



BSI Standards Publication

Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF)

National foreword

This British Standard is the UK implementation of EN ISO 24444:2020+A1:2022. It is identical to ISO 24444:2019 incorporating amendment 1:2022. It supersedes BS EN ISO 24444:2020, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted to Technical Committee CW/217, Cosmetics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2022
Published by BSI Standards Limited 2022

ISBN 978 0 539 16523 4

ICS 71.100.70

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 January 2020.

Amendments/corrigenda issued since publication

Date	Text affected
31 October 2022	Implementation of ISO amendment 1:2022 with CEN endorsement A1:2022

English Version

**Cosmetics - Sun protection test methods - In vivo
determination of the sun protection factor (SPF) (ISO
24444:2019)**

Cosmétiques - Méthodes d'essai de protection solaire -
Détermination in vivo du facteur de protection solaire
(FPS) (ISO 24444:2019)

Kosmetik - Untersuchungsverfahren für
Sonnenschutzmittel - In-vivo-Bestimmung des
Sonnenschutzfaktors (SSF) (ISO 24444:2019)

This European Standard was approved by CEN on 9 December 2019.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 24444:2020) has been prepared by Technical Committee ISO/TC 217 "Cosmetics" in collaboration with Technical Committee CEN/TC 392 "Cosmetics" the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2020, and conflicting national standards shall be withdrawn at the latest by July 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 24444:2010.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 24444:2019 has been approved by CEN as EN ISO 24444:2020 without any modification.

European foreword to amendment A1

This document (EN ISO 24444:2020/A1:2022) has been prepared by Technical Committee ISO/TC 217 "Cosmetics" in collaboration with Technical Committee CEN/TC 392 "Cosmetics" the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2022, and conflicting national standards shall be withdrawn at the latest by September 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 24444:2019/Amd 1:2022 has been approved by CEN as EN ISO 24444:2020/A1:2022 without any modification.

Contents

Page

Foreword	v
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General principle	3
5 Test subjects	3
5.1 Selection of the test subjects	3
5.1.1 General	3
5.1.2 Skin colour of the test subjects	4
5.1.3 Age restriction	4
5.1.4 Frequency of participation in tests	4
5.1.5 Ethics and consent	4
5.2 Number of test subjects	4
6 Apparatus and materials — Source of ultraviolet radiation	5
6.1 General	5
6.2 Quality of ultraviolet radiation	5
6.3 Total irradiance (UV, visible and near infrared rays)	5
6.4 Uniformity of beam	5
6.4.1 General	5
6.4.2 Film densitometry	6
6.4.3 UV sensor	6
6.4.4 Large beam source	6
6.4.5 Small beam source	6
7 Maintenance and monitoring the UV solar simulator output	7
7.1 Spectroradiometry	7
7.2 Radiometry	8
8 Reference sunscreen formulations	9
8.1 General	9
8.2 Reference standard to be used	9
9 Procedure	9
9.1 Main steps	9
9.2 Test conditions	10
9.3 Position of the test subjects	10
9.4 Product application	10
9.5 Procedure for MED assessment	14
9.5.1 General	14
9.5.2 Time of assessment of MED	14
9.5.3 Data rejection criteria	15
9.5.4 Test failure criteria	16
9.5.5 Expression of MEDs	16
10 Calculation of the sun protection factor and statistics	16
10.1 Calculation of the individual SPF (SPF _i)	16
10.2 Calculation of product SPF	16
10.3 Statistical criterion	16
10.4 Validation of the test	17
11 Test report	17
11.1 Overview	17
11.2 General information	17
11.3 Data in tabular form for each test subject	17

11.4	Statistics for the test products	18
Annex A	(normative) Selection criteria for the test subjects	19
Annex B	(normative) Definition of the UV solar simulator output	21
Annex C	(normative) SPF reference sunscreen formulations	28
Annex D	(normative) Calculations and statistics	41
Annex E	(normative) Colourimetric determination of skin colour typing and prediction of the minimal erythematous dose (MED) without UV exposure	47
Annex F	(informative) Visual guidance for erythema grading	51
Annex G	(Normative) Sample report form	55
Bibliography		59

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

This second edition cancels and replaces the first edition (ISO 24444:2010), which has been technically revised.

The main changes compared to the previous edition are as follows.

- The definition of the minimal erythema response (MED) criteria has been revised.
- The choice of eligible test subjects is now based solely on individual typology angle (ITA°) with a requirement for the average ITA° for the test panel to be within the range 41° to 55°, with a minimum of three subjects within two of the three ITA° ranges.
- The ITA° is used to define the range of unprotected MED doses for the provisional or the test day unprotected MED determination (if no provisional MEDu determination is made).
- Three new reference standard sunscreens have been validated and added to the method to validate SPF test panels for products with SPF equal to 25 or higher (P5, P6 and P8).
- New test methods are provided to determine the uniformity of the beam of both large and small beam size solar simulators. A requirement for uniformity greater than or equal to 90 % has been added.
- Sunscreen application procedures have been described in greater detail.
- An informative [Annex F](#) has been added with photographic examples of erythema responses with guidelines for grading.
- The reporting tables in [Annex G](#)) and the requirements in [Clause 11](#) have modified to provide more complete information on the results of the testing.
- The bibliography has been updated.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The level of sun protection provided by sunscreen products has traditionally been estimated using the sun protection factor or SPF test, which uses the erythema response of the skin to ultraviolet (UV) radiation. The SPF is a ratio calculated from the energies required to induce a minimum erythema response with and without sunscreen product applied to the skin of human test subjects. It uses ultraviolet radiation usually from an artificial source.

Different standard methods are available and described in ISO/TR 26369^{[1]-[3]}.

Since the publication of the first version of this document, harmonization has been achieved in many member countries. The objective of this updated version is to further improve reproducibility between test sites, so as to obtain the same SPF value.

Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF)

1 Scope

This document specifies a method for the in vivo determination of the sun protection factor (SPF) of sunscreen products. It is applicable to products that contain any component able to absorb, reflect or scatter ultraviolet (UV) rays and which are intended to be placed in contact with human skin.

This document provides a basis for the evaluation of sunscreen products for the protection of human skin against erythema induced by solar ultraviolet rays.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

ultraviolet radiation

UVR

electromagnetic radiation in the range of 290 nm to 400 nm

3.1.1

ultraviolet B

UVB

electromagnetic radiation in the range of 290 nm to 320 nm

3.1.2

ultraviolet A

UVA

electromagnetic radiation in the range of 320 nm to 400 nm

Note 1 to entry: UVA II = 320 nm to 340 nm; UVA I = 340 nm to 400 nm.

3.1.3

erythema effective irradiance

E_{er}

radiometric quantity derived by multiplying the spectral irradiance $E(\lambda)$ of the solar simulator with the erythema action spectrum^[4] $s_{\text{er}}(\lambda)$ at each wavelength λ and integrating over wavelength range of 290 nm to 400 nm

$$E_{\text{er}} = \int_{290}^{400} E(\lambda) s_{\text{er}}(\lambda) d\lambda \quad \text{unit: W/m}^2 \text{ (eff.)}$$

3.1.4

erythema effective radiant exposure **erythema dose**

H_{er}

radiometric quantity defined as time integral of erythema effective irradiance $E_{\text{er}}(t)$

$$H_{\text{er}} = \int_t E_{\text{er}}(t) dt \quad \text{unit: J/m}^2 \text{ (eff.)}$$

3.2

erythema

reddening of the skin caused by UV radiation

3.3

sunscreen products

products containing any component able to absorb, reflect or scatter UV rays, which are intended to be placed on the surface of human skin with the purpose of protecting against *erythema* (3.2) and other ultraviolet induced damage

3.4

minimal erythema dose

MED

lowest *erythema effective radiant exposure* (H_{er}) (3.1.4) that produces the first perceptible unambiguous erythema with defined borders appearing over more than 50 % of UV exposure subsite, 16 h to 24 h after UV exposure

Note 1 to entry: [Annex F](#) contains visual references and guidance for the acceptable MED appearance.

3.4.1

MED_u

minimal erythema dose on unprotected skin

3.4.1.1

MED_{iu}

minimal erythema dose of an individual subject on unprotected skin

3.4.2

MED_p

minimal erythema dose on product protected skin

3.4.2.1

MED_{ip}

minimal erythema dose of an individual subject on protected skin

3.5

individual sun protection factor

SPF_i

ratio of the individual minimal erythema dose on product protected skin (MED_{ip}) to the (individual) minimal erythema dose on unprotected skin (MED_{iu}) of the same subject:

$$\text{SPF}_i = \frac{\text{MED}_{\text{ip}}}{\text{MED}_{\text{iu}}}$$

Note 1 to entry: SPF_i is expressed to one decimal place by truncation.

3.6

sun protection factor of a product

SPF

arithmetic mean of all valid individual SPF_i values obtained from all subjects in the test

Note 1 to entry: SPF is expressed to one decimal place by truncation.

3.7**test area**

area for testing on the back between the scapula line and the waist

Note 1 to entry: Skeletal protrusions and extreme areas of curvature should be avoided.

3.8**test site**

area of the skin where a product is applied or the site used for the determination of the unprotected MED

3.9**exposure sub-sites**

areas of skin that are exposed to UV-irradiation within a test site

3.10**individual typology angle****ITA°**

value characterizing the skin colour of the subject as measured by a skin contact reflectance spectrophotometer or skin colourimeter

Note 1 to entry: Refer to [Annex E](#) for the detailed requirements of the equipment/measurement.

4 General principle

The SPF test method is a laboratory method that utilizes a xenon arc lamp solar simulator (or equivalent) of defined and known output to determine the protection provided by sunscreen products on human skin against erythema induced by solar ultraviolet rays.

The test shall be restricted to the area of the back of selected human subjects.

A section of each subject's skin is exposed to ultraviolet light without any protection while another (different) section is exposed after application of the sunscreen product under test. One further section is exposed after application of an SPF reference sunscreen formulation, which is used for validation of the procedure.

To determine the sun protection factor, incremental series of delayed erythematous responses are induced on a number of small sub-sites on the skin. These responses are visually assessed for presence of erythema 16 h to 24 h after UV radiation, by the judgment of a trained and competent evaluator.

The individual minimal erythematous dose for unprotected skin (MED_{iu}) and the individual MED obtained after application of a sunscreen product (MED_{ip}) shall be determined on the same subject on the same day. An individual sun protection factor (SPF_i) for each subject tested is calculated as the ratio of individual MED on product protected skin divided by the individual MED on unprotected skin, as in the formula given in [3.5](#).

The sun protection factor for the product (SPF) is the arithmetic mean of all valid SPF_i results from each subject in the test expressed to one decimal place.

5 Test subjects**5.1 Selection of the test subjects****5.1.1 General**

There are strict requirements governing the inclusion and non-inclusion of test subjects which should be adhered to. The criteria shall be as set out in [Annex A](#).

5.1.2 Skin colour of the test subjects

Test subjects included in the SPF test shall have an ITA° value of at least 28° by colourimetric methods (see [Annexes A](#) and [E](#)) and be untanned on the test area.

The average of the subjects making up a test panel shall have an ITA° between 41° and 55°. When possible, there should be subjects with ITA°s in each of the three ITA° bands, 28° to 40°, 41° to 55°, and >56°. Where this is not possible, there shall be at least three individuals in each of two of the three ITA° bands described in the previous sentence.

A trained and competent scientist or technician should examine each subject to ensure that there is no condition which might put the subject at risk and that the outcome of the test cannot be compromised by adverse skin conditions such as sun damage, pigmentation marks and previous history of abnormal response to the sun (see [Annex A](#)).

The test sites intended for UV exposure shall be free from blemishes and hair, and have an even colour tone with no variation in ITA° greater than 5° from each other or the MED_u test area.

5.1.3 Age restriction

Test subjects below the locally regulated age of consent or older than 70 years shall not be included in the SPF test panel.

5.1.4 Frequency of participation in tests

Subjects may participate in a test provided that at least 8 weeks have elapsed since they participated in a previous UV exposure study (i.e. SPF, UVA-PF, photoallergy, phototoxicity test), and all skin tanned marks from that previous test have cleared from the test sites on the back and are no longer visible.

5.1.5 Ethics and consent

All testing shall be done in accordance with the Declaration of Helsinki^[7]. Any national regulations regarding human studies should also be taken into account.

Informed, written (signature) consent shall be obtained from all test subjects and retained.

5.2 Number of test subjects

The minimum number of valid SPF_i results shall be 10 and the maximum number of valid SPF_i results shall be 20. In order to achieve between 10 and 20 valid results, a maximum of five individual invalid results may be excluded from the calculation of the mean SPF. For the test to be considered valid for the first 10 subjects, the resulting range of the 95 % CI of the mean shall be within ±17 %. Consequently, the actual number of test subjects used will fall between a minimum of 10 and a maximum of 25 subjects (i.e. a maximum of 20 valid results plus 5 rejected invalid results).

Results may only be declared invalid and excluded from the calculation of the mean SPF according to [9.5.3](#) or because of non-compliance with the related protocol.

In order to determine the number of test subjects, the 95 % confidence interval (95 % CI) on the mean SPF shall be taken into account. A minimum of 10 subjects shall be tested. The test shall be considered valid for the first 10 subjects if the resulting range of the 95 % CI of the mean SPF shall be within ±17 % of the mean SPF. If it is not within ±17 % of the mean SPF, the number of subjects shall be increased stepwise from the minimum number of 10 until the 95 % CI statistical criterion is met (up to a maximum of 20 valid results from a maximum of 25 subjects tested). If the statistical criterion has not been met after 20 valid results from a maximum of 25 subjects, then the test shall be rejected. For details on statistical definitions, sequential procedure and calculations, refer to [Annex D](#).

6 Apparatus and materials — Source of ultraviolet radiation

6.1 General

The artificial light source used shall comply with the source spectral specifications as described in [6.2](#) and [Annex B](#). A xenon arc solar simulator with appropriate filters shall be used.

6.2 Quality of ultraviolet radiation

6.2.1 The solar UV simulator shall emit a continuous spectrum with no gaps or extreme peaks of emission in the UV region. The output from the solar UV simulator shall be stable, uniform across the whole output beam and suitably filtered to create a spectral quality that complies with the required acceptance limits (see [Table B.1](#)).

6.2.2 To ensure that appropriate amounts of UVA radiation are included in the spectrum of the solar UV simulator, the total radiometric proportion of the UVA II (320 nm to 340 nm) irradiance of the simulator shall be ≥ 20 % of the total UV (290 nm to 400 nm) irradiance. Additionally, the UVA I region (340 nm to 400 nm) irradiance shall be ≥ 60 % of the total UV irradiance.

6.2.3 The source spectral specification is described in terms of cumulative erythral effective irradiance by successive wavelength bands from <290 nm up to 400 nm. The erythral effective irradiance of each wavelength band is expressed as a percentage of the total erythral effective irradiance from <290 nm to 400 nm, or as the percentage relative cumulative erythral effectiveness (% RCEE). The definition and calculation of % RCEE values is described in [Annex B](#) and the acceptance limits are given in [Table B.1](#).

6.3 Total irradiance (UV, visible and near infrared rays)

If total irradiance is too intense, an excessive feeling of heat or pain may be induced in the irradiated skin of subjects and heat induced erythema may result. Therefore, total irradiance shall not exceed $1\,600\text{ W/m}^2$. When total irradiance is $<1\,600\text{ W/m}^2$, it shall still be confirmed, prior to conducting an SPF test, that the irradiance to be used (UV, visible and near-infrared rays) will not induce an excessive feeling of heat in the skin. The output of the solar simulator shall be measured with a broad spectrum sensor (capable of measuring between 280 nm and $1\,600\text{ nm}$) calibrated against a standard reference source over the range of 280 nm to $1\,600\text{ nm}$. Alternatively, the source may be measured with a calibrated spectroradiometer over this same wavelength range to determine the total irradiance.

6.4 Uniformity of beam

6.4.1 General

Uniformity of the beam shall be measured depending on the solar simulator type using either UV sensitive film or UV sensor methods (see [6.4.2](#) and [6.4.3](#)). Solar simulators with large beams ($>1,3$ cm diameter) or with multiple output ports shall be measured at least every 6 months, or when any modifications are made to the lamp optical components, or when non-uniform erythema spots are seen in test subsites. Solar simulators with a single output port beam ($\leq 1,3$ cm diameter) shall be measured at least every 1 month, or when any modifications are made to the lamp optical components, or when non-uniform erythema spots are seen in test subsites.

Uniformity measurements may be conducted using UV sensitive paper that darkens with exposure, or by using a UV sensor that is smaller in active area compared to the beam size by a ratio of at least 1:4.8 with sufficient measurements to cover more than 75 % of the beam area.

Measurements are to be made using the orientation of the source output as used for subject exposures.

6.4.2 Film densitometry

Exposure doses of the UV sensitive film shall be calibrated to achieve film darkening (converted to grey scale) to a density in the mid-range of the scale (on a 0 to 255 range of black to white). A series of exposures shall be used to determine the mid-range density exposure using a calibrated scanning measurement device with at least 600 dots per inch (dpi) resolution. Exposures can be modified by use of neutral density filters or exposure times to achieve this level of exposure for uniformity measurements. Areas to be measured shall be the same as those diagrammed below (see [Figures 1](#) and [2](#)). Films are to be scanned for density values, and average values for each area of the beam as outlined above shall be calculated, and beam uniformity calculated as per [Formula \(1\)](#) (see [6.4.4.3](#)).

6.4.3 UV sensor

Alternatively, a small aperture (quadrant) UV sensor with a mechanical alignment fixture may be used to measure sub-sections of the output beam intensity as outlined below and the beam uniformity calculated as per [Formula \(1\)](#) (see [6.4.4.3](#)).

6.4.4 Large beam source

When a large-beam UV source is used to simultaneously expose several sub-sites (i.e. at least two sub-sites) within an irradiation series by varying the exposure time, the intensity of the beam shall be as uniform as possible. A UV film densitometry method or a UV radiometer method may be used. The minimum number of sample sites of equal area within the beam (Area of Interest – AOI) to be assessed shall be determined by dividing the area of the beam by 6,45. (For example, if the beam is 232 cm² in area, then the minimum number of measurements shall be 36).

6.4.4.1 UV film densitometry method: The UV sensitive film at least as large as the beam shall be exposed by the entire beam so that the entire beam fits inside the borders of the film.

6.4.4.2 UV Radiometer method: A UV radiometer sensor may be used to sample the beam intensity at multiple sites. Measurements shall be made at equally distributed points.

6.4.4.3 The uniformity shall be ≥90 % as calculated by [Formula \(1\)](#):

$$\text{Uniformity \%} = (1 - (\text{max} - \text{min}) / (\text{average})) \% \quad (1)$$

If the uniformity is less than 90 %, then optical components should be adjusted or appropriate compensation for different irradiance shall be made in the exposure time on each sub-site.

6.4.5 Small beam source

For a small beam UV source, which exposes sub-sites individually, the beam intensity uniformity shall be as measured. A UV sensitive film densitometry method or a UV radiometer method may be used.

6.4.5.1 Single output device. For a single output device, five equal size areas of the beam intensity shall be measured to assess the uniformity within the beam as shown in [Figure 1](#). The uniformity shall be $\geq 90\%$ as calculated by [Formula \(1\)](#).

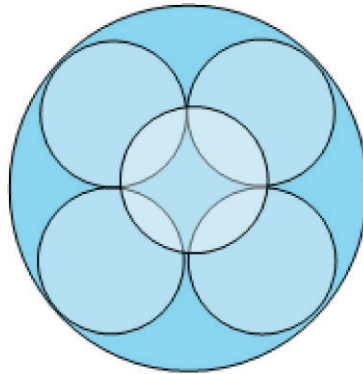


Figure 1 — Single output device

6.4.5.2 Multiple output device. For a multiple output device, the intensity uniformity of each output beam shall be determined by measuring at least 4 circles of equal area of each output beam (see [Figure 2](#)), as calculated [Formula \(1\)](#).

- A1** The average uniformity of all beams for the multiple output device shall be $\geq 90\%$, with no individual port having uniformity of $< 85\%$. **A1**

If the uniformity is less than prescribed above, then adjustments to the lamp optical system shall be made to bring the uniformity within the limits above.

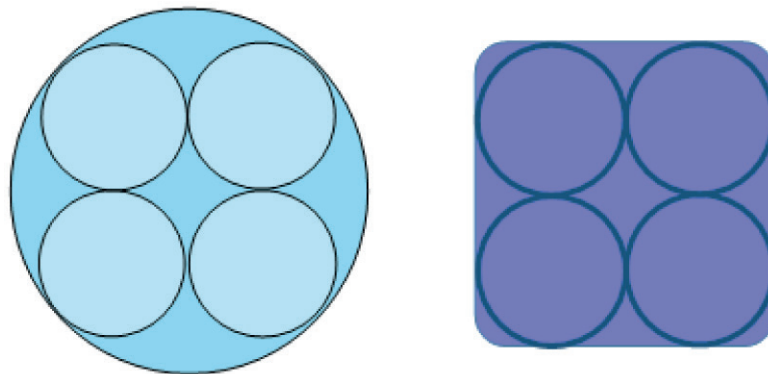


Figure 2 — Multiple output device

7 Maintenance and monitoring the UV solar simulator output

7.1 Spectroradiometry

There shall be a spectroradiometric check of the spectrum of each solar simulator output port (UVA and UVB) and intensity made by the laboratory at least once every 12 months or after 2 500 h of lamp running time and after changing any significant physical (optical) component (including the bulb) of the solar simulator. The simple use of specific filters is not in itself adequate assurance that the UV output is of the correct quality. This periodical inspection should be conducted by a trained, competent, and suitably qualified person (internal or external) using a spectroradiometer that has been calibrated against a standard lamp that is traceable to a national or an international calibration standard, with a band width of 2 nm or smaller and having a dynamic range of at least 5 decades which is usually met by

spectroradiometers equipped with double monochromator. Measurements shall be recorded at 1 nm increments.

Optical alignment fixtures shall be used to assure accurate radiometer alignment and reproduction of the simulator output at the same optical reference plane measured with the spectroradiometer.

Detailed instructions for ensuring correct lamp output are given in [Annex B](#).

7.2 Radiometry

Prior to making any measurements of the simulator output with a radiometric device, the front surface of the radiometer sensor shall be cleaned with a dry cotton cloth, and the optical tips of the light guides from the xenon source shall be cleaned with alcohol or optical cleaning fluid with lint-free cloth to remove any visible or invisible materials or residual sunscreen.

Before UV exposure of each test site, the UV irradiance shall be measured and recorded with an erythema weighted radiometer cross-calibrated against a spectroradiometric measurement of the solar simulator output as detailed in [7.1](#). Optical alignment shall be configured to ensure accurate radiometer alignment and reproduction of the simulator output at the same optical reference plane measured with the spectroradiometer. A calibration factor Y for each radiometer shall be determined by [Formula \(2\)](#):

$$Y = \frac{E_{\text{ersp}}}{E_{\text{err}}} \quad (2)$$

where

Y is the calibration factor for each radiometer;

E_{ersp} is the erythema effective irradiance E_{er} (W/m² erythema weighted) of the solar simulator as measured by a spectroradiometer;

E_{err} is the erythema weighted irradiance E_{er} (W/m²) of the solar simulator as measured by the radiometer.

The UV exposure time (in seconds) for a given test shall be calculated using [Formula \(3\)](#):

$$t = \frac{H_{\text{er}}}{E_{\text{ersp}}} = \frac{H_{\text{er}}}{Y * E_{\text{err}}} \quad (3)$$

where

t is the time, in seconds, for the UV exposures for a given test;

H_{er} are the desired doses;

E_{ersp} is the erythema effective irradiance as measured by spectroradiometer;

E_{err} is the erythema effective irradiance as measured by radiometer;

Y is the calibration factor.

Output intensity should be measured before exposure of each test site in order to ensure the correct intensity is applied for each exposure. Where the solar simulator is capable of continuous monitoring of output intensity, it should be measured during the exposure of the test subjects. The average intensity of the solar simulator as measured by the calibrated radiometer shall be included on the test study report (W/m² eff.), as well as the doses (J/m² eff.) for the MED_{iu} and MED_{ip} for each subject.

8 Reference sunscreen formulations

8.1 General

The method is controlled by the use of one of five reference sunscreen formulations to verify the test procedure. Therefore, one of the prescribed reference formulations shall be measured on the same day as products are tested. Whether a low or high SPF reference formulation is to be used depends on the expected SPF of the test products.

8.2 Reference standard to be used

8.2.1 Preliminary testing: When testing is being done on a preliminary basis, such as for product development investigations, any reference standard listed in [Annex C](#) may be used for each subject.

8.2.2 Establishment of SPF for product claim: When testing is conducted for the purpose of supporting a label claim of a product intended for market the following reference standards shall be used for testing with the test product:

- Ⓐ) — SPF Claim ≤ 24 : any reference standard listed in Annex C may be used for each subject; Ⓐ)
- SPF ≥ 25 but less than SPF 50: P5 or P6 reference standard (on at least 5 subjects) and P2 or P3 on remaining subjects;
- SPF ≥ 50 : P8 reference standard (on at least 5 subjects) and P2 or P3 on the remaining subjects.

Additional subjects may be added as necessary to achieve means for the reference standards that are within the acceptance range.

Assignment of the reference standards to be used on specific subjects shall be randomized.

If P5, P6, or P8 reference standard is used on a subject, there is no necessity to include a lower SPF reference standard on that subject even though there may be lower SPF test products included in the same test. (Only one SPF reference standard sunscreen shall be required on each subject). Acceptance SPF ranges for the reference standard sunscreens are shown in [Annex C](#). If the mean SPF of the reference standard sunscreens obtained in any test do not fall within their acceptance limits shown in [Annex C](#) for that reference standard, then the entire test (i.e. all test products) shall be rejected.

The formulae details and manufacturing instructions for the reference formulations are given in [Annex C](#).

9 Procedure

9.1 Main steps

- Acclimatization period for the skin;
- determination of ITA° on the back of the subject;
- delineation of test sites on the back of the subject;
- weighing of the product for application to the test site;
- application of the product to the test site;
- waiting period before UV exposure to the test site;
- UV exposure;
- MED assessment;

— calculations.

9.2 Test conditions

Product application, UV exposures and MED assessment should be carried out in stable conditions, with the room temperature maintained between $(23 \pm 3) ^\circ\text{C}$.

9.3 Position of the test subjects

Product shall be applied to subjects in the same position as will be utilized for the irradiation procedure (sitting or prone). Powder and products which may flow (very low viscosity liquids) should be tested in the prone position to prevent the samples from falling off the surface.

9.4 Product application

The amount of product applied and the uniformity of spreading on the test sites affect the magnitude and variability of the test results. It is therefore very important to follow the procedures set out in [9.4.1](#) to [9.4.9](#).

9.4.1 The test sites intended for UV exposure shall be free from blemishes and hair, and have an even colour tone with no variation in ITA° greater than 5° from each other or the MED_u test area. When necessary, hair shall be shaved more than three days prior to the test, but not thereafter. If necessary, hair may be clipped or cut with scissors on the test day.

9.4.2 The minimum total area for a test site for product application shall be 30 cm^2 and the maximum shall be 60 cm^2 .

9.4.3 The positions of the test products and reference sunscreen test sites shall be distributed randomly on the backs of subjects over the whole test group in order to reduce error arising from anatomical differences in skin. The unprotected test site used to determine MED_u shall be randomized as one of the test sites across the test area and across subjects.

9.4.4 There shall be a minimum distance of 1 cm between the borders of adjacent test sites.

9.4.5 Before product application, the test area may be cleaned by using a dry cotton pad or equivalent.

9.4.6 The test sites shall be delineated by a method which does not interfere with the test or harm the subject such as skin marker and/or a template made from non-absorbent material. The skin marker shall be indelible so as to be discernible at the time of MED evaluations 16 h to 24 h post UV-exposure.

9.4.7 Amount of product applied

9.4.7.1 The amount of test product and reference sunscreen formulation applied to the skin after spreading shall be $(2,00 \pm 0,05) \text{ mg/cm}^2$.

9.4.7.2 The balance used to weigh the products should be capable of weighing to the nearest 0,1 mg.

9.4.7.3 All products shall be homogeneous and shall be shaken before weighing, to ensure uniform dispersion.

9.4.7.4 When handling the product during weighing or before application to the skin, take appropriate measures to prevent evaporative loss of the volatile components. It is important that the total quantity of weighed product is transferred to the product application site. The amount of product to be applied

shall be weighed in a syringe or in another device such as a watch glass. A method of weighing by loss is required.

9.4.8 Mode of delivery

It is recommended to practice application and spreading of the test materials on a subject (not in the test) to determine the best procedure to obtain uniform product spreading. The use of a finger cot (i.e. latex, nitrile, etc.) shall be required except in cases when use of a finger cot interferes with even application of the product. A new finger cot shall be used for each new application of product and shall not be pre-saturated with the test product. When a naked finger, is used a maximum of 2,1 mg/cm² (additional 5 %) shall be applied to the test area to account for the additional area of the application finger, and the finger shall be cleaned between product applications with an alcohol wipe.

9.4.8.1 Product application technique

The application technique to be used is dependent on the product type.

Form	Recommended application method
Lotion	Method A
Cream	Method A
Oil	Method A
Liquid	Method A
Gel	Method A
Stick	Method B
Balm	Method B
Aerosol spray	Degas then Method A
Pump spray	Method A
Roll on	Method A or B
Powder	Method C
Foaming Formulations	Method D

Method A: Fluid products. To aid uniform coverage, droplets (at least 15 per 30 cm², 30 per 60 cm²) of the product should be deposited within the test site using a syringe/pipette at one time, then spread over the whole test site, first with circular movements to gather the droplets and second in horizontal and vertical directions using light pressure as shown in [Figure 3](#). It is recommended that during the whole process, the application finger stays in contact with the skin.

Spray products provided in a pressurized container should first be degassed by puncturing a very small pinhole in the container to relieve all of the pressure. Degassing shall be done with appropriate safety precautions by securing the can within a ventilated safety hood with appropriate personnel safety equipment. The degassed can shall be allowed to rest for 24 h at room temperature when the product shall be decanted into a separate closed container with minimal headspace to minimize evaporation.