SLOVENSKI STANDARD
SIST EN ISO 24443:2012

01-december-2012

Kozmetika - Določevanje zaščitnega faktorja UVA in vitro (ISO 24443:2012)

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

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

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

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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of an identical text or by endorsement, at the latest by December 2012, and conflicting national standards shall be withdrawn at the latest by December 2012.

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INTERNATIONAL STANDARD

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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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