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Bestämning av den ljusskyddande effekten av solskydd UVA in vitro
(ISO 24443:2012)

Determination of sunscreen UVA photoprotection in vitro
(ISO 24443:2012)

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Denna standard är framtagen av kommittén för Analysmetoder för allergiframkallande ämnen, SIS/TK 495.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 24443

June 2012

ICS 71.100.70

English Version

Determination of sunscreen UVA photoprotection in vitro (ISO 24443:2012)

Détermination in vitro de la photoprotection UVA (ISO 24443:2012)

In vitro Bestimmung des UVA-Schutzes von Sonnenschutzmitteln (ISO 24443:2012)

This European Standard was approved by CEN on 24 May 2012.

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Foreword

This document (EN ISO 24443:2012) 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of an identical text or by endorsement, at the latest by December 2012, and conflicting national standards shall be withdrawn at the latest by December 2012.

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Endorsement notice

The text of ISO 24443:2012 has been approved by CEN as a EN ISO 24443:2012 without any modification.

Determination of sunscreen UVA photoprotection *in vitro*

1 Scope

This International Standard specifies an *in vitro* procedure to characterize the UVA protection of sunscreen products. Specifications are given 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 a 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 (UVAPF) [correlating with *in vivo* UVAPF 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 *in vivo* SPF results for scaling the UV absorbance curve.

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

2 Terms and definitions

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

2.1
***in vitro* UVA protection factor**
UVAPF
in vitro UVA protection factor of a sun protection product against UVA radiation, which can be derived mathematically with *in vitro* spectral modelling

2.2
***in vitro* calculation of SPF**
$SPF_{in\ vitro}$
protection factor of a sun protection product against erythema-inducing radiation calculated with spectral modelling

2.3
action spectrum for erythema
$E(\lambda)$
relative effects of individual spectral bands of an exposure source for an erythema response

NOTE See References [1] and [2].

2.4
action spectrum for PPD
$P(\lambda)$
relative effects of individual spectral bands of an exposure source for a persistent pigment response

NOTE See References [3] and [4].

2.5
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

2.6
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 + UVB irradiance; from 320 nm to 400 nm for UVA irradiance.

2.7
spectral irradiance for SPF testing or PPD testing
$I(\lambda)$
irradiance per unit wavelength, $I(\lambda)$, expressed in W/m^2/nm

2.8
spectrophotometer
instrument that measures absorbance (or transmission) properties of a test medium as a function of wavelength

2.9
spectroradiometer
instrument that measures spectral irradiance (intensity in watts per unit area per nanometre) of electromagnetic sources

NOTE Limited to ultraviolet, visible and short infrared ranges in this International Standard.

2.10
radiometer
instrument that measures broad band irradiance (intensity in watts per unit area) of electromagnetic sources

NOTE Limited to ultraviolet, visible and short infrared ranges in this International Standard.

3 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. 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.

4 Apparatus

4.1 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 cm^2 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 flash lamp is a convenient solution). Therefore the UV dose during one measurement cycle should not exceed 0,2 J/cm^2.

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.

4.2 Calibration of the UV spectrophotometer

The UV spectrophotometer shall be validated at regular intervals (recommended at least 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.

4.3 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[5] as defined by COLIPA[6] or in DIN 67501[7]. 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]	8:22
[a] 320 nm to 400 nm.	
[b] 290 nm to 320 nm.	

The UV exposure source device should have the ability to maintain samples within the range of 25 °C to 35 °C. It is important that the temperature of the sample itself be measured and not just the surrounding air temperature. To maintain samples at a temperature less than or equal to 35 °C, a filter system that particularly reduces IR radiation should be used to achieve the specified temperature range. Cooling trays for the sample plates or ventilators should be used to maintain a temperature below 35 °C and warming devices to maintain samples at or above 25 °C.

4.4 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 18 months, or after 3 000 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. 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