
सौन्दर्य प्रसाधन कच्ची सामग्री और सहायक सामग्री का वर्गीकरण

**भाग 4 प्रतिबंध के साथ कॉस्मेटिक में अनुमत
यू.वी. फिल्टर की सूची**

(पांचवां पुनरीक्षण)

Classification of Cosmetic Raw Materials and Adjuncts

**Part 4 List of U.V. filters Allowed in
Cosmetics with Restriction**

(Fifth Revision)

ICS 71.100.70

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FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Cosmetics Sectional Committee was 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 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 renamed 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.

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 update the list of U.V. filters in line with the latest EC 1223/2009 and this part of the standard also contains the list of U.V. filters as given in Annex D 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.

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Indian Standard

CLASSIFICATION OF COSMETIC RAW MATERIALS AND ADJUNCTS

PART 4 LIST OF U.V. FILTERS ALLOWED IN COSMETICS WITH RESTRICTION

(*Fifth Revision*)

1 SCOPE

This standard (Part 4) lists cosmetics raw materials and adjuncts which can be classified as U.V. Filters 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 UV filters, which are allowed with restrictions in Cosmetics

ANNEX A

(*Clauses 1 and 3.1*)

LIST OF PERMITTED U.V. FILTERS WHICH COSMETIC PRODUCTS MAY CONTAIN

For the purpose of this Standard, U.V. Filters are substances, which contained in cosmetic sunscreen products, are specifically intended to filter certain U.V. rays in order to protect the skin from certain harmful effects of these rays. These U.V. filters

may be added to other cosmetic products within the limits and under the condition laid down in this annex. Other U.V. filters used in cosmetic products solely for the purpose of protecting the product against U.V. rays are not included in this list.

Table 1 List of U.V. Filters Allowed in Cosmetics with Restriction

(Clause 3.1)

Sl No.	Substance	Maximum Authorized Concentration, Percent	Other Limitations and Requirements	Conditions of Use and Warnings which must be Printed on the Label
(1)	(2)	(3)	(4)	(5)
i)	<i>N,N,N-Trimethyl-4-(2-oxoborn-3-yldenemethyl) anilinium methyl sulphate</i> (CAS No. 52793-97-2) Camphor Benzalkonium Methosulfate	6	—	—
ii)	Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester/Homosalate (CAS No. 118-56-9) Homosalate	10	—	—
iii)	2-Hydroxy-4-methoxybenzophenone/ Oxybenzone (CAS No. 131-57-7) Benzophenone-3	6	Not more than 0.5 percent to protect product formulation.	Contains Benzophenone-3 ⁽¹⁾
iv)	2-phenylbenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts/Ensulizole (CAS No. 27503-81-7) Phenylbenzimidazole Sulfonic Acid	8 (as acid)	—	—

Table 1 (Continued)

Sl No.	Substance	Maximum Authorized Concentration, Percent	Other Limitations and Requirements	Conditions of Use and Warnings which must be Printed on the Label
(1)	(2)	(3)	(4)	(5)
v)	3,3'-(1,4-Phenylenedimethylene) bis (7,7-dimethyl-2-oxobicyclo-[2,2,1] hept-1-yl-methanesulfonic acid) and its salts/Ecamsule (CAS No. 92761-26-7/90457-82-2) Terephthalylidene Dicamphor Sulfonic Acid	10 (as acid)	—	—
vi)	1-(4-tert-Butylphenyl)-3-(4-methoxyphenyl) propane-1,3-dione/Avobenzene (CAS No. 70356-09-1) Butyl Methoxydibenzoylmethane	5	—	—
vii)	alpha-(2-Oxoborn-3-ylidene)-toluene-4-sulphonic acid and its salts (CAS No. 56039-58-8) Benzylidene Camphor Sulfonic Acid	6 (as acid)	—	—
viii)	2-cyano-3,3-diphenyl acrylic acid, 2-ethylhexyl ester/Octocrylene (CAS No. 6197-30-4) Octocrylene	10 (as acid)	—	—

Table 1 (Continued)

Sl No.	Substance	Maximum Authorized Concentration, Percent	Other Limitations and Requirements	Conditions of Use and Warnings which must be Printed on the Label
(1)	(2)	(3)	(4)	(5)
ix)	Polymer of N-{(2 and 4)-[(2-oxoborn-3-ylidene)methyl]benzyl} acrylamide (CAS No. 113783-61-2) Polyacrylamidomethyl Benzylidene Camphor	6	—	—
x)	2-Ethylhexyl 4-methoxycinnamate/Octinoxate (CAS No. 5466-77-3) Ethylhexyl Methoxycinnamate	10	—	—
xi)	Ethoxylated Ethyl-4-Aminobenzoate (CAS No. 116242-27-4) PEG-25 PABA	10	—	—
xii)	Isopentyl-4-methoxycinnamate /Amiloxate (CAS No. 71617-10-2) Isoamyl p-Methoxycinnamate	10	—	—
xiii)	2,4,6-Trianiino-(p-carbo-2'-ethylhexyl-1'-oxy)-1,3,5-triazine (CAS No. 88122-99-0) Ethylhexyl Triazone	5	—	—

Table 1 (Continued)

Sl No.	Substance	Maximum Authorized Concentration, Percent	Other Limitations and Requirements	Conditions of Use and Warnings which must be Printed on the Label
(1)	(2)	(3)	(4)	(5)
xiv)	Phenol,2-(2H-benzotriazol-2-yl)-4-methyl-6-(2-methyl-3-(1,3,3,3-tetramethyl-1-(trimethylsilyl)oxy)-disiloxanyl)propyl (CAS No. 155633-54-8) Drometrizole Trisiloxane	15	—	—
xv)	Benzoic acid, 4,4-((6-((4-(((1,1-dimethylethyl) amino) carbonyl) phenyl) amino)-1,3,5-triazine-2,4-diyl)diimino)bis-, bis (2-ethylhexyl) ester/Iscotrizinol (USAN) (CAS No. 154702-15-5) Diethylhexyl Butamido Triazole	10	—	—
xvi)	3-(4-Methylbenzylidene)-d1 camphor/Enzacamene (CAS No. 38102-62-4/36861-47-9) 4-Methylbenzylidene Camphor	4	—	—
xvii)	2-Ethylhexyl salicylate (Octisalate) (CAS No. 118-60-5) Ethylhexyl Salicylate	5	—	—

Table 1 (Continued)

Sl No. (1)	Substance (2)	Maximum Authorized Concentration, Percent (3)	Other Limitations and Requirements (4)	Conditions of Use and Warnings which must be Printed on the Label (5)
xviii)	2-Ethylhexyl 4-(dimethylamino)benzoate/ Padimate O (USAN : BAN) (CAS No. 21245-02-3) Ethylhexyl Dimethyl PABA	8	—	—
xix)	2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid and its sodium salt/Sulisobenzene (CAS No. 4065-45-6/6628-37-1) Benzophenone-4, Benzophenone-5	5 (as acid)	—	—
xx)	2,2'-Methylene-bis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethyl-butyl)phenol)/Bisoctrizole (CAS No. 103597-45-1) Methylene Bis-Benzotriazolyl Tetramethylbutylphenol	10 ³⁾	—	—
xxi)	Sodium salt of 2,2'-bis(1,4-phenylene)-1H-benzimidazole-4,6-disulphonic acid/Bisdisulizole disodium (USAN) (CAS No. 180898-37-7) Disodium Phenyl Dibenzimidazole Tetrasulfonate	10 (as acid)	—	—
xxii)	2,2'-(6-(4-Methoxyphenyl)-1,3,5-triazine-2,4-diyl)bis(5- (2-ethylhexyl)oxy)phenol/Bemotrizinol (CAS No. 187393-00-6) Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	10	—	—

Table 1 (Continued)

Sl No. (1)	Substance (2)	Maximum Authorized Concentration, Percent (3)	Other Limitations and Requirements (4)	Conditions of Use and Warnings which must be Printed on the Label (5)
xxiii)	Dimethicodiethylbenzalmalonate (CAS No. 207574-74-1) Polysilicone-15	10	—	—
xxiv)	Titanium dioxide ²⁾ (CAS No. 13463-67-7/1317-70-0/1317-80-2)	25	—	—
xxv)	Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexylester (CAS No. 302776-68-7) Diethylamino Hydroxybenzoyl Hexyl Benzoate	10	—	—
xxvi)	Zinc Oxide (CAS No. 1314-13-2)	25	Not to be used in applications that may lead to exposure of the end user's lungs by inhalation.	—
xxvii)	1,3,5-Triazine, 2,4,6- tris[1,1'-biphenyl]-4-yl- (CAS No. 31274-51-8) Tris-biphenyl triazine	10	Not to be used in sprays.	—
xxviii)	3,3'-(1,4-Phenylene)bis(5,6-diphenyl1,2,4-triazine) (CAS No. 55514-22-2) (Phenylene Bis-Diphenyltriazine)	5	Not to be used in applications that may lead to exposure of the end user's lungs by inhalation.	—

Table 1 (Concluded)

Sl No.	Substance	Maximum Authorized Concentration, Percent	Other Limitations and Requirements	Conditions of Use and Warnings which must be Printed on the Label
(1)	(2)	(3)	(4)	(5)
xxix)	2-ethoxyethyl (2Z)-2-cyano2-[3-(3-methoxypropylamino)cyclohex-2-en-1- ylidene]acetate Methoxypropylamino Cyclohexenylidene Ethoxyethylcyanoacetate (CAS No. 1419401-88-9)	3	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation — Do not use with nitrosating agents — Maximum nitrosamine content : 50 µg/kg — Keep in nitrite-free containers	—

NOTES

1 Not required if concentration is 0.5 percent or less and when it is used only for product protection purposes.

2 For use as a colorant, see IS 4707 (Part 1 : Colorants), No 144.

3 In case of combined use of methylene bis — Benzotriazolyltetramethylbutylphenol and methylene bis —benzotriazolyltetramethylbutylphenol (nano), the sum shall not exceed the limit given.

ANNEX B
(Foreword)

Cosmetics Sectional Committee, PCD 19

Cosmetics Sectional Committee, PCD 19

<i>Organization</i>	<i>Representative(s)</i>
Central Drugs Standard Control Organization, New Delhi	DR V. G. SOMANI (<i>Chairperson</i>)
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Cavinkare Private Limited, Chennai	DR T. KUMAR DR GIREESH KUMAR (<i>Alternate I</i>) DR S. SANKAR KALIDAS (<i>Alternate II</i>)
Central Drugs Standard Control Organization, New Delhi	DR S. P. SHANI
Central Drugs Testing Laboratory, Chennai	MS C. VIJAYA LAKSHMI DR. J. UMA MAHESWARI (<i>Alternate</i>)
Central Drugs Testing Laboratory, Mumbai	DR RAMAN MOHAN SINGH SHRIMATI S. U. WARDE (<i>Alternate I</i>) SHRIMATI SUJATA S. KAISARE (<i>Alternate II</i>)
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Colgate Palmolive India Limited, Mumbai	SHRI MANAS V. VYAS MS SHARDA GANESH (<i>Alternate I</i>) SHRI PURUSHOTTAM JADHAV (<i>Alternate II</i>)
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Directorate of Food and Drugs Administration, Goa	SHRIMATI JYOTI J. SARDESSAI
Drugs Control Department, Delhi	SHRI A.K. NASA SHRI K. R. CHAWLA (<i>Alternate I</i>)
Drugs Controller For The State of Karnataka, Bengaluru	SHRI P RAMESH
EnvisBE Solutions Private Limited, Mumbai	SHRI BENEDICT M. MASCARENHAS
Essential Oil Association of India, Delhi	SHRI AJAY K. JAIN
Food and Drug Administration, Mumbai	SHRI O. S. SADHWANI
Food and Drugs Administration, Haryana	SHRI NARENDER KUMAR AHOOJA SHRI MANMOHAN TANEJA (<i>Alternate I</i>)
Food and Drugs Control Administration, Ahmedabad	SHRI H.G. KOSHIA SHRI V. R. SHAH (<i>Alternate I</i>)
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SHRI SOURAV MONDAL
 SCIENTIST 'B'/ASSISTANT DIRECTOR
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This Indian Standard has been developed from Doc No.:PCD 19 (17650).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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