



SLOVENSKI STANDARD
oSIST prEN ISO 23675:2024
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Kozmetika - Preskusne metode za zaščito pred soncem - Določanje faktorja zaščite pred soncem (SPF) in vitro (ISO/DIS 23675:2023)

Cosmetics - Sun protection test Methods - In Vitro determination of Sun Protection Factor (SPF) (ISO/DIS 23675:2023)

Kosmetische Mittel - Untersuchungsverfahren für Sonnenschutzmittel - In vitro Bestimmung des Sonnenschutzfaktors (SSF) (ISO/DIS 23675:2023)

Cosmétiques - Méthodes d'essai de protection solaire - Détermination in vitro du facteur de protection solaire (FPS) (ISO/DIS 23675:2023)

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Cosmetics — Sun protection test methods — In Vitro determination of Sun Protection Factor (SPF)

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Contents

	Page
Foreword.....	v
Introduction.....	vi
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Principles.....	4
5 Reagents and/or materials.....	4
5.1 Sample substrate/plate.....	4
5.2 Reference sunscreen.....	4
5.3 Finger-cot.....	4
5.4 Blank.....	4
6 Apparatus.....	4
6.1 Spectrophotometers.....	4
6.1.1 Specification.....	4
6.1.2 Monitoring.....	5
6.2 Automatic positive-displacement pipette.....	5
6.3 Analytical Balance.....	5
6.4 Robot.....	5
6.5 Solar simulator.....	5
6.5.1 Quality of solar simulator radiation.....	6
6.5.2 Maintenance and monitoring the solar simulator.....	6
7 Procedure.....	7
7.1 Outline of the test procedure (Annex G).....	7
7.2 Preparation of reagents and materials.....	7
7.2.1 Plate preparation and handling.....	7
7.2.2 Finger cot.....	7
7.3 Product application on substrates and robot automatic spreading.....	8
7.3.1 Weighing of product and deposit on plates.....	8
7.3.2 Automatic spreading.....	9
7.4 Measurement of initial absorbance using two plate types (290 nm to 400 nm).....	9
7.4.1 Blank measurement.....	9
7.4.2 Initial absorbance measurement.....	9
7.4.3 Calculation of Pre-irradiation <i>In Vitro</i> SPF_i	10
7.5 Calculation of irradiation dose (based on Pre-irradiation <i>In Vitro</i> SPF_i).....	10
7.6 Irradiation with calculated dose.....	11
7.7 Measurement of Post-irradiation absorbance using two plate types.....	11
7.8 Calculation of Post-irradiation <i>In Vitro</i> SPF_i	11
7.9 Calculation of Final <i>In Vitro</i> SPF_i of each pair of plates.....	12
7.10 Calculation of Final <i>In Vitro</i> SPF of the product.....	12
7.10.1 Validation of <i>In Vitro</i> SPF.....	12
8 Test report.....	13
Annex A (normative) UV exposure and erythema action spectra and solar simulator UV spectrum.....	14
Annex B (normative) Specification sample substrate.....	18
Annex C (normative) SPF reference sunscreen products.....	21
Annex D (normative) White Petroleum.....	34
Annex E (normative) Spectrophotometers specification and monitoring.....	35
Annex F (normative) Robot specification.....	40

ISO/DIS 23675:2023(E)

Annex G (informative) Key steps of the methods.....42
Bibliography.....43

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Foreword

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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).

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

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.

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ISO/DIS 23675:2023(E)

Introduction

Chronic exposure to solar ultraviolet radiation (UVR) is the main environmental source of damage to human skin. Consumer protection against exposure to solar UVB and UVA radiation is, therefore, an important public health issue. The use of sunscreens is a critical part of holistic programs of consumer UVR protection, including the use of appropriate clothing, hats and minimising exposure to the sun around its zenith.

The *in vivo* Sun Protection Factor (SPF) is historically measured by an *in vivo* method (ISO 24444) to communicate the amplitude of protection offered by sunscreens from erythemally-effective solar UVR. [1,2] In recent years, it has been seen the additional development of test methods to measure the breadth of protection from solar UVR, namely the *in vivo* human Persistent Pigment Darkening (PPD) test (and associated UVA-PF) and an *In Vitro* equivalent[3-7].

Invasive methods based on tests conducted on human beings are ethically problematic, time-consuming and very costly. Therefore, it has long been a desire to develop an *In Vitro* SPF Test Method, recognising the potential advantages of such methodology, including (i) the use of a non-human model, (ii) the significant improvements in speed and cost, (iii) the improved repeatability and reproducibility, (iv) the elimination of technically-challenging procedures (e.g., MED determination) and (v) the use of a method which is significantly more amenable to continuous improvement[8-12].

This *in-vitro* SPF method is based on UVR transmittance spectroscopy, whereby spectrophotometric measurement of UVR transmission through appropriate UVR-transparent substrates, allows prediction of *in vivo* SPF values. This *In Vitro* SPF method revealed a strong reproducibility and correlation with *in vivo* SPF values.

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Cosmetics — Sun protection test methods — In Vitro determination of Sun Protection Factor (SPF)

1 Scope

This international standard specifies a method for the *In Vitro* determination of Sun Protection Factor (SPF). This method is applicable to sunscreen products in form of an emulsion or hydroalcoholic one-phase formulation, excluding in form of a loose or compressed powder or stick. Specifications are given to enable determination of the spectral absorbance characteristics of SPF protection in a reproducible manner.

Use of this method is strictly for the determination of a static Sun Protection Factor. It is not validated for the determination of water-resistance properties of a sun-protection product.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 24444, *Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF)*

ISO 24443, *Cosmetics — Sun protection test methods — Determination of sunscreen UVA photoprotection in vitro*

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: <https://www.iso.org/obp> and <http://www.electropedia.org/>

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>
- CIE International Lighting Vocabulary (ILV): available at <https://cie.co.at/e-ilv>

3.1

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 and other ultraviolet induced damage

3.2

emulsion

fine dispersion of minute droplets of one liquid in other(s) in which it is not soluble or miscible

3.2.1

solution/one phase formulation

formulation that is made in form of a single phase

ISO/DIS 23675:2023(E)

3.3

***In Vitro* Sun Protection Factor**

SPF_{*In Vitro*}

protection factor of a sun protection product against erythema-inducing radiation calculated with spectral modelling

3.4

ultraviolet radiation (UVR) calculation

$I_{\text{sol}}(\lambda)$ or $E_{\gamma,\text{sol}}(\lambda)$

spectral irradiance of mid-summer sunlight in the spectral range of 290 nm to 400 nm, at a latitude of 40 °N, a solar zenith angle of 20° and an ozone layer thickness of 0,305 cm as defined in [Annex A](#)

3.5

solar ultraviolet radiation (UVR) simulator

the solar ultraviolet radiation simulator is a light source emitting a continuous spectrum with no gaps or extreme peaks of emission in the UV region. The solar simulator has a spectral quality that complies with the required acceptance limits in [Annex A](#)

3.6

action spectrum for erythema

$A_{\text{er}}(\lambda)$

function representing the spectral dependence of the ability of ultraviolet radiation to produce just perceptible erythema in human skin

Note 1 to entry: Note that the symbol for the erythemal action spectrum is defined as $s_{\text{er}}(\lambda)$ in ISO 17166:2019 and $E(\lambda)$ in the ISO 24443:2021.

Note 2 to entry: This entry was numbered 17-401 in CIE S 017:2011.

[SOURCE: CIE-ILV 17-26-065]

3.7

spectrophotometer

instrument for measuring the ratio of 2 values of a radiometric quantity at the same wavelength

Note 1 to entry: This entry was numbered 17-1235 in CIE S 017:2011.

[SOURCE: CIE-ILV 17-25-008] [/standards/sist/6ef516ed-2c61-47ad-9ee8-10b95847ac38/osist-pren-iso-23675-2024](https://standards/6ef516ed-2c61-47ad-9ee8-10b95847ac38/osist-pren-iso-23675-2024)

3.8

monochromatic absorbance

$A(\lambda)$

sunscreen absorbance at wavelength λ . Logarithm to base 10 of the reciprocal of the spectral internal transmittance, $\tau(\lambda)$

$$A(\lambda) = \log_{10} \tau(\lambda)$$

Note 1 to entry: This entry was numbered 17-1207 in CIE S 017:2011.

[SOURCE: CIE-ILV 17-24-090]

3.9

irradiance at a point of surface

$I(\lambda)$ or $E(\lambda)$

quotient of the radiant flux $d\Phi_e$ incident on an element of the surface containing the point, by the area dA of that element.

Note 1 to entry: Expressed in $\text{W}\cdot\text{m}^2$.

Note 2 to entry: Note that the symbol for the irradiance is defined as E in CIE-ILV 017:2020 but because it could be confused with the symbol used in ISO 24443:2021 for the erythemal action spectrum, here we use $I(\lambda)$.

Note 3 to entry: This entry was numbered 17-608 in CIE S 017:2011.

[SOURCE: CIE-ILV 17-21-053]

3.10

spectroradiometer

instrument for measuring radiometric quantities in narrow wavelength intervals over a given spectral region

Note 1 to entry: This entry was numbered 17-1236 in CIE S 017:2011.

[SOURCE: CIE-ILV 17-25-007]

3.11

radiometer

instrument for measuring radiometric quantities

Note 1 to entry: In the context of this standard, a UV radiometer measures the irradiance for the UV spectral range from 290 nm to 400 nm.

Note 2 to entry: This entry was numbered 17-1031 in CIE S 017:2011.

[SOURCE: CIE-ILV 17-25-006]

3.12

reference sunscreen formula

reference sunscreen product used to validate the testing procedure

3.13

dose

UV exposure dose for pre-irradiation of sunscreen products. The UV dose is the product of UV intensity (expressed as energy per unit surface area) and time

3.14

substrate/plate

a piece of Polymethylmethacrylate (PMMA) complying with definitions of [Annex B](#) on which test product is to be applied for absorbance measurements

3.15

erythmal irradiance

$E_{ER}(\lambda)$

effective irradiance with the spectral irradiance, E_{λ} , spectrally weighted with the erythema spectral weighting function, $s_{er}(\lambda)$, normalized to 1 at its maximum

Note 1 to entry: Expressed in $W \cdot m^2$.

Note 2 to entry: This entry was numbered 17-403 in CIE S 017:2011.

[SOURCE: CIE-ILV 17-26-067]

3.16

UVB

electromagnetic radiation in the range of 290 nm to 320 nm

3.17

UVA

electromagnetic radiation in the range of 320 nm to 400 nm

3.18

UVA-I

electromagnetic radiation in the range of 340 nm to 400 nm

ISO/DIS 23675:2023(E)

3.19

UVA-II

electromagnetic radiation in the range of 320 nm to 340 nm

3.20

%RCEE

percentage relative cumulative erythematous effectiveness

4 Principles

The test is based on the assessment of UV-transmittance through a thin film of sunscreen spread on at least three moulded PMMA plates and on at least three sandblasted surface PMMA plates, before and after exposure to a controlled dose of radiation from a solar simulator.

5 Reagents and/or materials

5.1 Sample substrate/plate

Moulded and sandblasted PMMA plates shall be used as the substrate for sunscreen application according to this method ([Annex B](#)).

5.2 Reference sunscreen

The formulae details and manufacturing instructions for the reference formulations are given in [Annex C](#). At least once month, the following reference standards shall be tested: P2 or P3 reference standard, and P5 or P6 reference standard, and P8 reference standard. The results shall be within the respective acceptance ranges given in [Annex C](#).

5.3 Finger-cot

Finger-cots should be manufactured from untextured, un-powdered latex and of a medium size. If alternative finger-cots are used, a validated equivalent result shall be demonstrated in this method. The finger-cot should be tight on the robot finger probe without ripples or breaks where product could get caught.

5.4 Blank

Glycerin or a modified glycerin solution ([Table B.2](#)), or white petroleum ([Annex D](#)) shall be used for blank measurement.

6 Apparatus

6.1 Spectrophotometers

6.1.1 Specification

The spectrophotometer shall span the spectral range from 290 nm to 400 nm. The wavelength increment step shall be 1 nm. A spectrophotometer that does not use a monochromator to analyze the reflected or transmitted radiation from the test sample should employ a fluorescence rejection filter. Its input optics should be designed for diffuse illumination and/or diffuse collection of the transmitted irradiance through the roughened polymethylmethacrylate (PMMA) substrate, with and without the sunscreen layer spread on its surface. The size of the diameter of the entrance port of the spectrophotometer probe should be smaller than the size of the light spot to be measured at the sample level (in order to account for stray light). The area of each reading site shall be at least 0,5 cm² in order to reduce the variability between readings and to compensate for the lack of uniformity in the product

layer. The wavelength should be accurate to within 1 nm, as checked using a holmium-doped filter ([Annex E](#)). The ability of an instrument to accurately measure absorbance is limited by the sensitivity of the instrument. The minimum required dynamic range for this methodology is 2,2 absorbance units as determined according to [Annex E](#). The maximum measured absorbance should be within the dynamic range of the device used. If the test measurements yield absorbance curves that exceed the determined upper limit of the spectrophotometer, the product should be re-tested using an instrument with increased sensitivity and dynamic range.

In order to minimise scatter, the distance between the closest side of the plate and the emission source or the integrating sphere should not be more than 2 mm. The substrate shall be positioned in a horizontal plane during all steps including UV measurement steps.

The lamp in the spectrophotometer (or spectroradiometer) that is used to measure the absorbance shall emit a continuous spectrum of radiation (with no gaps or extreme peaks of emission in the UV region) over the range of 290 nm to 400 nm, and the level of irradiance should be sufficiently low, so that the photostability of the product is not unduly challenged, wherein the UV dose during one measurement cycle should not exceed 0,2 J/cm².

6.1.2 Monitoring

The spectrophotometer shall be validated every month by measurements of reference materials.

A three-fold test is required, as described in [Annex E](#):

- dynamic range of the spectrophotometer;
- linearity test of the spectrophotometer;
- wavelength accuracy test.

6.2 Automatic positive-displacement pipette

Positive displacement pipettes, micro-pipettes, automatic pipettes or any similar device should use piston-driven displacement and shall be capable of delivering accurate and repeatable aliquots of approximately 1,6 mg to 1,8 mg of a sunscreen product (as described in [7.3.1](#)).

NOTE 1,6 mg to 1,8 mg correspond to approximately 1,6 µl to 1,8 µl respectively.

6.3 Analytical Balance

A laboratory balance with at least 10⁻⁴ g precision shall be used.

6.4 Robot

The robot shall have (i) positional repeatability of at least ±0,1 mm in x, y and z axes, (ii) degrees of freedom equal to at least 6 rotating joints, (iii) a payload of at least 0,5 kg, (iv) a vertical force (z axis), measured in the centre of the plate (with the finger tool and finger cot, without x and y axis movement), of (6,0 ± 0,5) N. See also [Annex F](#).

6.5 Solar simulator

A xenon arc solar simulator with appropriate filters should be used and shall comply with the spectral specifications described in [Annex A](#). It shall be able to maintain a stable, sample-level temperature of (27 ± 2) °C.

ISO/DIS 23675:2023(E)

6.5.1 Quality of solar simulator radiation

The output from the solar UVR simulator shall be continuous, uniform, stable, with no gaps or extreme peaks of emission in the UVR region and suitably filtered to create a spectral quality that complies with the required acceptance limits (see Table A).

To ensure that appropriate amounts of UVA radiation are included in the spectrum of the solar UV simulator, the total radiometric proportion of UVA-II irradiance of the simulator (320 nm to 340 nm) shall be $\geq 20,0$ % of total UVR irradiance (290 nm to 400 nm) to be aligned with ISO 24444 which requires the same solar irradiance. Additionally, UVA-I region (340 nm to 400 nm) irradiance shall be ≥ 60 % of total UVR irradiance. The source spectral specification is described in terms of cumulative erythral effective irradiance by successive wavelength bands, 290 nm to 400 nm. The erythral effective irradiance of each wavelength band is expressed as a percentage of total erythral effective irradiance, 290 nm to 400 nm, or as percentage relative cumulative erythral effectiveness (%RCEE). The definition and calculation of %RCEE values is described in [Annex A](#) and acceptance limits are shown in Table A.

Total irradiance shall not exceed 200 W/m^2 . The output of the solar simulator shall be measured with a broad-spectrum sensor (capable of measuring between 280 nm and 1 600 nm) calibrated against a standard reference source over the range of 280 nm to 1 600 nm. Alternatively, the source may be measured with a calibrated spectroradiometer over this same wavelength range to determine the total irradiance.

In broad-beam UV-sources, spectra from different locations under the beam shall be recorded over at least 5 different locations (a location is defined for each plate) in order to account for uniformity.

The uniformity shall be ≥ 90 % as calculated by the following equation:

$$U = (1 - (\max - \min) / (\bar{X}))$$

where

U is the uniformity in percentage;

\bar{X} is the average.

If the uniformity is less than 90 %, then optical components should be adjusted (and a new beam uniformity control shall be performed) or appropriate compensation for different irradiance shall be made in the exposure time on each plate.

6.5.2 Maintenance and monitoring the solar simulator

The emission of the UV exposure source used for exposure shall be checked for compliance with the given acceptance limits by a suitably qualified expert (at least) every 12 months, or 2 500 hours of lamp running time and after changing any significant physical (optical) component of the solar simulator (including the bulb only if the bulb was not already previously calibrated with the associated solar simulator). The inspection should be conducted with a spectroradiometer that has been calibrated against a standard lamp that is traceable to a national or an international calibration standard. Prior to the UV exposure of sample, the UV intensity of the exposure source output shall be measured and recorded with a spectroradiometer (as detailed in [6.5.2](#)) or an erythema weighted radiometer cross-calibrated against a spectroradiometric measurement of each assigned solar simulator output as detailed in [6.5.2](#). Optical alignment shall be configured to ensure accurate radiometer alignment and reproduction of the assigned simulator output at the same optical reference plane measured with the spectroradiometer. A calibration factor Y for each radiometer with assigned solar simulator output shall be determined by the following equation:

$$Y = E_{\text{ersp}} / E_{\text{err}}$$