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Cosmetics- — Measurement of the sunscreen efficacy by diffuse reflectance spectroscopy

Cosmétiques~~— Mesure~~ — Mesurage de l'efficacité des produits de ~~l'écran~~protection solaire par spectroscopie de ~~reflectance~~réflectance diffuse

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This document was prepared by Technical Committee ISO/TC 217, *Cosmetics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 392, *Cosmetics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

Exposure to solar ultraviolet radiation (UVR) is the main environmental source of acute and chronic damage to human skin. Skin cancer is the most prevalent form of cancer of the body and is primarily driven by exposure to sunlight. Protection against exposure to solar UVB and UVA radiation is, therefore, an important public health issue. The use of topically applied sunscreens is a critical part of holistic programs of consumer UVR protection, including the use of appropriate clothing, hats and minimizing exposure to the sun.

The sun protection factor (SPF) has historically been measured by an in vivo method (see ISO 24444[1]) to communicate the magnitude of the protection provided by sunscreens from sunburning UVR. Other test methods have been developed and provided to assess the breadth and magnitude of the protection in the UVA portion of the sun's spectrum (see ISO 24442[2] and ISO 24443[3]).

This test method given in this document is an alternative to ISO 24443[3] and ISO 24444[1] methods.

Invasive methods based on tests conducted on human beings are ethically problematic, time-consuming and very costly. Therefore, it has long been desired to develop alternative methods to assess both the magnitude and breadth of protection afforded by sunscreens that do not require invasive procedures and that reliably provide equivalent testing sensitivity and accuracy as the existing invasive in vivo testing methods.

The hybrid diffuse reflectance spectroscopy method described herein, provides a non-invasive optical assessment of the protection provided by topically applied sunscreen products as measured in situ on human skin as used by consumers, without requiring physiological responses and causing no physical harm to the test subject. By combining full spectrum in vitro spectroscopic measurements of the sunscreen, with optical measurements of the sunscreen transmission in the UVA on human skin, a hybrid spectrum is derived that provides full assessment of both magnitude and breadth of sunscreen protection in both the UVB and UVA regions of the sun's spectrum, correlating closely with in vivo SPF, in vitro UVA-PF and critical wavelength test results demonstrating equivalence of this test method against ISO 24444[1] and ISO 24443[3] methods.

Cosmetics – — Measurement of the sunscreen efficacy by diffuse reflectance spectroscopy

1 Scope

This document provides a procedure to characterize the sun protection factor (SPF), UVA protection factor (UVA-PF) and critical wavelength (CW) protection of sunscreen products without requiring biological responses. The test method is applicable for emulsions and single-phase products. The method has not been evaluated for use with powder forms sunscreen products.

This document gives specifications to enable determination of the absolute spectral absorbance characteristics of a sunscreen product on skin to estimate sunburn and UVA protection. 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.

2 ~~Informative~~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, the latest edition of the referenced document (including any amendments) applies.~~

~~— ISO 24442:2022, *Cosmetics – Sun protection test methods – In vivo determination of sunscreen UVA protection*~~
~~— ISO 24443:2021, *Cosmetics – Determination of sunscreen UVA photoprotection*~~
~~— ISO 24444:2019, *Cosmetics – Sun protection test methods – In vivo* determination of sun protection~~

There are no normative references in this document.

3 Terms, definitions~~,~~ and symbols

3.1 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~~https://www.iso.org/obp

— ~~—~~IEC Electropedia: available at ~~http://www.electropedia.org/~~https://www.electropedia.org/

~~3.1 Terms and Definitions~~

~~3.1.1~~
3.1.1
absorbance
A
measure of the energy blocked; either by optical absorption or by physical scattering/reflection~~.~~

3.1.2
absorbance spectrum
A~~(λ)~~(λ)
sunscreen optical absorbance at wavelength ~~λ.~~ λ

Note 1 to ~~this~~ entry: Logarithm to the base 10 of the reciprocal of the spectral transmittance ~~τ(λ).~~τ(λ). A~~(λ).~~(λ) = -[$\log_{10}$ ~~τ(λ)~~]τ(λ)].

~~3.1.3~~

3.1.3

absorbance by diffuse reflectance spectroscopy ~~(~~

absorbance by DRS~~)~~

A_{DRS}**(λ)**

absorbance spectrum calculated from DRS as a function of wavelength λ

Note 1 to entry: ~~absorbance~~ Absorbance spectrum relevant to this standard is 320 nm to 400 nm.

~~3.1.4~~

3.1.4

absorbance after hybridization

A_{HDRS}**(λ)**

final absorbance spectrum calculated from the hybridized signals as a function of wavelength λ after correction for photo-degradation

Note 1 to entry: The final absorbance spectrum is 290 nm to 400 nm

3.1.5

calibration factor

C_{cal}

correction applied to a measured quantity value to compensate for a known systematic effect

3.1.6

in vitro UV absorbance spectrum pre irradiation~~3.1.6~~

in vitro absorbance before UV exposure (pre irradiation)

A_{vt0}**(λ)**

arithmetic mean in vitro absorbance spectrum of a sunscreen product measured before UV exposure

Note 1 to entry: The absorbance spectrum is 290 nm to 400 nm.

3.1.7

in vitro UV absorbance spectrum post irradiation ~~3.1.7~~

in vitro absorbance after UV exposure (post irradiation)

A_{vt1}**(λ)**

arithmetic mean in vitro absorbance spectrum of a sunscreen product measured after UV exposure

Note 1 to entry: The absorbance spectrum is 290 nm to 400 nm.

~~3.1.8~~

3.1.8

hybridization constant

C_{Ai}

scalar factor to adjust an in vitro spectrum A_{vt1} ~~(λ)~~(λ) at each wavelength to the individual A_{DRSi}

~~3.1.9~~
3.1.9
critical wavelength
CW~~,~~
λc

wavelength at which the area under the absorbance curve represents 90 % of the total area under the curve in the UV region

~~3.1.10~~
3.1.10
dose
D
UVA radiant exposure dose for pre-irradiation of sunscreen products (1~~,~~2 x UVA-PF_{DRS} J/cm^2)

~~3.~~3.1.11
wavelength step
$d\lambda$
differential of integration (1 nm)

~~3.~~3.1.12
diffuse reflectance spectroscopy
DRS
technique used to measure the remitted light from skin or skin remittance.

Note 1 to entry: Using this technique, the UVA absorbance spectrum of a sunscreen product applied on skin in vivo can be determined.

Note 2 to entry: The term "light" is used generically to describe electromagnetic radiation from both UV and visible wavelengths of optical spectrum throughout the document. It is differentiated as needed in specific sections of the document.

Note 3 to entry: The UV energy that is measured is not energy reflected from the surface of the skin or the applied sunscreen. The UV energy being measured has passed through the sunscreen, entered the surface of the skin, and been scattered therein. Some of this energy is remitted back to the surface of the skin through the sunscreen a second time and picked up by the DRS optical probe. The term "remittance" is used throughout this document whereas historical use of the term "reflectance" has had precedence in published literature.

~~3.~~3.1.13
erythema action spectrum
E(λ)
relative effects of individual spectral bands of an exposure source causing an erythema response in skin ~~see Annex E~~

~~3.~~Note 1 to entry: See Annex E.

3.1.14
hybrid diffuse reflectance spectroscopy
HDRS
method to evaluate the protection provided by a sunscreen product applied on skin in vivo wherein the UVA Protection Factor is measured by DRS and the UVB part of the spectrum by in vitro thin film spectroscopy, and the two spectra are merged to form a hybrid absorbance spectrum.

Note 1 to entry: The spectral distributions determined by the two different methods are merged to form the hybrid spectral absorption $A_{HDRS}(\lambda)$.

~~3.1.15~~
3.1.15
hybridization wavelength
HW
λ_{HW}
wavelength at which the in vivo DRS spectrum and the in vitro absorbance spectrum are merged

3.1.16
PPD action spectrum
P(λ)
relative effects of individual spectral bands of an exposure source to cause persistent pigment darkening (PPD) ~~– see Annex E~~

Note 1 to entry: See Annex E.

3.1.17
sun protection factor by hybrid DRS
SPF_{HDRS}
SPF of a sunscreen product calculated from hybridized UV absorbance spectrum adjusted by spectral ratio of photo-degradation (SRPD) ~~(λ)~~(λ)

3.1.18
spectral ratio of photo-degradation ~~(λ)~~(λ)
S_{RPD}(λ)
ratio of the in vitro absorbance spectra (post- and pre-irradiation) representing the photo-degradation of the sunscreen product as function of wavelength

Note 1 to entry: SRPD ~~(λ)~~(λ) spectrum is 290 nm to 400 nm

3.1.19
subsite
area within a test site where the DRS probe is placed to take the individual skin remittance measurement denoted by index j

3.1.20
test site
defined area of the skin to which a test sunscreen material is applied and where DRS measurements are conducted

3.21
Student's t value
t
two tail Student's t-test critical value for 0,05, with n-1 degrees of freedom

3.1.22
transmittance spectrum by DRS
T_{DRS}(λ)
in vivo transmittance spectrum of a sunscreen product calculated from DRS as a function of wavelength λ

Note 1 to entry: The in vivo transmittance spectrum is 320 nm to 400 nm.