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Cosmetics — Measurement of the sunscreen efficacy by diffuse reflectance spectroscopy

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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 prevelant 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 (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 (ISO 24442,[2] and ISO 24443[3]).

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 and *in vitro* UVA-PF test results as demonstrated during validation of this test method.

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Cosmetics — Measurement of the sunscreen efficacy by diffuse reflectance spectroscopy

1 Scope

This test method 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 method has been validated for emulsions and single-phase products. Specifications are given 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. This method is an alternative to ISO 24443[3] and ISO 24444[1] methods.

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 24442:2022, *Cosmetics — Sun protection test methods — In vivo determination of sunscreen UVA protection*[2]

ISO 24443:2021, *Cosmetics — Determination of sunscreen UVA photoprotection in vitro*[3]

ISO 24444:2019, *Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF)*[1]

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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 https://www.electropedia.org/

3.1
absorbance
A
absorbance is the measure of the energy blocked; either by optical absorption or by physical scattering/ reflection

3.2
absorbance spectrum
A(λ)
sunscreen optical absorbance at wavelength λ. Logarithm to the base 10 of the reciprocal of the spectral transmittance $\tau(\lambda)$. $A(\lambda) = -\log 10\ \tau(\lambda)$

3.3
absorbance by DRS
$A_{DRS}(\lambda)$
absorbance spectrum (320-400 nm) calculated from DRS as a function of wavelength λ

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3.4
absorbance after hybridization
$A_{HDRS}(\lambda)$
final absorbance spectrum (290-400 nm) calculated from the hybridized signals as a function of wavelength λ after correction for photo-degradation

3.5
Calibration Factor
C_{cal}
a correction applied to a measured quantity value to compensate for a known systematic effect

3.6
***in vitro* absorbance before UV exposure (pre irradiation)**
$A_{vt0}(\lambda)$
arithmetic mean *in vitro* absorbance spectrum (290-400 nm) of a sunscreen product measured before UV exposure

3.7
***in vitro* absorbance after UV exposure (post irradiation)**
$A_{vt1}(\lambda)$
arithmetic mean *in vitro* absorbance spectrum (290-400 nm) of a sunscreen product measured after UV exposure

3.8
hybridization constant
C_{Ai}
scalar factor to adjust an *in vitro* spectrum A_{vt1} (λ) at each wavelength to the individual A_{DRSi}

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3.9
dose
D
UVA exposure dose for pre-irradiation of sunscreen products (1,2 x UVA-PF_{DRS} J/cm^2)

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3.10
wavelength step
dλ
differential of Integration (1 nm)

3.11
Diffuse Reflectance Spectroscopy
DRS
technique used to measure the remitted light from skin or skin remittance. Using this technique, the UVA absorbance spectrum of a sunscreen product applied on skin *in vivo* can be determined.

Note 1 to entry: The UV energy that is measured is not energy reflected from the surface of the skin or the applied sunscreen, but rather energy that has passed through the sunscreen, entered the surface of the skin, been scattered therein, some of which 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).

3.12
erythema action spectrum
E(λ)
relative effects of individual spectral bands of an exposure source causing an erythema response in skin (Annex E)

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3.13
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

3.14
hybridization wavelength
HW
the wavelength at which the in vivo DRS spectrum and the *in vitro* absorbance spectrum are merged

3.15
remitted intensity of unprotected skin using polychromatic method for an individual subsite
I_u
intensity of remitted UVA from unprotected skin with polychromatic DRS measurement device

3.16
remitted intensity of sunscreen protected skin using polychromatic method for an individual subsite
I_p
intensity of remitted UVA from sunscreen-treated skin with polychromatic DRS measurement device

3.17
index for individual subject
i
index for individual subjects

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3.18
index for individual subsite
j
index for individual test subsite

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3.19
index for individual PMMA plate (in vitro measurement)
k
index for individual PMMA plate (*in vitro* measurement)

3.20
index for individual spot of in vitro measurement
l
index for individual spot of *in vitro* measurement

3.21
number of subsites
m
number of subsite measurements per site

3.22
number of context dependent elements
n
number of elements. These elements can be the subjects, the spots on a PMMA plate or the valid test results. Which element is chosen, depends on the context of the section

3.23
PPD action spectrum
P(λ)
relative effects of individual spectral bands of an exposure source to cause Persistent Pigment Darkening (PPD) Annex E

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3.24
remittance (product-treated skin)
R_p (λ)
intensity of remittance spectrum (320-400 nm) of product-treated skin

3.25
remittance (unprotected skin)
R_u(λ)
intensity of remittance spectrum (320-400 nm) of unprotected skin

3.26
spectral irradiance
S(λ)
spectral irradiance of the light source used to expose the plates

3.27
scalar multiplier for spectrum
s
scalar multiplier for scaling *in vitro* spectra

3.28
Sun Protection Factor by Hybrid DRS
SPF_{HDRS}
SPF of a sunscreen product calculated from hybridized UV absorbance spectrum adjusted by SRPD

3.29
Spectral Ratio of Photo-Degradation
SRPD(λ)
ratio of the *in vitro* absorbance spectra (post- and pre-irradiation) representing the photo-degradation of the sunscreen product as function of wavelength

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3.30
standard deviation
stdev
standard deviation of the ln transformed UVA-PF_{HDRSi} values or the ln transformed SPF_{HDRSi} values (context dependent)

3.31
subsite
area within a test site where the DRS probe is placed to take the individual skin remittance measurement denoted by index j

3.32
test site
defined area of the skin to which a test sunscreen material is applied

3.33
Student's t value
t
two tail Student's T-test critical value for 0,05, with n-1 degrees of freedom

3.34
transmission by DRS
T_{DRS}(λ)
in vivo transmission spectrum (320-400 nm) of a sunscreen product calculated from DRS as a function of wavelength *λ*

3.35
***in vitro* transmission (pre irradiation)**
T_{vt0}(λ)
in vitro transmission spectrum (290-400 nm) before UV-exposure

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3.36
***in vitro* transmission (post irradiation)**
$T_{vt1}(\lambda)$
in vitro transmission spectrum (290-400 nm) after UV-exposure

3.37
UVA protection factor by DRS
$UVA\text{-}PF_{DRS}$
initial UVA protection factor of a sunscreen product calculated using the measured *in vivo* absorbance spectrum from DRS before correction for photo-degradation

3.38
UVA protection factor by HDRS
$UVA\text{-}PF_{HDRS}$
UVA protection factor of a sunscreen product calculated from hybridized UV absorbance spectrum adjusted by SRPD

3.39
***in vitro* UVA protection factor before UV exposure**
$UVA\text{-}PF_{vt0}$
in vitro UVA Protection Factor of a sunscreen product calculated using the absorbance spectrum A_{vt0}

3.40
***in vitro* UVA protection factor after UV exposure**
$UVA\text{-}PF_{vt1}$
in vitro UVA Protection Factor of a sunscreen product calculated using the absorbance spectrum A_{vt1}

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3.41
in vitro
vt
index for *in vitro*

4 Principle

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This method provides a hybrid *(in vitro* and *in vivo*) testing procedure to characterize UV protection provided by sun care preparations. The primary outputs of this test procedure are measures of the spectral absorbance characteristics of a sunscreen product. Different approaches to generate hybridized absorbance spectra are available, e.g. monochromatic as well as polychromatic measurement techniques.

The UVA-PF can be predicted by Diffuse Reflectance Spectroscopy DRS measuring the UVA absorbance of skin (320-400 nm)[4][5][6][7] and has been shown to correlate with *in vivo* assessment using ISO 24442,[2] as well as UVA-PF's using ISO 24443.[3] Because of the high UVB absorbance characteristics of the stratum corneum and epidermis, the human skin does not remit enough UVB radiation for absorbance measurements. Therefore, the spectral absorbance 'shape' in the UVB region must be assessed separately by *in vitro* thin film transmission spectroscopy using ISO 24443[3] methodology. To account for sunscreen products photo-instability of the sunscreen under evaluation, the same approach used in ISO 24443[3] is applied. The *in vitro* thin film sunscreen sample is subjected to a controlled dose of simulated sunlight radiation to determine the shape of the spectrum after UV exposure which is used to adjust the HDRS absorbance spectrum.

In order to obtain a full UV absorbance spectrum, the *in vitro* absorbance is scaled to match the DRS absorbance values and then the *in vitro* UVB portion is mathematically attached to the UVA portion (from DRS technique). This Hybrid Diffuse Reflectance Spectroscopy (HDRS) absorbance spectrum is then used to calculate the UVA Protection Factor (UVA-PF), Sun Protection Factor (SPF) and Critical Wavelength (CW) of the sunscreen products being tested[8][9].

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5 Materials and methods

5.1 In vitro UV Spectrophotometer

The *in vitro* UV spectrophotometer should follow the specifications and calibration procedure as described in Annex B.

5.2 In vitro substrate / plate

The substrate / plate is the material to which the test product is applied for the *in vitro* part of this method. Polymethylmethacrylate (PMMA) plates with one rough side of the substrate are to be used and prepared as specified per Annex D.

5.3 In vivo Diffuse Reflectance Spectrometers (DRS) Specifications

5.3.1 Monochromatic DRS system

In vivo Monochromatic DRS measurements are to be conducted using a bifurcated optical fiber system and two monochromators for excitation / emission measurements. The monochromatic system shall have specifications as described in sections 5.3.1.1 through 5.3.1.5.

5.3.1.1 Monochromators

Monochromators used for excitation or emission can be single or double monochromators with a wavelength accuracy of +/- 0,1 nm. The ratio of stray light (at a distance from the peak wavelength that is 10 x the bandwidth at half maximum of the laser line peak intensity), to the peak intensity of a laser line shall be less than 5 x 10^{-5}. Furthermore, installed filters shall be used to block any visible light from entering the photomultiplier detector.

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5.3.1.2 DRS optic source

A short arc xenon bulb emitting continuous radiation over the range of 290 - 400 nm is recommended. A maximum exposure dose of 21 J/m^2 eff dose shall not to be exceeded for any measurement sub-site.

5.3.1.3 DRS Illumination/Collection Fibers

A UV grade fused silica bifurcated fiber probe comprised of a fiber arrangement as described in Annex I, with approximately 1,5 m common probe length and two 0,5 m short arms (one for excitation and one for emission) is recommended.

5.3.1.4 Detector system

A bi-alkali photo multiplier cathode detector is recommended. To obtain a better signal to noise ratio it is recommended that the detector should be cooled (i.e. -20 °C). The PMT temperature should be approximately 40° K lower than room temperature.

5.3.1.5 Sensitivity requirements

A linear response detection shall be at least 5 decades (100,000:1), (6 decades (1,000,000:1) are recommended) in the range of 290 - 400 nm. Usually this can be achieved by a double monochromator spectrophotometer with a good stray light rejection and an appropriated, cooled photomultiplier tube (PMT). The chosen voltage of the PMT (gain) should allow a high sensitivity at lower wavelength (<320 nm) and avoid an overload of the PMT at higher wavelength (>370).

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5.3.2 Polychromatic DRS system

In vivo polychromatic DRS measurements are to be conducted using a light source with spectral output as described in Annex E (UVA Radiation Source); a bifurcated optical fiber system having a diffuse reflectance optical head (as describe in Annex I-Optical Fibers and Calibration), and a PMT detector system with a response spectrum similar to the human PPD action spectrum as described in Annex E. Any differences between the PMT detector system X spectral output of the source and the human PPD action spectrum X spectral output of the source shall be corrected with a spectral mismatch calculation routine. The system shall have the specifications as described in sections 5.3.2.1 through 5.3.2.3.

5.3.2.1 DRS optic source

A short arc xenon bulb emitting continuous radiation over the range of 290 - 400 nm is recommended. For the polychromatic DRS system, a UVB blocking filter, and a visible light and infrared blocking filter shall be used to limit the output to only UVA radiation according to the specifications described in Annex E (UVA Radiation Source). A maximum exposure dose of 21 J/m^2 eff dose shall not to be exceeded for any measurement sub-site. The maximum exposure intensity at skin surface shall be less than 5 mW/cm^2.

5.3.2.2 Detector system

A visible light ("black glass") blocking filter should be included before a broad-spectrum photo multiplier cathode detector to eliminate measurement of visible fluorescence using the polychromatic DRS system and to shape the action spectrum of the detector to be similar to the skin's PPD action spectrum as described in Annex E (PPD Action Spectrum).

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5.3.2.3 Sensitivity requirements

The system shall have a linear response range capable of at least 2500:1.

5.4 Monitoring the DRS system

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5.4.1 Monochromatic DRS system

Wavelength accuracy shall be checked regularly either with a Holmium-Oxide-Filter (according to Appendix B.2) or with a low-pressure mercury, "cold quartz" or equivalent lamp following usual calibration procedures.

A periodic inspection of the DRS wavelength accuracy and fiber output intensity (at least once every 12 month or as recommended by manufacturer instructions) should be conducted by a trained, competent and suitably qualified person (internal or external).

5.4.2 Polychromatic DRS system

The illumination beam of the polychromatic DRS system shall be checked periodically to assure conformance to the specifications described for the UVA Radiation Source in Annex E. A spectroradiometric inspection of the spectrum shall be conducted at least once every 12 months by a trained, competent and suitably qualified person (internal or external) using a system calibrated to a traceable national or international calibration standard lamp.

5.5 Test conditions

Baseline DRS measurement and product application assessment should be carried out in stable conditions, with the room temperature maintained between (23 ± 3) °C.

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5.6 Test Method for Remittance Measurement

5.6.1 Subject exclusion criteria

Exclusion criteria shall be checked before testing.

The following conditions shall automatically disallow inclusion of a subject in the test group:

a. Children or persons below the locally legal age of consent.

b. Subjects with systemic dermatological conditions in the test area (including dysplastic nevi).

c. Subjects having excessive hair in the area on the test on the day of testing (may be shaved up to 3 days prior to the test day, or clipped on the test day).

d. Subjects with average ITA <28.

e. Subjects having relevant UV-dose applied to the test sites, (i.e. SPF (ISO 24444[1]), UVA-PF (ISO 24442[2]), photo-allergy or photo-toxicity test, or sun-tanning) within the past 8 weeks and having pigmentation or erythema marks in the test sites.

5.6.2 Skin colour of the test subjects

Test subjects shall have an ITA° value ≥ 28 as determined by colorimetric methods with the same acceptance criteria for number of subjects in each of the three ITA bands that is stipulated in ISO 24444[1] Section 5.1.2. The average of the subjects making up a test panel shall have an ITA° between 41° and 55°. When possible, there should be subjects with ITA°s in each of the three ITA° bands, 28° to 40°, 41° to 55°, and >56° (ITA values are to be truncated with no significant digits). Where this is not possible, there shall be at least three individuals in each of two of the three ITA° bands described in the previous sentence.

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The test sites intended for UV exposure shall be free from blemishes and hair and have an even colour tone with no variation in ITA° greater than 5° from each other with < 5° difference in ITA° within a given test site and free of hairs. Hair may be shaved up to 3 days prior to the test date, but not thereafter. Hair may be shaved up to the test date or clipped on the test date.

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5.6.2.1 Frequency of participation in tests

Subjects may participate in a HDRS-test at most once per seven days (to ensure clearance of applied sunscreen).

5.6.2.2 Number of test subjects

Valid results from at least 10 subjects is required. Additional subjects may be needed, as required by local regulations or to meet the statistical test requirements as described in Annex F. Proposed: "A maximum number of valid results shall be 20. In order to achieve between 10 and 20 valid results, a maximum of five individual results may be excluded from the calculation of the mean values based on statistical outlier analysis (see Annex F).

5.6.3 Ethics and consent

All testing shall be done in accordance with the Declaration of Helsinki[10] and any national regulations regarding human studies. Informed, written (signature) consent shall be obtained from all test subjects and retained.

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