CAS No. 3697-42-5)	0.3 % (as chlorhexidine)		
41	1-Phenoxypropan-2-ol (*) Phenoxyisopropanol (CAS No. 770-35-4)	1.0 %	Only for rinse-off products	

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42	Alkyl (C 12-22) trimethyl ammonium bromide and chloride Behentrimonium Chloride (*) (CAS No. 17301-53-0) Cetrimonium bromide (CAS No. 57-09-0) Cetrimonium chloride (*) (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 (*) (CAS No. 112-03-8)	0.1 %		
43	4,4-Dimethyl-1,3-oxazolidine Dimethyl Oxazolidine (CAS No. 51200-87-4)	0.1 %	pH > 6	
44	N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl) urea Diazolidinyl Urea (CAS No. 78491-02-8)	0.5 %		
45	Benzenecarboximidamide, 4,4'-(1,6-hexanediylbis (oxy))bis- and its salts (including isethionate and p-hydroxybenzoate) Hexamidine, (CAS No. 3811-75-4) Hexamidine diisethionate (CAS No. 659-40-5) Hexamidine paraben/ Hexamidine diparaben (CAS No. 93841-83-9)	0.1 %		
46	Glutaraldehyde (Pentane-1,5-dial) Glutaral (CAS No. 111-30-8)	0.1 %	Not to be used in aerosols (sprays).	Contains glutaral ⁽⁵⁾
47	5-Ethyl-3,7-dioxo-1-azabicyclo [3.3.0] octane 7-Ethylbicyclooxazolidine	0,3 %	Not to be used in oral products and in products applied on mucous membranes	

	(CAS No. 7747-35-5)			
48	3-(p-Chlorophenoxy)-propane-1,2 diol Chlorphenesin (CAS No. 104-29-0)	0,3 %		
49	Sodium hydroxymethylamino acetate Sodium Hydroxymethylglycinate (CAS No. 70161-44-3)	0,5 %		
50	Silver chloride deposited on titanium dioxide Silver chloride (CAS No. 7783-90-6)	0,004 % (as AgCl)	20 % AgCl (w/w) on TiO ₂ . Not to be used in products for children under 3 years of age, in oral products and in eye and lip products.	
51	Benzenemethanaminium, N,N-dimethyl-N-[2-[4-(1,1,3,3,-tetramethylbutyl)phenoxy] ethoxy]ethyl]-, chloride Benzethonium Chloride (CAS No. 121-54-0)	0,1 %	(a) Rinse-off products (b) Leave-on products other than oral products	
52	Benzalkonium chloride, bromide and saccharinate (*) 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 % (as Benzalkonium chloride)		Avoid contact with eyes
53	Methanol, (phenylmethoxy-) Benzylhemiformal (CAS No. 14548-60-8)	0.15%	Rinse-off products	
54	3-Iodo-2-propynylbutylcarbamate Iodopropynyl butylcarbamate (CAS No. 55406-53-6)	(a) 0.02 % (b) 0.01 %, (c) 0.0075 %	Not to be used in oral and lip products (a) Rinse-off products Not to be used in products for children under 3 years of age, except in bath products/ shower gels and shampoo (b) Leave-on products Not to be used in body lotion and body cream ⁽⁴⁾	(a) Not to be used for children under 3 years of age ⁽⁵⁾ (b) and (c) Not to be used in products for children under 3 years of age. ⁽⁶⁾

			(c) Deodorants/Anti-perspirants (b) and (c) Not to be used in products for children under 3 years of age.	
55.	2-Methyl-2H-isothiazol-3-one Methylisothiazolinone ⁽⁷⁾ (CAS No. 2682-20-4)	0.0015%	Rinse-off products	
56.	Ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride (*) Ethyl Lauroyl Arginate HCl (CAS No. 60372-77-2)	a) 0.15% b) 0.4%	(a) Mouthwashes Not to be used in preparations for children under 10 years of age (b) Other products Not to be used in lip products, oral products (other than mouthwashes), and spray products	(a) Not to be used in preparations for children under 10 years of age
57.	1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate and 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, silver (¹⁺) salt, monohydrate. Citric acid (and) Silver citrate	0.2 %, corresponding to 0.0024 % of silver	Not to be used in oral products and eye products	
58.	4-(3-ethoxy-4-hydroxyphenyl)butan-2-one Hydroxyethoxy- phenyl Butanone (CAS No. 569646-79-3)	0.7%		

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- Note:
- (1) Solely for products which might be used for children under 3 years of age.
 - (2) Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin
 - (2) Methylisothiazolinone is also regulated in entry 55. 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.
 - (3) Only if the concentration exceeds 0.05 %.
 - (4) Concerns any products aimed to be applied on a large part of the body.
 - (5) Solely for products, other than bath products/shower gels and shampoo, which might be used for children under 3 years of age.
 - (6) Solely for products which might be used for children under 3 years of age.
 - (7) Methylisothiazolinone is also regulated in entry 37 of Part 3 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.