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BUREAU OF INDIAN STANDARDS

Draft Indian Standard

SUNSCREEN COSMETIC PRODUCTS — SPECIFICATION

ICS 71.100.70

Cosmetics sectional committee	Last date for receipt of comments is
PCD 19	**08 January 2023**

FOREWORD

(*Formal clauses will be added later*)

Sunscreen products are the cosmetic products extensively used by consumers to help prevent sunburn, and certain sunscreens also help reduce the risk of skin cancer and premature skin aging caused by the sun. When sunscreens first came on the market, they were used only occasionally at the beach and often as tanning aids. Now a days, people of all ages, ethnicities, and complexions are encouraged to use sunscreens liberally and reapply frequently whenever they are out in the sun and in conjunction with other sun-protective measures like seeking shade at peak hours and wearing protective clothing, hats, and sunglasses.

Increasing concerns over the effectiveness of sunscreen products available in the market for protection against harmful UV radiations of sunrays led to the need for the formulation of Indian Standard to ensure that the sunscreen products are safe and effective in achieving their purpose of protection against harmful UV radiation of sunrays as per the claim made.

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 off value should be the same as that of the specified value in this standard.

1 SCOPE

This standard prescribes the requirements and methods for sampling and test for Sunscreen Skincare leave-on products.

NOTE — Indian standard specifications are available for a number of cosmetics. In case, such cosmetics claim to have sun protection properties, they shall conform to the requirements of this standard along with the relevant Indian Standard.

2 REFERENCES

The standards which are necessary adjuncts to this standard are listed below. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standard:

IS No.	*Title*
IS 3958 : 2021	Methods of sampling cosmetics (*second revision*)
IS 4011 : 2018	Methods of test for safety evaluation of cosmetics (*third revision*)
IS 4707	Classification of cosmetic raw materials and adjuncts
(Part 1) : 2020	Colourants (*fourth revision*)
(Part 2) : 2017	List of raw materials generally not recognized as safe for use in cosmetics (*fourth revision*)
IS 17492 : 2021/ ISO 24442 : 2011	Cosmetics — Sun protection test methods — *In vivo* determination of sunscreen UVA protection
IS 17493 : 2021/ ISO 24443 : 2012	Cosmetics — Sun protection test methods — *In vitro* determination of sunscreen UVA protection
IS 17494 : 2021/ ISO 24444 : 2019	Cosmetics — Sun protection test methods — *In vivo* determination of sun protection factor (SPF)
IS 17660 : 2021/ ISO 16217 : 2020	Cosmetics — Sun protection test methods — Water resistance — Water immersion procedure

3 TERMINOLOGY

For the purpose of this standard the following definitions shall apply.

3.1 Sunscreen Products — Any leave-on skin care preparation (such as creams, Lotions, oils, gels, sprays etc.) intended to be placed in contact with the human skin for the purpose of absorbing, reflecting, or scattering radiation in the ultraviolet (UV) range at wavelengths from 290 to 400 nm.

3.2 Ultraviolet A (UVA) Radiation — electromagnetic radiation in the range of 320 nm. to 400 nm.

NOTE — UVA II = 320 nm to 340 nm; UVA I = 340 nm to 400 nm.

3.3 Ultraviolet B (UVB) Radiation — electromagnetic radiation in the range of 290 nm. to 320 nm.

3.4 Sun Protection Factor of a Product (SPF) — the ratio of minimum erythemal dose on skin protected by a sunscreen product to the minimum erythemal dose on the same unprotected skin

3.5 UVA Protection Factor of a Product (UVA PF)/(PA) — the ratio of the minimum UVA dose necessary to induce a persistent pigment darkening on the skin protected by a sunscreen product to the minimal UVA dose necessary to induce the minimal darkening effect on the same unprotected skin.

3.6 Critical Wavelength (λ_c) – the wavelength at which the integral of the absorption spectrum curve starting at 290 nm reaches 90% of the integral between 290 and 400 nm; for the type "Broad spectrum Protection". Refer Clause 4.3.

4 TYPES

4.1 Sunscreen Products with UVA Protection — based on UVA Protection Factor. IS 17492 to be prescribed as the test method for UVA Protection Factor.

4.2 Sunscreen Products with UVB Protection — based on Sun Protection Factor. IS 17494 to be prescribed as the test method for Sun Protection Factor.

4.3 Sunscreen Products with Broad Spectrum protection - The UVAPF/SPF Ratio must be at least 1/3 and the Critical Wavelength must be at least 370 nm. IS 17493 or the method mentioned in Annex B to be prescribed as the test method for Broad Spectrum.

4.4 Water Resistant Sunscreen Products — based on water resistance of sunscreen products. Water resistance of sunscreen product may be of 40 minutes or 80 minutes. IS 17660 to be prescribed as the test method for Water Resistance.

5 REQUIREMENTS

5.1 Unless specified otherwise, all the raw materials used in the manufacture of sunscreen products shall conform to the requirements prescribed in the relevant Indian Standards where these exist.

5.2 All ingredients of sunscreen products shall comply with the provisions of IS 4707 (Part 1) and IS 4707 (Part 2) subject to the provisions of the Drugs and Cosmetics Act, 1940 and Rules, 2020 framed there under.

5.3 The U.V. filters used in sunscreen products shall conform to IS 4707 (Part 4).

5.4 For safety evaluation of novel ingredients used in formulation of sunscreen products; it shall comply to IS 4011.

5.5 The minimum degree of protection provided by the sunscreen products shall be as follows:

(a) A UVB protection of Sun Protection Factor 10.0; and
(b) A UVA protection of UVA protection factor (PA) of 1/3 of the Sun Protection Factor.
(c) A Critical wavelength of 370nm or more

5.6 The sunscreen product with Sun Protection Factor claim shall also comply with the requirements given in Table 1 when tested as prescribed in col **4** of the Table 1.

NOTE — SPF claimed shall be as per result or one lower value

Table 1 Sun Protection Factor (SPF) Labelling Ranges for Sunscreen Products
(*Clause* **5.6**)

Sl No.	SPF Label	Measured SPF	Method of Test, Ref to IS
(1)	(2)	(3)	(4)
i)	10	10.0 – 14.9	IS 17494:2021
ii)	15	15.0 – 19.9	
iii)	20	20.0 – 24.9	
iv)	25	25.0 – 29.9	
v)	30	30.0 – 39.9	
vi)	40	40.0 – 49.9	
vii)	50	50.0 – 59.9	
viii)	50+	≥60.0	

NOTE — The SPF claimed on pack can be as per the result obtained within the brackets specified or lower allowed number

5.7 The sunscreen product with UVA Protection Factor claim shall also comply with the requirements given in Table 2 when tested as prescribed in col **4** of the Table 2.

Table 2 UVA Protection Factor Labelling Ranges for Sunscreen Products
(*Clause* **5.7**)

Sl No.	UVA Protection Factor Label	Measured UVA Protection Factor	Method of Test, Ref to IS
(1)	(2)	(3)	(4)
i)	PA+	2.0 – 3.9	IS 17492 : 2021 or IS 17493 : 2021
ii)	PA++	4.0 – 7.9	
iii)	PA+++	8.0 – 15.9	
iv)	PA++++	≥16.0	

NOTE — In case of any dispute, IS 17492 shall be treated as the referee method.

5.8 The sunscreen product with water resistance claim shall be tested for water resistance of 40 minutes or 80 minutes as per the test method prescribed in IS 17660.

5.9 For Broad Spectrum protection claim — The UVAPF/SPF Ratio must be at least 1/3 and the Critical Wavelength must be at least 370 nm. IS 17493 or the method mentioned in Annex B to be prescribed as the test method for Broad Spectrum.

6 PACKING AND MARKING

6.1 Packing

The sunscreen product shall be packed in suitable well closed containers.

6.2 Marking

The containers shall be legibly marked with the following information:

6.2.1 The wording "Sunscreen" or equivalent and "[dosage form]" (for example "lotion"/ "spray");

6.2.2 The wording "SPF [determined SPF value]", if applicable as per Clause 4 (types);

6.2.3 The wording "PA [determined UVA PF value]", if applicable as per Clause 4 (types);

6.2.4 The wording "Broad Spectrum SPF [determined SPF value]", if applicable as per Clause 4 (types);

6.2.5 The wording "Water resistant ([determined water resistance value] minutes)", if applicable as per Clause 4 (types);

6.2.6 Manufacturer's name and its recognized trade-mark, if any;

6.2.7 Net mass;

6.2.8 Batch number;

6.2.9 No claim shall be made that implies the following characteristics:

(i) 100 percent protection from UV radiation (such as 'sunblock', 'sunblocker' or 'total protection');

(ii) No need to re-apply the product under any circumstances (such as 'all day prevention').

6.2.10 Sunscreen products shall display warnings indicating that they do not provide 100 percent protection and advice on precautions to be observed in addition to their use. This may include warnings such as:

(i) 'Do not stay too long in the sun, even while using a sunscreen product';

(ii) 'Keep babies and young children out of direct sunlight';

(iii) 'Over-exposure to the sun is a serious health threat'.

6.2.11 Sunscreen products shall carry instructions for use that will ensure that the claim made for the effectiveness of the product can be achieved. This may include instructions such as:

(i) 'Apply the sunscreen product before exposure';

(ii) 'Re-apply frequently to maintain protection, especially after perspiring, swimming or toweling

6.2.12 Sunscreen products shall carry instructions for use to ensure that a sufficient quantity is applied on the skin to achieve the effectiveness claimed for the product.

6.2.13 List of ingredients as per statutory requirements.

6.2.14 Caution: "Children under 6 months of age : Consult a doctor.";

6.2.15 Warnings such as :

(i) "Do not use on damaged or broken skin."

(ii) "When using this product : Keep off eyes. Rinse with water to remove."

(iii) "Stop use and ask a doctor if rash occurs."

6.2.16 In addition to the above, the frequently asked questions as given at Annex A shall also be given (in the leaflet which is inserted in the container packing of the sunscreen product, or may be printed on the carton itself, as the case may be); and

6.2.17 Any other information required by statutory authorities.

6.3 BIS Certification Marking

The product may also be marked with the Standard Mark.

6.3.1 The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the standard mark.

7 SAMPLING

7.1 Representative samples of the product shall be drawn as prescribed in IS 3958.

7.2 Test for all characteristics shall be carried out on the composite sample.

7.3 The product shall be taken to have confined to the specification if the composite sample passes all the tests.

ANNEX A
(*Clause* **6.2.16)**

Sunscreen Products Related Frequently Asked Questions (FAQs) What is SPF?

'SPF' stands for 'Sun Protection Factor' which is the ratio of minimum erythemal dose on skin protected by a sunscreen product to the minimum erythemal dose on the same unprotected skin. SPF is more accurately the sun burn protection factor, as it primarily shows the level of protection against UVB, not the protection against UVA. SPFs are rated on a scale of 10-50^+ based on the level of protection they offer. Sun protection products are generally divided into the following four protection classes, termed as Low, Moderate, High and Very High, based on the level of their SPF label claims.

Label SPF	**Protection Class**
10	Low Protection
15, 20, 25	Medium Protection
30, 40,50	High Protection
50^+	Very High

A-1 WHAT IS TAN?

The dark pigment that gives the skin its natural colour is called melanin. Melanin is made in the skin by pigment cells called melanocytes. After our skin has been exposed to sunlight the melanocytes produce more melanin in attempt to absorb further UV radiation, and so the skin becomes darker. A tan is actually a sign that the skin has been damaged and is trying to protect itself.

A-2 WHO NEEDS SUNSCREEN?

Everyone regardless of age, gender or race. Sunscreen use can help prevent skin damage by protecting you from the sun's harmful ultraviolet rays.

A-3 WHAT ARE UVA AND UVB RADIATIONS?

Ultra Violet (UV) radiation from the sun is transmitted in three wavelengths – UVA (wavelength range from 320 nm to 400 nm), UVB (290 nm to 320 nm) and UVC (100 to 280 nm). UVC does not penetrate the earth's atmosphere, so we only need to protect against UVA and UVB.

UVA irradiation is associated with skin ageing. UVA affects the elastin in the skin and leads to wrinkles and sun-induced skin ageing (for example coarse wrinkles, leathery skin and brown pigmentation), as well as skin cancer. UVA can penetrate window glass and penetrates the skin more deeply than UVB. UVA protection in a sunscreen will help defend the skin against photo ageing and potentially skin cancer.

UVB is most responsible for sunburn and has strong links to malignant melanoma and basal cell carcinoma risk (types of skin cancer).

A-4 Why UVA protection factor labelling is important?

When compared to UVB, UVA is less dangerous but its penetration is deeper than UVB and sometimes its higher dose induces photo toxicity with or without exogenous sensitizers present in the blood. Thus, to avoid the phototoxic dose of UVA protectant should be applied on skin. Therefore, UVA PF labelling is important.

A-5 What is UVA rating system?

When you buy sunscreen containing UVA protection, you may notice a PA+/ ++/ +++/ ++++ rating on the packaging. The PA ranging from + to ++++ indicates the level of protection from UVA radiation.

A-6 WHAT DO YOU MEAN BY ORGANIC AND INORGANIC FILTERS?

Organic filters absorb harmful UV radiation and convert and give this energy back out as infrared. These are sometimes known as 'absorbers', or 'chemical' sunscreens. Note that organic filters does not mean 'organic' in the environmental sense.

Inorganic filters (also known as 'physical', 'natural', 'reflective', 'zinc') contain titanium dioxide or zinc oxide, which reflect UV radiation away from the skin.

It can be helpful to think of organic filters as sponges, mopping up the UV radiation, and inorganic filters as mirrors, bouncing UV straight back off the skin.

A-7 HOW MUCH SUNSCREEN SHOULD I APPLY?

To obtain the intended protection, you must follow the manufacturers' instructions for use and application. Therefore, always apply the amount of sunscreen indicated on the label and re-apply frequently. Remember the easily forgotten areas: tops of ears, behind knees, ankles, feet and eyelids.

Regardless of which sunscreen you choose, be sure to apply it generously to achieve the UV protection indicated on the product label.

A-8 WHEN SHOULD I USE SUNSCREEN?

Every day you go outside. The sun emits harmful UV rays year-round. Even on cloudy days, up to 80 percent of the sun's harmful UV rays can penetrate your skin. Snow, sand and water increase the need for sunscreen because they reflect the sun's rays.

A-9 HOW OFTEN SHOULD I APPLY SUNSCREEN?

Sunscreen should be re-applied frequently to maintain protection, especially after perspiring, swimming or towelling. You should always follow the manufacturers' instructions for use, application and re-application.

The frequency of re-application should correspond to how and when the product is being used, for example, when exposed to direct sunlight, on the beach, when swimming, doing sports, etc.

A-10 DO YOU USE SUNSCREEN TO STAY IN THE SUN LONGER?

Sunscreen products should not be used as a means to stay in the sun for prolonged periods. Over- exposure to the sun can be harmful and the use of sunscreen is one part of 'sun safe' behaviour.

A-11 DO YOU READ THE INFORMATION ON THE LABEL TO HELP YOU CHOOSE THE APPROPRIATE PRODUCT AND APPLY IT CORRECTLY?

Always read the label and choose the most appropriate product based on your skin sensitivity and the conditions under which you will be exposed to the sun. UV ray intensity will depend on the time of day, your geographical location and the weather.

A-12 WILL A HIGH SPF SUNSCREEN STOP ME GETTING A TAN?

No, you can still get a tan while wearing a high factor SPF. Wearing sunscreen will lower your risk of skin damage.

A-13 WILL USING SUNSCREEN LIMIT THE AMOUNT OF VITAMIN D I GET?

Using sunscreen may decrease your skin's production of vitamin D.

A-13.1 If you are concerned that you are not getting enough vitamin D, you should discuss your options for getting vitamin D with your doctor.

A-13.2 Many people can get the vitamin D they need from foods and/or vitamin supplements. This approach gives you the vitamin D you need without increasing your risk for skin cancer.

A-14 WHAT SPF NUMBER DO YOU THINK IS ENOUGH FOR YOU?

The higher the number, the greater the protection. But do not think of the SPF number as a mathematical formula indicating multiples of the amount of time you could stay out in the sun without sunscreen before you burn. Choose an SPF that suits your skin and the way in which you apply sunscreens.

Sunscreen products that offers the following maybe used depending on the time of day, your geographical location and the weather:

A-14.1 Broad-spectrum protection (protects against UVA and UVB rays)

A-14.2 SPF 10 or higher
□□□□□UVA PF (PA +/ ++/ +++/ ++++)

A-14.3 Water resistance (40 minutes/ 80 minutes)

A sunscreen that offers the above helps to protect your skin from sunburn, early skin aging and skin cancer. However, sunscreen alone cannot fully protect you. In addition to wearing sunscreen, dermatologists recommend taking the following steps to protect your skin and find skin cancer early:

A-14.4 Seek shade when appropriate, remembering that the sun's rays are strongest between 11 a.m. and 3 p.m.

A-14.5 Dress to protect yourself from the sun by wearing loose-fitting clothing and a wide- brimmed hat with a good pair of sunglasses, when possible.

A-14.6 Use extra caution near water, snow and sand as they reflect the damaging rays of the sun, which can increase your chance of sunburn.

A-14.7 Get vitamin D safely through a healthy diet that may include vitamin supplements.

A-14.8 Avoid tanning beds.

A-14.9 Keep babies and young children out of direct sunlight

ANNEX B
(*Clauses* 4.3 and 5.9)

BROAD SPECTRUM PROTECTION – USFDA MONOGRAPH TEST PROCEDURE

BROAD SPECTRUM TEST PROCEDURE

1 UV SPECTROMETRY

1.1 Plate — Use optical-grade polymethylmethacrylate (PMMA) plates suitable for UV transmittance measurements. The plate should be roughened on one side to a three dimensional surface topography measure (Sa) between 2 and 7 micrometers and must have a rectangular application area of at least 16 square centimeters (with no side shorter than 4 cm).

1.2 Sample holder — The sample holder should hold the PMMA plate in a horizontal position to avoid flowing of the sunscreen drug product from one edge of the PMMA plate to the other. It should be mounted as close as possible to the input optics of the spectrometer to maximize capture of forward scattered radiation. The sample holder should be a thin, flat plate with a suitable aperture through which UV radiation can pass. The PMMA plate should be placed on the upper surface of the sample holder with the roughened side facing up.

1.3 Light source — The light source should produce a continuous spectral distribution of UV radiation from 290 to 400 nanometers.

1.4 Input optics — Unless the spectrometer is equipped with an integrating sphere, an ultraviolet radiation diffuser should be placed between the sample and the input optics of the spectrometer. The diffuser will be constructed from any UV radiation transparent material (e.g., Teflon or quartz). The diffuser ensures that the radiation received by the spectrometer is not collimated. The spectrometer input slits should be set to provide a bandwidth that is less than or equal to 1 nanometer.

1.5 Dynamic range of the spectrometer — The dynamic range of the spectrometer should be sufficient to measure transmittance accurately through a highly absorbing sunscreen product at all terrestrial solar UV wavelengths (290 to 400 nm).

2 SUNSCREEN PRODUCT APPLICATION TO PMMA PLATE

The accuracy of the test depends upon the application of a precisely controlled amount of sunscreen product with a uniform distribution over the PMMA plate. The product is applied at 0.75 mg per square centimeter to the roughened side of the PMMA plate. The sunscreen product should be applied in a series of small dots over the entire PMMA plate and then spread evenly using a gloved finger. Spreading should be done with a very light spreading action for approximately 30 seconds followed by spreading with greater pressure for approximately 30 seconds. The plate should then be allowed to equilibrate for 15 minutes in the dark before the pre-irradiation described in paragraph (c) of this section.

3 SUNSCREEN PRODUCT PRE-IRRADIATION

To account for lack of photostability, apply the sunscreen product to the PMMA plate as described in paragraph (b) of this section and then irradiate with a solar simulator described in section 352.70(b) of this chapter. The irradiation dose should be 4 MEDs which is equivalent to an erythemal effective dose of 800 J/m ^{2} (i.e., 800 J/m ^{2}-eff).

4 CALCULATION OF MEAN TRANSMITTANCE VALUES

After pre-irradiation described in paragraph (c) of this section, mean transmittance values should be determined for each wavelength [λ] over the full UV spectrum (290 to 400 nanometers). The transmittance values should be measured at 1 nanometer intervals. Measurements of spectral irradiance transmitted for each wavelength [λ] through control PMMA plates coated with 15 microliters of glycerin (no sunscreen product) should be obtained from at least 5 different locations on the PMMA plate [C1(λ), C2(λ), C3(λ), C4(λ)], and C5(λ)]. In addition, a minimum of 5 measurements of spectral irradiance transmitted for each wavelength [$\boldsymbol{\lambda}$] through the PMMA plate covered with the sunscreen product will be similarly obtained after pre-irradiation of the sunscreen product [P1(λ), P2(λ), P3(λ), P4(λ), and P5(λ)].

The mean transmittance for each wavelength,

$\overline{T(\boldsymbol{\lambda})}$

is the ratio of the mean of the C($\boldsymbol{\lambda}$) values to the mean of the P($\boldsymbol{\lambda}$) values, as follows:

$$\overline{\boldsymbol{T}(\boldsymbol{\lambda})} = \frac{\sum_1^n \boldsymbol{P}(\boldsymbol{\lambda})/\mathbf{n}}{\sum_1^n \boldsymbol{C}(\boldsymbol{\lambda})/\mathbf{n}}$$

Where n = 5

5 CALCULATION OF MEAN ABSORBANCE VALUES

5.1 Mean transmittance values,

$$\overline{T(\boldsymbol{\lambda})}$$

are converted into mean absorbance values,

$$\overline{A(\boldsymbol{\lambda})}$$

at each wavelength by taking the negative logarithm of the mean transmittance value as follows:

$$A(\boldsymbol{\lambda}) = -\log \overline{T(\lambda)}$$

5.2 The calculation yields 111 monochromatic absorbance values in 1 nanometer increments from 290 to 400 nanometers.

6 NUMBER OF PLATES

For each sunscreen product, mean absorbance values should be determined from at least three individual PMMA plates. Because paragraph (d) of this section requires at least 5 measurements per plate, there should be a total of at least 15 measurements.

7 CALCULATION OF THE CRITICAL WAVELENGTH

The critical wavelength is identified as the wavelength at which the integral of the spectral absorbance curve reaches 90 percent of the integral over the UV spectrum from 290 to 400 nm. The following equation defines the critical wavelength:

$$\int_{290}^{\lambda c} A(\lambda)\mathrm{d}(\lambda) = 0.9 \int_{290}^{400} A(\lambda)\mathrm{d}(\lambda)$$

Where [λ]c = critical wavelength

A[λ]) = mean absorbance at each wavelength

d[λ] = wavelength interval between measurements

A mean critical wavelength of 370 nm or greater is classified as broad spectrum protection.