**IS 4707 (PART 3): 2024**

***भारतीय मानक***

***Indian Standard***

**कॉस्मेटिक कच्चे माल और सहायक**

**पदार्थों का वर्गीकरण**

**भाग 3 सौंदर्य प्रसाधनों में प्रतिबंध के साथ अनुमत परिरक्षकों की सूची**

*(पांचवां पुनरीक्षण)*

**Classification of Cosmetic Raw Materials and Adjuncts**

**Part 3 List of Preservatives Allowed in Cosmetics with Restriction**

*(Fifth Revision)*

ICS 71.100.70

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भारतीय मानक ब्यूरो



BUREAU OF INDIAN STANDARDS

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**December 2024 Price Group X**

Cosmetics Sectional Committee, PCD 19

FOREWORD

This Indian Standard (Part 3) (Fifth Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Cosmetics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

With the objective of taking effective step in guarding against harmful substances being used in cosmetics, the Cosmetics Sectional Committee had decided to prepare 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 no. 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 (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. 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.

Currently all the ingredients prescribed in this standard have been classified into four categories:

a) Annex A — Ingredients which must not form part of the composition of cosmetic products;

b) Annex B — Ingredients which cosmetic products must not contain except subject to restrictions and conditions laid down;

c) Annex C — Preservatives (with restrictions) which cosmetic products may contain; and

d) Annex D — U.V. filters which cosmetic products (with restrictions) may contain.

Now the committee has decided to trifurcate the standard as Part 2, Part 3, and Part 4. Part 2 will contain the list of substances as given in Annex A and Annex B. Part 3 will contain the list of preservatives as given in Annex C. Part 4 will contain the list of U.V. filters as given in Annex D.

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.

The fifth revision is being done to further align the standard in line with the latest EC 1223/2009 and this part of the standard also contains the list of preservatives allowed in cosmetics with restriction in as given in Annex C of IS 4707 (Part 2): 2017.

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

The composition of the Committee responsible for the formulation of this revision is listed in Annex B.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (second revision)’. The number of significant places retained in the rounded value should be the same as that of the specified value in this standard.

*Indian Standard*

CLASSIFICATION OF COSMETIC RAW MATERIALS AND ADJUNCTS

**PART 3 LIST OF PRESERVATIVES ALLOWED IN COSMETICS WITH RESTRICTION**

*(Fifth Revision)*

**1 SCOPE**

This standard (Part 3) lists cosmetics raw materials and adjuncts, which can be classified as Preservatives, and 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.

**2.3 Preservatives** — Preservatives are substances, which may be added to cosmetic products for the primary purpose of inhibiting the development of microorganisms in such products.

**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 in Cosmetics.

NOTES

**1** 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.

**2** 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.

**3** 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.

**4** 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.

**ANNEX A**

(*Clause* 3.1)

**LIST OF PRESERVATIVES ALLOWED WITH RESTRICTIONS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sl. 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) | 1. (a) 2.5 percent (acid) 2. (b) 1.7 percent (acid) 3. (c) 0.5 percent (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 percent (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 percent (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) | (a) Salicylic acid: 0.5 percent (acid)  (b) Salicylic acid salts: 0.5 percent (acid) | (a) Salicylic 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.  (b) Salicylic acid salts:  Not to be used in products for children under 3 years of age, except for shampoos. | Salicylic acid:  Not to be used for children under 3 years of age 1)  Salicylic acid salts:  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)  Sodium sorbate  (CAS No. 7757-81-5)  Potassium sorbate  (CAS No. 24634-61-5) | 0.6 percent (acid) |  |  |
| 6 | Biphenyl-2-ol,  o-Phenylphenol  (CAS No. 90-43-7) | 1. (a) 0.2 percent (as phenol) 2. (b) 0.15 percent (as phenol) | (a) Rinse-off products  (b) Leave-on products | Avoid contact with eyes |
| 7 | Pyrithione zinc (\*)  (CAS NO. 13463-41-7)  Zinc pyrithione | 1. (a) 1.0 percent 2. (b) 0.5 percent | (a) Hair products  (b) Other products  Only in rinse-off products  Not to be used in oral products |  |
| 8 | 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  (CAS No. 7631-90-5)  Sodium metabisulfite  (CAS No.7681-57-4)  Potassium metabisulfite  (CAS No. 16731-55-8) | 0.2 percent (as free SO2) |  |  |
| 9 | Chlorobutanol  (CAS No. 57-15-8) | 0.5 percent | Not to be used in aerosol dispensers (sprays). | Contains Chlorobutanol |
| 10 | a) 4-Hydroxybenzoic acid and its Methyl- and Ethyl- esters, and their salts  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)  b) 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) | 1. (a) 0.4 percent (as acid) for single ester, 0.8 percent (as acid) for mixtures of esters 2. (b) 0.14 percent (as acid) for sum of the individual concentration, 0.8 percent (as acid) for mixtures of substances mentioned in entry 11a and b, where the sum of the individual concentrations of butyl and propyl paraben and their salts does not exceed 0.14 percent | 1. Not to be used in leave-on products designed for application on the nappy area of children under three years of age. | 1. For leave-on products designed for children under three years of age. “Do not use on the nappy area.” |
| 11 | 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 percent (as acid) | Not to be used in aerosol dispensers (sprays) |  |
| 12 | Formic acid and its sodium salt  Formic acid  (CAS No. 64-18-6)  Sodium formate  (CAS No. 141-53-7) | 0.5 percent (as acid) |  |  |
| 13 | 3,3'-Dibromo-4,4'-hexamethylenedioxydibenzamidine and its salts (including isethionate)  Dibromohexamidine Isethionate  (CAS No. 93856-83-8) | 0.1 percent |  |  |
| 14 | Thiomersal  Thimerosal  (CAS NO. 54-64-8) | 0.007 percent (of Hg)  If mixed with other mercurial compounds authorised by this Standard, the maximum concentration of Hg remains fixed at 0.007 percent | Eye products | Contains Thiomersal |
| 15 | Phenylmercuric salts (including borate)  Phenyl Mercuric Acetate  (CAS No. 62-38-4)  Phenyl Mercuric Benzoate  (CAS No. 94-43-9) | 0.007 percent (of Hg)  If mixed with other mercurial compounds authorised by this Standard, the maximum concentration of Hg remains fixed at 0.007 percent | Eye products | Contains Phenylmercuric compounds |
| 16 | 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  (CAS No. 84471-25-0)  MEA-undecylenate  (CAS No. 56532-40-2) | 0.2 percent (as acid) |  |  |
| 17 | 5-Pyrimidinamine, 1,3-bis (2-ethylhexyl) hexahydro-5-methyl-  Hexetidine  (CAS No. 141-94-6) | 0.1 percent |  |  |
| 18 | 5-Bromo-5-nitro-1,3-dioxane  (CAS No. 30007-47-7) | 0.1 percent | Rinse-off products  Avoid formation of nitrosamines |  |
| 19 | Bronopol  2-Bromo-2-nitropropane-1,3-diol  (CAS No. 52-51-7) | 0.1 percent | Avoid formation of nitrosamines |  |
| 20 | 2,4-Dichlorobenzyl alcohol  Dichlorobenzyl Alcohol  (CAS No. 1777-82-8) | 0.15 percent |  |  |
| 21 | 1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl) urea (\*)  Triclocarban  (CAS No. 101-20-2) | 0.2 percent | Purity criteria: 3,3',4,4'-Tetrachloroazobenzene <1 ppm 3,3',4,4'-Tetrachloroazoxybenzene <1 ppm |  |
| 22 | Chlorocresol  p-Chloro-m-Cresol  (CAS No. 59-50-60) | 0.2 percent | Not to be used in products applied on mucous membranes |  |
| 23 | 5-Chloro-2- (2,4- dichlorophenoxy) phenol  Triclosan  (CAS No. 3380-34-5) | 1. 0.3 percent 2. 0.2 percent | 1. 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 2. Mouthwashes | ―  ― |
| 24 | Chloro-xylenol  Chloroxylenol  (CAS No. 88-04-0/1321-23-9) | 0.5 percent |  |  |
| 25 | N,N″-methylenebis[N′-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]  Imidazolidinyl urea  (CAS No. 39236-46-9) | 0.6 percent |  |  |
| 26 | Poly hexamethylenebiguanide hydrochloride  Polyaminopropyl biguanide  (CAS No. 32289-58-0, 27083-27-8,/ 28757-47-3/133029-32-0) | 0.1 percent |  | Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation’ |
| 27 | 2-Phenoxyethanol  Phenoxyethanol  (CAS No. 122-99-6) | 1.0 percent |  |  |
| 28 | Methenamine  (CAS No. 100-97-0) | 0.15 percent |  |  |
| 29 | 1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one (\*)  Climbazole (\*)  (CAS No. 38083-17-9) | 1. (a) 0.2 percent 2. (b) 0.2 percent 3. (c) 0.2 percent 4. (d) 0.5 percent | 1. Hair lotions 2. Face creams 3. Foot care products 4. Rinse-off shampoo |  |
| 30 | 1,3-Bis (hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione  DMDM Hydantoin  (CAS No. 6440-58-0) | 0.6 percent |  |  |
| 31 | Benzyl alcohol (\*)  (CAS No. 100-51-6) | 1.0 percent |  |  |
| 32 | 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. (a) 1.0 percent 2. (b) 0.5 percent | a) Rinse-off products  b) others products |  |
| 33 | 2,2’-methylenebis(6-bromo-4-chlorophenol)  Bromochlorophene  (CAS No. 15435-29-7) | 0.1 percent |  |  |
| 34 | 4-Isopropyl-m-cresol  o-Cymen-5-ol  (CAS No. 3228-02-2) | 0.1 percent |  |  |
| 35 | Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one  Methylchloroisothiazolinone and Methylisothiazolinone(2A)  (CAS No. 26172-55-4, 2682-20-4, 55965-84-9) | 0.0015 percent (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 |  |
| 36 | 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 percent (as chlorhexidine) |  |  |
| 37 | 1-Phenoxypropan-2-ol (\*)  Phenoxyisopropanol  (CAS No. 770-35-4) | 1.0 percent | Only for rinse-off products |  |
| 38 | 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)  Laurtrimonium bromide  (CAS No. 1119-94-4)  Laurtrimonium chloride  (CAS No. 112-00-5)  Steartrimonium bromide  (CAS No. 1120-02-1)  Steartrimonium chloride (\*)  (CAS No. 112-03-8) | 0.1 percent |  |  |
| 39 | 4,4-Dimethyl-1,3-oxazolidine  Dimethyl Oxazolidine  (CAS No. 51200-87-4) | 0.1 percent | pH > 6 |  |
| 40 | N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolidinyl-4)-N’-(hydroxymethyl) urea  Diazolidinyl Urea  (CAS No. 78491-02-8) | 0.5 percent |  |  |
| 41 | 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 percent |  |  |
| 42 | Glutaraldehyde (Pentane-1,5-dial)  Glutaral  (CAS No. 111-30-8) | 0.1 percent | Not to be used in aerosols (sprays). | Contains glutaral(3) |
| 43 | 5-Ethyl-3,7-dioxa-1-azabicyclo [3.3.0] octane  7-Ethylbicyclooxazolidine  (CAS No. 7747-35-5) | 0.3 percent | Not to be used in oral products and in products applied on mucous membranes |  |
| 44 | 3-(p-Chlorophenoxy)-propane-1,2 diol  Chlorphenesin  (CAS No. 104-29-0) | 0.3 percent |  |  |
| 45 | Sodium hydroxymethylamino acetate  Sodium Hydroxymethylglycinate  (CAS No. 70161-44-3) | 0.5 percent | 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 |  |
| 46 | Silver chloride deposited on titanium dioxide  Silver chloride  (CAS No. 7783-90-6) | 0.004 percent (as AgCl) | 20 percent AgCl (*w/w*) on TiO2. Not to be used in products for children under 3 years of age, in oral products and in eye and lip products. |  |
| 47 | Benzenemethanaminium, N,N-dimethyl-N-[2-[2-[4-(1,1,3,3,-tetramethylbutyl)phenoxy] ethoxy]ethyl]-, chloride  Benzethonium Chloride  (CAS No. 121-54-0) | 0.1 percent | 1. Rinse-off products 2. Leave-on products other than oral products |  |
| 48 | 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 percent (as Benzalkonium chloride) |  | Avoid contact with eyes |
| 49 | Methanol, (phenylmethoxy-)  Benzylhemiformal  (CAS No. 14548-60-8) | 0.15 percent | Rinse-off products |  |
| 50 | 3-Iodo-2-propynylbutylcarbamate  Iodopropynyl butylcarbamate  (CAS No. 55406-53-6) | (a) 0.02 percent  (b) 0.01 percent  (c) 0.0075 percent | 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)  (c) Deodorants/Anti-perspirants  (b) and (c) Not to be used in products for children under 3 years of age. | (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) |
| 51 | 2-Methyl-2H-isothiazol-3-one  Methylisothiazolinone(7)  (CAS No. 2682-20-4) | 0.0015 percent | Rinse-off products |  |
| 52 | Ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride (\*)  Ethyl Lauroyl Arginate HCl  (CAS No. 60372-77-2) | 1. (a) 0.15 percent 2. (b) 0.4 percent | 1. (a) Mouthwashes   Not to be used in preparations for children under 10 years of age   1. (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 |
| 53 | 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 percent, corresponding to 0.0024 percent of silver | Not to be used in oral products and eye products |  |
| 54 | 4-(3-ethoxy-4-hydroxyphenyl)butan-2-one  Hydroxyethoxy­ phenyl Butanone (CAS No. 569646-79-3) | 0.7 percent |  |  |

NOTES:

(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.

(2A) 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 percent.

(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.

**ANNEX B**

(*Foreword*)

**COMMITTEE COMPOSITION**

Cosmetics Sectional Committee, PCD 19

|  |  |
| --- | --- |
| *Organization* | *Representative(s)* |
| Central Drugs Standard Control Organization, New Delhi | DR. RAJEEV SINGH RAGHUVANSHI (***Chairperson***) |
| All India Cosmetic Manufacturers Association, Gurugram | MS KAJAL ANAND  SHRI VIRENDRA V. CHAVAN (*Alternate*) |
| CSIR - Indian Institute of Toxicology Research, Lucknow | DR. R. S. RAY  DR. A. B. PANT (*Alternate*) |
| Cavinkare Private Limited, Chennai | DR. T KUMAR  DR. GIREESH KUMAR (*Alternate*) |
| Central Drugs Standard Control Organization, New Delhi | SHRI ASEEM SAHU  MS SHRADDHA SRIVASTAVA (*Alternate*) |
| Central Drugs Testing Laboratory, Chennai | MS C. VIJAYA LAKSHMI |
| Central Drugs Testing Laboratory, Mumbai | SHRIMATI S. U. WARDE  SHRIMATI SUJATA S. KAISARE (*Alternate*) |
| [Central Revenue Control Laboratory, New Delhi](javascript:;) | SHRI V. SURESH  SHRI SHIVRAJ SINGH (*Alternate I*)  SHRI MRITUNJOY MAITY *(Alternate* II) |
| Chemstar Limited, Thane | SHRI SUNIL JOSHI |
| Colgate Palmolive India Limited, Mumbai | SHRI MANAS V. VYAS  MS SHRUTI HARDIKAR (*Alternate I*)  SHRI PURUSHOTTAM JADHAV *(Alternate* II) |
| Consumer Guidance Society of India, Mumbai | DR. SITARAM DIXIT  DR. M. S. KAMATH (*Alternate*) |
| Consumer Voice, New Delhi | SHRI H. WADHWA |
| Dabur India Limited, Sahibabad | SHRI PRASUN BANDYOPADHYAY  SHRI SONU PANWAR (*Alternate*) |
| Directorate of Drugs Control, West Bengal, Kolkata | SHRI K.R. CHAWLA |
| Directorate of Food and Drugs Administration, Goa | SHRIMATI JYOTI J. SARDESSAI |
| Drugs Control Department, Delhi | SHRI A.K. NASA  SHRI K. R. CHAWLA (*Alternate*) |
| Drugs Controller For The State of Karnataka, Bengaluru | SHRI P RAMESH |
| EnvisBE Solutions Private Limited, Mumbai | SHRI BENEDICT M. MASCARENHAS |
| [Food Safety and Drug Administration, Lucknow](javascript:;) | DR. ANITA BHATNAGAR JAIN  SHRI DINESH KUMAR TIWARI (*Alternate*) |
| Food and Drug Administration, Mumbai | SHRI O. S. SADHWANI |
| Food and Drugs Administration, Haryana | SHRI MANMOHAN TANEJA |
| Food and Drugs Control Administration, Ahmedabad | SHRI H.G. KOSHIA  SHRI V.R. SHAH (*Alternate*) |
| Galaxy Surfactants Limited, Mumbai | SHRI R. K. SINGH  SHRI SAGAR TRAILOKYA (*Alternate I*)  SHRI PRAMOD SABAT (*Alternate II*) |
| Godrej Consumer Products Limited, Mumbai | MS RUPINDER KAUR RAWAT  DR. MANOJ GAUR (*Alternate*) |
| [Himalaya Wellness Company , Bengalore](javascript:;) | SHRI SUKUMARAN D  DR. CHANDRIKA MAHENDRA (*Alternate*) |
| Hindustan Unilever Limited, Mumbai | MS VRINDA RAJWADE  DR. NIMISH SHAH (*Alternate*) |
| Hygienic Research Institute Private Limited, Mumbai | MS JAYASHREE ANAND  SHRI MANOJ SARKAR (*Alternate*) |
| ITC Life Sciences and Technology Centre, Bengaluru | DR. GURU PRASAD KV  DR. JOHN BOSCO STANISLAUS (*Alternate I*)  DR. JAMES BHASKAR (*Alternate II*) |
| Indian Beauty and Hygiene Association, Mumbai | MS MALATHI NARAYANAN |
| Indian Pharmacopoeia Commission, Ghaziabad | DR. ANIL KUMAR TEOTIA  DR. MANOJ KUMAR PANDEY (*Alternate*) |
| Johnson and Johnson Private Limited, Mumbai | DR. DILIP TRIPATHI  SHRI RAJNEESH KUMAR (*Alternate*) |
| [Kaya Limited, Mumbai](javascript:;) | MS RUCHI SUSHEEL MITTAL  MS MOHINI KUTE (*Alternate*) |
| Kelkar Education Trust's Scientific Research Centre, Mumbai | DR. S. S. BARVE |
| [Koel Colours Private Limited, Mumbai](javascript:;) | SHRI DHRUBHAI DESAI  SHRI RISHABH D. DESAI (*Alternate*) |
| Loreal India Private Limited, Mumbai | SHRI DHIMOY ROY  DR. GURUBASAVARAJA K. M. (*Alternate*) |
| [MSME Testing Center, New Delhi](javascript:;) | SHRI MANOJ KUMAR  SHRI VIPUL GAIKWARD (*Alternate*) |
| Marico Limited, Mumbai | DR. SHILPA VORA  SHRI PRABODH S. HALDE (*Alternate I*)  SHRI ASHISH YEKHE (*Alternate II*) |
| PETA India, Mumbai | DR. MANILAL VALLIYATE  DR. ANKITA PANDEY (*Alternate*) |
| Procter and Gamble India, Mumbai | SHRI GIRISH PARHATE |
| Voluntary Organisation in Interest of Consumer Education (VOICE), New Delhi | SHRI M. A. U. KHAN |
| [IN PERSONAL CAPACITY](javascript:;) (*1098, 10th Cross,7th Block, HMT Layout, Vidyaranyapura, Bengaluru - 560097*) | DR. SUNDARAM RAMACHANDRAN |
| BIS Directorate General | SHRIMATI MEENAL PASSI, SCIENTIST ‘F’/SENIOR DIRECTOR AND HEAD (PCD) [REPRESENTING DIRECTOR GENERAL (*Ex-Officio*)] |
| *Member Secretary*  SHRI RAJAT GUPTA  SCIENTIST ‘C’/ DEPUTY DIRECTOR  (PETROLEUM, COAL AND RELATED PRODUCTS), BIS | |