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Determination of sunscreen UVA photoprotection in vitro

Détermination in vitro de la photoprotection UVA

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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).

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

This second edition cancels and replaces the first edition (ISO 24443:2012), which has been technically revised.

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

This International Standard specifies the procedure to determine the Ultraviolet A Protection Factor (UVAPF) of a sunscreen product using the *in vitro* UVAPF according to the principles recommended by COLIPA in 2011. The outcome of this test method can be used to determine the UVA classification of topical sunscreen products according to local regulatory requirements.

Topical sunscreen products are primarily rated and labelled according to their ability to protect against sunburn, using a test method to determine the *in vivo* Sun Protection Factor (see ISO 24444). This rating evaluates filtration of sunburn generating radiation across the electromagnetic UV spectrum (290 nm to 400 nm). However, knowledge of the Sun Protection Factor (SPF) rating does not provide explicit information on the magnitude of the protection provided specifically in the UVA range of the spectrum (320 nm to 400 nm), as it is possible to have high SPF products with very modest UVA protection (e.g. SPF 50 with a UVAPF of only 3 to 4). There is demand among medical professionals, as well as knowledgeable consumers, to have fuller information on the UVA protection provided by their sunscreen product, in addition to the SPF, in order to make a more informed choice of product, providing a more balanced and broader-spectrum protection. Moreover, there also a demand to prevent UVA-induced darkening of the skin from a cultural point of view even without sunburn. The UVAPF value of a product provides information on the magnitude of the protection provided explicitly in the UVA portion of the spectrum, independent of the SPF values.

The test method outlined in this International Standard is derived primarily from the *in vitro* UVAPF test method as developed by COLIPA.

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Determination of sunscreen UVA photoprotection in vitro

1 Scope

This document specifies an *in vitro* procedure to characterize the UVA protection of sunscreen products. Specifications are proposed to enable determination of the spectral absorbance characteristics of UVA protection in a reproducible manner.

In order to determine relevant UVA protection parameters, the method has been created to provide an UV spectral absorbance curve from which a number of calculations and evaluations can be undertaken. Results from this measurement procedure can be used for other computations, as required by local regulatory authorities. These include calculation of the Ultraviolet-A protection factor (UVA-PF) [correlating with *in vivo* UVA-PF from the persistent pigment darkening (PPD) testing procedure], critical wavelength and UVA absorbance proportionality. These computations are optional and relate to local sunscreen product labelling requirements. This method relies on the use of static *in vivo* SPF results for scaling the UV absorbance curve.

This document is not applicable to powder products such as pressed powder and loose powder products.

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)*

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

***in vitro* UVA protection factor** **UVA-PF**

in vitro UVA protection factor of a sun protection product against UVA radiation, which can be derived mathematically with *in vitro* spectral modelling

3.2

***in vitro* protection factor**

SPF_{in vitro}, protection factor of a sun protection product against erythema-inducing radiation calculated with spectral modelling

3.3

λ_c

critical wavelength, calculated from spectral data. It corresponds to the wavelength at which the area under the absorbance curve represents 90 % of the total area under the curve in the UV region

3.4
action spectrum for erythema [1] [2].

$E(\lambda)$

relative effects of individual spectral bands of an exposure source for an erythema response

3.5
action spectrum for PPD [3] [4].

$P(\lambda)$

relative effects of individual spectral bands of an exposure source for a persistent pigment response

3.6
monochromatic absorbance

A_λ

sunscreen absorbance at wavelength, λ , related to the sunscreen transmittance, T_λ , by

$$A_\lambda = -\log(T_\lambda)$$

where transmittance, T_λ , is the fraction of incident irradiance transmitted by the sunscreen film

3.7
irradiance

I

fluence rate per unit area, expressed in W/m^2 , for a defined range of wavelengths

EXAMPLE From 290 nm to 400 nm for UVA + UV-B irradiance; from 320 nm to 400 nm for UVA irradiance.

3.8
spectral irradiance for SPF testing or PPD testing (standards.iteh.ai)

$I(\lambda)$

irradiance per unit wavelength, $I(\lambda)$, expressed in $\text{W}/\text{m}^2/\text{nm}$

3.9
spectrophotometer

equipment for measuring the reflection or transmission properties of a material as a function of wavelength limited to ultraviolet, visible and short infrared ranges in this document

3.10
spectroradiometer

device designed to measure the spectral density of illuminants

3.11
radiometer

device for measuring the radiant flux (power) of electromagnetic radiation

3.12
reference product

reference sunscreen product used to validate the testing procedure

3.13
solar simulator

Equipment used to simulate the solar irradiance and spectrum.

3.14
substrate plate

Material to which the test product is to be applied.

4 Principle

The test is based on the assessment of UV-transmittance through a thin film of sunscreen sample spread on a roughened substrate, before and after exposure to a controlled dose of radiation from a defined UV exposure source.

Because of the several variables that cannot be controlled with typical thin film spectroscopic techniques, each set of sunscreen transmission data is mathematically adjusted so that the *in vitro* SPF data yield the same measured *in vivo* SPF value that was determined by *in vivo* testing. As *in vivo* method could raise ethical consideration, any alternative SPF method, published as an ISO method, may be used.

Samples are then exposed to a specific measured dose of UV radiation to account for the photostability characteristics of the test product.

The resulting spectral absorbance data have been shown to be a useful representation of both the width and height of the UVA protection characteristics of the sunscreen product being tested. The mathematical modelling procedure has been empirically derived to correlate with human *in vivo* (persistent pigment darkening) test results.

5 Apparatus

5.1 UV spectrophotometer specifications

The UV spectrophotometer wavelength range shall span the primary waveband of 290 nm to 400 nm. The wavelength increment step shall be 1 nm.

A UV spectrophotometer that does not have a monochromator after the test sample should employ a fluorescence rejection filter.

The UV spectrophotometer 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 UV spectrophotometer probe shall 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 should 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 (see [Annex A](#)). 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 A](#).

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 UV spectrophotometer, the product should be re-tested using an instrument with increased sensitivity and dynamic range.

The lamp in the UV spectrophotometer that is used to measure the transmittance shall emit continuous radiation 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 (a xenon lamp is a convenient solution).

Therefore, the UV dose during one measurement cycle should not exceed 0,2 J/cm².

NOTE A UV spectrophotometer is used to measure the absorbance properties of the sunscreen on the test plates. A spectroradiometer is used to measure the spectral energy distribution and intensity of the UV exposure source or the UV spectrophotometer during the absorbance measurement of the sunscreen on the test plate. Coupled with an UV source, the radiometer can give similar results to a spectrophotometer.

5.2 Calibration of the UV spectrophotometer

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

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

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

5.3 Calibration of the UV exposure source

The spectral irradiance at the exposure plane of the UV exposure source that is used for irradiation (to take into account any photoinstability) shall be as similar as possible to the irradiance at ground level under a standard zenith sun.^[1] As defined by COLIPA,^[2] the reference standard sun has a total irradiance of 51.4 to 63.7 W/m² and a UVA to UVB irradiance ratio of 16.9 to 17.5.

Therefore, the UV irradiance shall be within the following acceptance limits (measured at sample distance).

Table 1 — UV exposure source specifications

UV exposure source specifications as measured with a spectroradiometer	
Total UV irradiance (290 nm to 400 nm)	40 W/m ² to 200 W/m ²
Irradiance ratio of UVA ^a to UVB ^b	11-22
^a 320 nm to 400 nm.	
^b 290 nm to 320 nm.	

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 $\geq 90\%$ as calculated by the equation:

$$(1 - (\max - \min) / (\text{average}))\% \geq 90\% *$$

*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 plate.

The UV exposure source device should have the ability to maintain samples within the range of 27 °C to 32 °C, with intra laboratory temperature ± 2 °C. It is important that the temperature of the sample itself on the plate shall be measured and not just the surrounding air temperature. Therefore, the measurement of the temperature shall be on plate level.

To maintain samples at required temperature, a filter system that particularly reduces Infrared radiation shall be used to achieve the specified temperature range. Cooling trays for the sample plates or ventilators shall be used to maintain a temperature lower than 32 °C and warming devices to maintain samples at or above 27 °C.

Measurement to be made using a sensor that is traceable to a national or an international calibration standard, within the range of use.

5.4 Monitoring of the UV exposure source

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 2500 hours of lamp running time. 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 provided

by an accredited ISO17025 laboratory. In addition to the spectroradiometric inspection, the intensity of the UV exposure source used for exposure shall be checked prior to each use.

This can be done using either a spectroradiometer or a radiometer with sensitivity in the UVA, calibrated for the same UV exposure source spectrum used for the exposure step of the procedure, applying the coefficient of calibration to adjust for variance between the UVA radiometer and the reference spectroradiometer.

5.5 Calibration of the UVA radiometer used to monitor the test sample irradiation

If a UVA radiometer is used, this device shall have been suitably calibrated. This requires that it be calibrated to the spectroradiometer used to measure the exposure source (as during annual solar simulator calibration).

Calibration shall be conducted in terms of UVA irradiance (320 nm to 400 nm) and shall be at the same level at which the test plates are exposed. Once calibrated with the spectroradiometer, the UVA radiometer may be used to determine the UV doses to be used during the exposure procedure on a day-to-day basis. [Annex B](#) provides the step-by-step calibration procedure.

5.6 Substrate/plate

The substrate/plate is the material to which the test product is to be applied. For this method, PMMA plates with one rough side of the substrate are to be used and are commercially available. The size of the substrate should be chosen such that the application area is not less than 16 cm².

The specifications and preparation of this type of plate^[2] are described in [Annex D](#).

6 Test method

6.1 Outline of the test procedure

6.1.1 Conduct the calibration and validation of the test equipment, including the UV spectrophotometer used for transmission/absorbance measurements and the UVA radiometer (or spectroradiometer) used to measure the UV exposure source, and verify the transmission properties of the test plates as described in [Annex D](#).

6.1.2 Conduct blank measurements of a glycerin-treated or Vaseline-treated plate for the reference “blank”, which will be used in the subsequent absorbance measurements.

6.1.3 Conduct *in vitro* absorbance measurements of the sunscreen product spread on a PMMA plate, prior to any UV irradiation. Acquire the initial mAf spectrum with $A_0(\lambda)$ data.

6.1.4 Conduct the mathematical adjustment of the initial UV absorbance spectrum using coefficient “C” (see the calculation in [6.7.2](#)) to achieve an *in vitro* SPF (no UV dose) equal to the measured static *in vivo* SPF. Initial UVA-PF₀ is calculated using $A_0(\lambda)$ and C. A single UV exposure dose, *D*, is calculated, equal to $1,2 \times \text{UVA-PF}_0$ in J/cm², for each plate

6.1.5 Conduct UV exposure of the same sample as in [6.1.3](#), according to the calculated UV exposure dose *D*.

6.1.6 Measure the *in vitro* absorbance of the sunscreen product after UV exposure. Acquire the second UV spectrum with $A(\lambda)$ data.

6.1.7 Conduct the mathematical adjustment of the second mAf spectrum (following UV exposure) by multiplying with the same “C” coefficient, previously determined in 6.1.4. The resulting absorbance curve is the final adjusted absorbance values.

6.2 Equipment calibration and validation of test plates

Test procedures as described in Annex A are to be completed to validate the wavelength accuracy, linearity and absorbance limits of the UV spectrophotometer/spectroradiometer to be used for the test procedure. Validation of the UV properties of the test PMMA plates shall also be conducted as described in Annex D.

6.3 Absorption measurements through the plate

It is necessary to first determine the absorbance of UV radiation through a “blank” PMMA plate. Prepare a “blank” plate by spreading a few microlitres of glycerin/vaseline on the roughened side of the plate. Choose the amount of glycerine/vaseline such that the entire surface is just completely covered (approximately 15 µl for a 50 mm × 50 mm plate).

Any excess of glycerine/vaseline should be avoided. Measure the absorbance through this “blank” plate and use this as the baseline measurement for subsequent absorbance measurements.

NOTE Many spectrophotometers have “baseline” functions to automatically incorporate this baseline measurement into the calculations of subsequent absorbance measurements.

6.4 Sample application iTeh STANDARD PREVIEW

The sunscreen product is applied to a new untreated roughened PMMA plate (with the roughened side uppermost) by mass, at an application rate of 1,3 mg/cm².

To ensure dose accuracy and repeatability, the application area should be not less than 16 cm².

The application dose may be determined by measuring the mass loss of the pipette before and after application of the product; alternatively, it may be applied based on volumetric measurements with consideration of the specific gravity of the test sample. Where possible, a positive-displacement automatic pipette should be used for this purpose.

Plates should be weighed after application phase for any non-volatile product.

The sunscreen is applied as at least twelve small droplets of approximate equal volume, distributed evenly over the whole surface of the plate.

Finger cots shall not be used to spread the product on the plate. The fingertip used for spreading shall be dipped into the test product and then wiped to remove excess product before spreading the test product applied to the plate. The fingertip used to spread the product shall be cleaned between applications of different test products.

Deposit and weighing shall not take more than 30s.

The first test plate applied should not be used for all the measurements, but to adjust the quantity.

After the sunscreen product is deposited on the surface of the plate, it shall be spread immediately over the whole surface using light strokes with human fingertip (without finger cot) or mechanical fingertip. Spreading should be completed in a two-phase process:

First, the product should be spread on the whole area of the plate, using circular movements with a minimum of four passages from the top to the bottom of the plate. At the end of the first pass, a turn of the plate has to be done (¼ turn) to alternate passages, with minimal pressure and repeat this movement three times at least (about 30s).

Then the sample should be rubbed on the plate surface using alternating horizontal and vertical strokes repeated at least three times alternate passages with a moderate but increased pressure. The second phase should last about 30s. with increased moderate pressure.

For alcoholic or oil products, application should be adapted:

First, the product shall be spread on the whole area of the plate, using circular movements with a minimum of three passages from the top to the bottom of the plate. At the end of the first pass, a turn of the plate has to be done ($\frac{1}{4}$ turn) to alternate passages, with minimal pressure and repeat this movement two times at least (about 20s to 25s).

Then the sample shall be rubbed on the plate surface using alternating horizontal and vertical strokes repeated at least two times alternate passages with a moderate but increased pressure. The second phase should last about 20s. with increased moderate pressure.

For all kind of product, the treated sample shall be allowed to dry for 30 min to 60 min in the dark **at the same temperature** that will be experienced under the UV exposure conditions (i.e. if UV source exposure conditions will be 30 °C, then the drying conditions should also be at 30 °C; or if the UV source exposure conditions will be 27 °C, then the drying conditions should also be 27 °C).

NOTE Spray products provided in a pressurized container must first be degassed by puncturing a very small pinhole in the container to relieve all of the pressure, and allowed to rest for at least 24 hours at room temperature before accessing the liquid for testing.

6.5 Absorbance measurements of the product-treated plate

The product-treated plate is placed in the light-path of the UV spectrophotometer and the absorbance of UV radiation through the sample is determined for each wavelength, from 290 nm to 400 nm, in 1 nm steps. One or more observations of absorbance may be made per plate and the mean value shall be determined for each plate.

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6.6 Number of determinations

At least four plates prepared with the test sunscreen shall be used to establish the protection aspects of the test sample. Additional plates shall be added to the sampling if the 95 % confidence interval (CI) is greater than 17 % of the mean value of the UVA-PF value, until the 95 % CI is less than 17 % of the mean UVA-PF value. Calculation procedures for this are described in [Annex F](#).

6.7 Determination of initial calculated SPF ($SPF_{in vitro}$), “C” value, initial UVA-PF (UVA-PF₀), and UV exposure dose

6.7.1 Determination of $SPF_{in vitro}$

The UV solar simulator radiation (UV-SSR) source spectrum, $I(\lambda)$, (see [Annex C](#)) is multiplied with the corresponding erythema action spectrum sensitivity value, $E(\lambda)$, (see [Annex C](#)) at that wavelength to yield the sunburning effective energy at that wavelength. The resulting sunburning effective irradiance is integrated over the 290 nm to 400 nm range. The sunscreen transmission values at each wavelength are multiplied with the erythema effective energy at that wavelength and integrated over the same interval to yield the effective sunburning energy transmitted through the test product. The ratio of these two integrals is the *in vitro* calculated SPF value.

Calculation of $SPF_{in vitro}$ is shown in [Equation \(1\)](#):

$$SPF_{in vitro} = \frac{\int_{\lambda=290}^{\lambda=400} E(\lambda) \times I(\lambda) \times d\lambda}{\int_{\lambda=290}^{\lambda=400} E(\lambda) \times I(\lambda) \times 10^{-A_0(\lambda)} \times d\lambda} \quad (1)$$

where