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

*Cosmétiques — Mesurage de l'efficacité des produits de protection solaire par spectroscopie de réflectance diffuse*

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# Contents

Page

**Foreword** ... **v**
**Introduction** ... **vi**
**1 Scope** ... **1**
**2 Normative references** ... **1**
**3 Terms, definitions and symbols** ... **1**
3.1 Terms and definitions ... 1
3.2 Symbols ... 4
**4 Principle** ... **5**
**5 Apparatus and test method** ... **5**
5.1 In vitro UV spectrophotometer ... 5
5.2 In vitro substrate/plate ... 6
5.3 In vivo diffuse reflectance spectrometers (DRS) specifications ... 6
5.4 Monitoring the DRS systems ... 7
5.4.1 Monochromatic system ... 7
5.4.2 Polychromatic system ... 7
5.5 Test method ... 7
5.5.1 General ... 7
5.5.2 Subject exclusion criteria ... 7
5.5.3 Skin colour of the test subjects ... 8
5.5.4 Frequency of participation in tests ... 8
5.5.5 Number of test subjects ... 8
5.5.6 Ethics and consent ... 8
5.5.7 Study preparations ... 8
5.5.8 Unprotected skin remittance measurement ... 8
5.5.9 Training for Technician performing sunscreen application ... 9
5.5.10 Sunscreen application to test subject ... 9
5.5.11 Protected skin remittance measurements ... 9
**6 In vitro spectrophotometer measurements** ... **11**
6.1 General ... 11
6.2 In vitro measurement preparation ... 12
6.2.1 Blank reference PMMA plate ... 12
6.2.2 Product application ... 12
6.2.3 Product spreading ... 12
6.2.4 Spreading for alcoholic products ... 12
6.3 In vitro measurement ... 13
6.4 Determination of $A_{vt0}$ ... 13
6.5 Determination of the UV exposure dose ... 13
6.6 Measurement of in vitro sunscreen-treated plates post-irradiation ... 14
6.6.1 General ... 14
6.6.2 Calculation of the $A_{vt1}(\lambda)$ post irradiated spectrum ... 14
6.7 Determination of the hybridization wavelength ... 14
6.7.1 Monochromatic system ... 14
6.7.2 Polychromatic system ... 15
**7 Spectral ratio of photo-degradation ($S_{RPD}$)** ... **15**
7.1 General ... 15
7.2 Determination of $S_{RPD}(\lambda)$ ... 15
**8 Calculations to estimate SPF and UVA-PF** ... **16**
8.1 Determination of $A_{HDRSi}(\lambda)$ ... 16
8.1.1 Determination of $A_{DRSi}(\lambda)$ (monochromatic system) ... 16
8.1.2 Determination of the $A_{DRSi}$ (polychromatic system) ... 16
8.1.3 Determination of the individual hybridization scalar value – $C_{Ai}$ ... 17
8.1.4 Calculation of final hybrid absorbance spectrum ... 17

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8.2 Calculate test material $SPF_{HDRSi}$ 18
8.3 Calculate test material $UVA\text{-}PF_i$ 18
8.4 Critical wavelength calculation 18
8.5 Calculation of the mean and standard deviations for SPF and UVA-PF 19
8.6 Statistical criterion 20
8.7 Reference standards for SPF and UVA-PF 20
8.7.1 Establishment of SPF and UVA-PF for product claim: 20
8.7.2 Other calculations 20
8.8 Data rejection criteria 20
8.8.1 Subject data rejection criterion 20
8.8.2 Site-specific data rejection criterion 21
8.9 Test failure criteria 21

**9 Test report 21**
9.1 General 21
9.2 Data in tabular form for each test subject 22

**Annex A** (informative) **Test flow chart monochromatic and polychromatic DRS 23**

**Annex B** (normative) **Calibration check of UV spectrophotometer and plate transmittance test (in vitro measurements) 25**

**Annex C** (normative) **Calibration of solar simulator irradiance and radiometer procedure 29**

**Annex D** (normative) **Test plate and surface specifications 35**

**Annex E** (normative) **Computation values — PPD and erythema action spectra and UVA and UV-SSR spectral irradiances 37**

**Annex F** (normative) **Statistics and calculations 40**

**Annex G** (normative) **SPF, UVA-PF and CW reference sunscreen formulations 43**

**Annex H** (informative) **Definition and examples of valid skin DRS results 44**

**Annex I** (normative) **Optical fibres and calibration 46**

**Annex J** (normative) **Product application 47**

**Annex K** (normative) **ISO 23698 test report 50**

**Bibliography 52**

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# Foreword

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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 document 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,* 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).

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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 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) 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 and ISO 24443).

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

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# 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 Normative references

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

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

**3.1.1**
**absorbance**
$A$
measure of the energy blocked, either by optical absorption or by physical scattering/reflection

**3.1.2**
**absorbance spectrum**
$A(\lambda)$
sunscreen optical absorbance at wavelength λ

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

**3.1.3**
**absorbance by diffuse reflectance spectroscopy**
**absorbance by DRS**
$A_{DRS}(\lambda)$
absorbance spectrum calculated from DRS as a function of wavelength λ

Note 1 to entry: The absorbance spectrum relevant to this document is 320 nm to 400 nm.

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**3.1.4**
**absorbance after hybridization**
$A_{HDRS}(\lambda)$
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**
**in vitro absorbance before UV exposure (pre irradiation)**
$A_{vt0}(\lambda)$
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**
**in vitro absorbance after UV exposure (post irradiation)**
$A_{vt1}(\lambda)$
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**
**hybridization constant**
$C_{Ai}$
scalar factor to adjust an in vitro spectrum $A_{vt1}$ (λ) at each wavelength to the individual $A_{DRSi}$

**3.1.9**
**critical wavelength**
**CW**
$\lambda_c$
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**
**dose**
**D**
UVA radiant exposure dose for pre-irradiation of sunscreen products (1,2 x UVA-$PF_{DRS}$ J/cm$^2$)

**3.1.11**
**wavelength step**
$d\lambda$
differential of integration (1 nm)

**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.

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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.

**3.1.13**
**erythema action spectrum**
E(λ)
relative effects of individual spectral bands of an exposure source causing an erythema response in skin

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 $A_{\mathrm{HDRS}}(\lambda)$.

**3.1.15**
**hybridization wavelength**
**HW**
$\lambda_{\mathrm{HW}}$
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)

Note 1 to entry: See Annex E.

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

**3.1.18**
**spectral ratio of photo-degradation (λ)**
**$S_{\mathrm{RPD}}(\lambda)$**
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) 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

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**3.1.21**
**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**
**$T_{DRS}(\lambda)$**
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.

**3.1.23**
**UVA protection factor by DRS**
**UVA-$PF_{DRS}$**
initial UVA protection factor of a sunscreen product calculated using the measured in vivo absorbance spectrum from DRS before correction for photo-degradation

**3.1.24**
**UVA protection factor by HDRS**
**UVA-$PF_{HDRS}$**
UVA protection factor of a sunscreen product calculated from hybridized UV absorbance spectrum adjusted by SRPD(λ)

## 3.2 Symbols

| | |
|---|---|
| $I_u$ | irradiance of remitted UVA from unprotected skin with polychromatic DRS measurement device |
| $I_p$ | irradiance of remitted UVA from sunscreen-treated skin with polychromatic DRS measurement device |
| $i$ | index for individual subject |
| ITA° | individual typology angle |
| $I_{rad,UVA}$ | calibrated UVA irradiance |
| $j$ | index for individual test subsite |
| $k$ | index for individual PMMA plate (in vitro measurement) |
| $l$ | number of subsite measurements on a PMMA plate |
| $m$ | index for individual spot of in vitro measurement |
| $n$ | number of context dependent elements (these elements can be the subjects, the spots on a PMMA plate or the valid test results) |
| $R_p(\lambda)$ | irradiance of remittance spectrum (320 nm to 400 nm) of product-treated skin |
| $R_u(\lambda)$ | irradiance of remittance spectrum (320 nm to 400 nm) of unprotected skin |
| $s_i$ | scalar multiplier for scaling in vitro spectra for an individual |
| $S(\lambda)$ | spectral irradiance of the light source used to expose the plates |
| *stdev*, $\sigma$ | standard deviation of the ln transformed $UVA\text{-}PF_{HDRSi}$ values or the ln transformed $SPF_{HDRSi}$ values (context dependent) |
| $T_{vt0}(\lambda)$ | in vitro transmittance spectrum (290 nm to 400 nm) before UV-exposure |

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| | |
|---|---|
| $T_{vt1}(\lambda)$ | in vitro transmittance spectrum (290 nm to 400 nm) after UV-exposure |
| $UVA\text{-}PF_{DRS}$ | initial UVA protection factor of a sunscreen product calculated using the measured in vivo absorbance spectrum from DRS before correction for photo-degradation |
| $UVA\text{-}PF_{HDRS}$ | UVA protection factor of a sunscreen product calculated from hybridized UV absorbance spectrum adjusted by SRPD |
| $UVA\text{-}PF_{vt0}$ | in vitro UVA Protection Factor of a sunscreen product calculated using the absorbance spectrum $A_{vt0}$ |
| $UVA\text{-}PF_{vt1}$ | in vitro UVA Protection Factor of a sunscreen product calculated using the absorbance spectrum $A_{vt1}$ |
| $vt$ | index for in vitro |
| $\lambda_c$ | critical wavelength (including calibration factor) |
| $\lambda_{c'}$ | raw critical wavelength |
| $\lambda_{HW}$ | hybridization wavelength |

## 4 Principle

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, i.e. 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 nm to 400 nm) and has been shown to correlate with in vivo assessment using ISO 24442 (see also References [5] and [6]), as well as UVA-PFs using ISO24443 (see References [7] to [13]. 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 transmittance spectroscopy. To account for sunscreen products photo-instability of the sunscreen under evaluation, the same approach used in ISO 24443 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 hybrid diffuse reflectance spectroscopy (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 the DRS technique. This HDRS absorbance spectrum is then used to calculate the UVA-PF, SPF and critical wavelength (CW) of the sunscreen products being tested[10],[11].

Samples submitted for testing should not have a SPF or UVA-PF target or other protection category description.

## 5 Apparatus and test method

### 5.1 In vitro UV spectrophotometer

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

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## 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 shall be used and prepared as specified in Annex D.

## 5.3 In vivo diffuse reflectance spectrometers (DRS) specifications

Common elements for the monochromatic and polychromatic DRS systems include the following.

### 5.3.1 Optical light source

A short arc xenon bulb emitting continuous radiation over the range of 290 nm to 400 nm is recommended. A maximum exposure dose of 10 J/m$^2$ eff dose shall not to be exceeded for any measurement subsite. The maximum exposure irradiance at skin surface shall be less than 5 mW/cm$^2$. Calibration of radiometers for this evaluation shall be done in accordance with Annex C. The spectral irradiance of the illuminating source shall be evaluated once per year to validate that the maximum exposure irradiance and dose are not exceeded during a subsite measurement.

### 5.3.2 DRS illumination/Collection fibres

A UV grade fused silica bifurcated fibre probe comprised of a fibre 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. The area of the common optical probe shall be less than 1,2 cm$^2$. The common bundle shall have ≥ 800 individual fibres with a ratio of illuminating fibres to collection fibres between 45:55 and 55:45.

Annular fibre optic bundles: the centre illuminating fibre bundle shall have a 200 µm spacer between it and the surrounding collection fibres.

Randomized fibre optic bundles: ≥ 95 % of the illuminating fibres shall be adjacent to a collection fibre with a minimum spacing between the centres of adjacent fibres of 280 µm. See Annex I for the fibre configuration.

### 5.3.3 Detector system

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

### 5.3.4 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 nm to 400 nm. Usually, this can be achieved by a double monochromator spectrophotometer with a good stray light rejection and an appropriated, cooled PMT. The chosen voltage of the PMT (gain) should allow a high sensitivity at lower wavelengths (<320 nm) and avoid an overload of the PMT at higher wavelengths (>370 nm).

### 5.3.5 Monochromatic DRS system 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 irradiance), to the peak irradiance 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. The system shall have the specifications as described in 5.3.1 to 5.3.4.

### 5.3.6 Polychromatic DRS system

In vivo polychromatic DRS measurements shall be conducted using a light source with spectral output as described in Annex E and a PMT detector system with a response spectrum similar to the human persistent

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pigment darkening (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 5.3.1 to 5.3.4.

A visible light ("black glass") blocking filter is recommended to 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.

## 5.4 Monitoring the DRS systems

### 5.4.1 Monochromatic system

Wavelength accuracy shall be checked regularly either with a holmium oxide filter (according to 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 fibre output irradiance at least once per year shall be conducted using calibrated equipment by a trained, competent and suitably qualified person (internal or external). The optical fibre bundle shall be inspected at least once per year to validate compliance with 5.3.2 and to check for broken fibres.

### 5.4.2 Polychromatic 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 per year by a trained, competent, and suitably qualified person (internal or external) using a system calibrated to a traceable national or international calibration standard lamp. The optical bundle shall be inspected at least once per year to validate compliance with 5.3.2 and to check for broken fibres.

## 5.5 Test method

### 5.5.1 General

DRS measurements and product application assessment are recommended to be carried out in stable conditions, with the room temperature maintained between (23 ± 3) °C.

### 5.5.2 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 cut or clipped on the test day);

d) subjects with average individual typology Angle (ITA°) <28°;

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

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### 5.5.3 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 (28°to 40°, 41°to 55°, and ≥56° as stipulated in ISO 24444:2019, 5.1.2). The average of the subjects making up a test panel shall have an ITA° between 41° and 55°. When possible, subjects with ITA°s in each of the three ITA° bands, 28° to 40°, 41° to 55°, and >56° (ITA°value shall 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.

The test sites intended for DRS measurements 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. Hair may be shaved up to 3 days prior to the test date, but not thereafter. If necessary, hair may be clipped or cut with scissors on the test date.

### 5.5.4 Frequency of participation in tests

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

### 5.5.5 Number of test subjects

Valid results from at least 10 subjects is required. 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).

### 5.5.6 Ethics and consent

All testing shall be done in accordance with the Declaration of Helsinki[14]. Informed, written (signature) consent shall be obtained from all test subjects and retained.

### 5.5.7 Study preparations

All equipment to be used for measuring and exposing the samples shall be turned on to warm up for at least 20 min prior to initiating measurement procedures or according with manufacturer instructions.

Devices used to apply a measured amount of product to the skin (e.g. micropipettes, syringes, weigh boats, etc.) shall deliver 2,00 mg/cm$^2$ ± 0,05 mg/cm$^2$ of the sunscreen. A finger cot shall be used for spreading the sunscreen on the skin for all products except in cases when use of a finger cot interferes with even application of the product. Sunscreen formulation application should follow procedures as described in Annex J. A new finger cot shall be used for each new application of product and shall not be pre-saturated with the test product. When a naked finger is used, a maximum of 2,1 mg/cm$^2$ (additional 5 %) shall be applied to the test area to account for the additional area of the application finger, and the finger shall be cleaned between product applications with an alcohol wipe.

### 5.5.8 Unprotected skin remittance measurement

#### 5.5.8.1 General

Test sites for sunscreen application are to be chosen wherein the skin colour is uniform, without pigmentation marks or mottled pigmentation, sun tanned areas, scars, or other skin lesions. Test sites shall be placed on the back according to Annex J. The test sites shall be at least 30 cm$^2$ in area (e.g. 5 cm x 6 cm) and the maximum shall be 60 cm$^2$. The corners of the test sites shall be marked with permanent marker or skin marker or a stamp template with non-absorb material. The identity code of the test site can be marked on the skin.

Measurements can be performed by directly placing the DRS optical probe on the subsite within the test site (constant and light pressure). Measurements may be made anywhere within test site as long as the measurement sites do not overlap. The subsequent steps are related to monochromatic and polychromatic DRS measurement and product application.

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#### 5.5.8.2 Unprotected skin monochromatic DRS measurement

Place the DRS optic probe on the first unprotected subsite, as described above. Perform a synchronous scan of the test subsite from at least 310 nm to 400 nm, using a measurement interval no greater than 2 nm (1 nm recommended). Instrument settings (adjusting PMT high voltage, changing monochromator slit width or manufacturer recommendation) shall be optimized to obtain maximum remittance signal without saturating the detector. Measurements with 2 nm interval may be linearly interpolated to 1 nm intervals for calculations. Record and save the scanned spectrum with an appropriate filename. A minimum of three measurements per test site is required (5 is recommended). Test subsites should not overlap each other. The unprotected skin remittance spectra scan is designated as $R_{uj}$ (λ). The arithmetic mean of the unprotected skin readings may be used to represent the baseline remittance for the test site $R_u$(λ).

#### 5.5.8.3 Unprotected skin polychromatic DRS measurement

Place the DRS optic probe on the first unprotected subsite, as described in 5.5.8.1. Record the measurement and repeat for an additional 8 subsites (3x3 array) in the test site (for a total of 9 measurements). The unprotected skin remittance measurements are designated as $I_{uj}$.

### 5.5.9 Training for Technician performing sunscreen application

The technician applying the sunscreen to the test sites shall undergo training in application techniques according to Annex J using the HDRS-generated UVA-PF values as the measure of application uniformity. This training shall be performed at least once a year or after a period of 3 months of inactivity of the technician performing applications. Test products shall include a variety of galenic properties by using: a) P5 or P8, b) S2, c) alcoholic single-phase product, and d) a product with high inorganic UV filters (at least 20 %) all tested within one trial. The technician shall demonstrate uniform spreading within each product test site such that the c value of each of the nine test subsites within a site is <0,17. The c value is calculated as the standard error of the nine subsite measurements [ln(UVA-PF) transformed values] multiplied by 2,306 [Student's t(0,05,8) value] according to Formula (1).

$$c = \frac{t_{0,05,8} \times \sigma_{\text{subsites}}}{\sqrt{9}} \tag{1}$$

where $\sigma_{\text{subsites}}$ is the standard deviation of the ln values of the subsite UVA-PF measurements.

### 5.5.10 Sunscreen application to test subject

Apply 2,00 mg/cm$^2$ ± 0,05 mg/cm$^2$ of sunscreen to the test site strictly following the application procedures described in Annex J. Wait a minimum of 15 min before initiating further skin remittance measurements.

### 5.5.11 Protected skin remittance measurements

#### 5.5.11.1 General

The tip of the probe used for remittance measurements shall be cleaned with a tissue between each subsite measurement. A dry wipe is recommended between each measurement. An alcoholic saturated wipe is recommended to be used between each test site. When a wet wipe (saturated with alcohol) is used, it shall be followed by a dry wipe. The remittance for monochromatic and polychromatic measurements are designated as $R_{pj}$(λ) and $I_{pj}$(λ) respectively.

#### 5.5.11.2 Monochromatic DRS measurement and calculation of UVA-PF$_{DRS}$

Place the probe on the first sunscreen-treated subsite and perform a synchronous scan as described in 5.5.8. Record and file the scanned spectrum with an appropriate filename. Clean the tip of the optic probe as described in 5.5.11.1 between each measurement. Repeat for at least five subsite measurements in the same test site (to obtain a minimum of 3 valid absorbance spectra as described in Annex H). The remittance

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spectrum of the protected subsite is referred as $R_{pj}(\lambda)$. Calculate $T_{DRSj}(\lambda)$ values at each wavelength for each subsite according to the Formula (2):

$$T_{DRSj}(\lambda)=\sqrt{\frac{R_{pj}(\lambda)}{R_{uj}(\lambda)}}$$

Or (2)

$$T_{DRSj}(\lambda)=\sqrt{\frac{R_{pj}(\lambda)}{R_{u}(\lambda)}}$$

where

$R_{pj}(\lambda)$ is the individual subsite irradiance of remittance spectrum (320 nm to 400 nm) of product-treated skin;

$R_{uj}(\lambda)$ is the individual subsite irradiance of remittance spectrum (320 nm to 400 nm) of unprotected skin;

$R_{u}(\lambda)$ is the arithmetic mean of the remittance spectrum (320 nm to 400 nm) of the unprotected j subsites measured.

The absorbance DRS spectrum $A_{DRSj}(\lambda)$ for each subsite shall be calculated as shown in Formula (3):

$$A_{DRSj}(\lambda)=-\log T_{DRSj}(\lambda) \quad (3)$$

where

$T_{DRSj}(\lambda)$ is the transmittance spectrum (320 nm to 400 nm) calculated as a function of wavelength λ;

log is the logarithm to base 10.

The $A_{DRSj}(\lambda)$ shall be calculated for each subsite on each test site. Calculate the $A_{DRSi}$ as the arithmetic mean of the $A_{DRSj}$.

UVA-$PF_{DRSj}$ for each subsite is calculated using the clinical UVA source spectrum S(λ) and the persistent pigment darkening spectrum $P(\lambda)$ (see Annex E) with the average $A_{DRSj}(\lambda)$ determined in Formula (4):

$$UVA-PF_{DRSj}=\frac{\int_{320}^{400}P(\lambda)\times S(\lambda)\times d(\lambda)}{\int_{320}^{400}P(\lambda)\times S(\lambda)\times 10^{-A_{DRSj}(\lambda)}\times d(\lambda)} \quad (4)$$

where

$P(\lambda)$ is the persistent pigment darkening (PPD) action spectrum (see Annex E);

$S(\lambda)$ is the spectral irradiance of the solar simulator source (see Annex E);

$A_{DRSj}(\lambda)$ is the absorbance for a subsite j at each wavelength $\lambda$ calculated in Formula (3);

$d(\lambda)$ is the 1 nm interval.

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The UVA-$PF_{DRSi}$ for the test site is the geometric mean from all subsites of a test site calculated by Formula (5) and then used to calculate the UVA-$PF_{DRS}$ of all subjects by Formula (6):

$$UVA-PF_{DRSi} = exp\left[\frac{\sum \ln\left(UVA-PF_{DRSj}\right)}{m}\right] \quad (5)$$

$$UVA-PF_{DRS} = exp\left[\frac{\sum \ln\left(UVA-PF_{DRSi}\right)}{n}\right] \quad (6)$$

where

UVA-$PF_{DRSj}$ is the initial UVA protection factor of a sunscreen product for a subsite calculated using the measured in vivo absorbance spectrum from DRS [$A_{DRSj}(\lambda)$, Formula (3)] from each subsite before correction for photo-degradation;

UVA-$PF_{DRSi}$ is the initial UVA protection factor of a sunscreen product for a test site/subject before correction for photo-degradation;

$m$ is the number of subsite measurements per test site;

$n$ is the number of subjects;

ln is the natural logarithm.

#### 5.5.11.3 Polychromatic DRS measurement and calculation of UVA-$PF_{DRS}$

Place the probe on the first sunscreen-treated subsite and measure the remitted light. Record the remitted light irradiance. Clean the tip of the optic probe between each measurement as described in 5.5.11.1 and then repeat the measurement for a total of 9 (j) subsites within each test site. Record the measurements as $I_{pj}$.

Calculate the UVA-PF values for each of the 9 subsites within the test site according to the Formula (7):

$$UVA-PF_{DRSj} = \sqrt{\frac{I_{uj}}{I_{pj}}} \quad (7)$$

where

$I_{pj}$ is the individual subsite irradiance of remittance spectrum of product-treated skin;

$I_{uj}$ is the individual subsite irradiance of remittance spectrum of unprotected skin.

Calculate the geometric mean UVA-$PF_{DRSi}$ for each test site-for each subject and then calculate a composite geometric mean UVA-$PF_{DRS}$ for all the test subjects using Formula (5) and Formula (6).

## 6 In vitro spectrophotometer measurements

### 6.1 General

Full spectrophotometric scans of the test product shall be conducted from 290 nm to 400 nm. All specifications for the spectrophotometer, calibrations of the spectrophotometer, the UV radiometer, calibration of test plates, and measurement procedures are found in Annexes B, C, D and E. The UV exposure light source shall have the same spectral distribution of the clinical solar simulator used for in vivo sun protection factor (SPF) measurements (see ISO 24444) and shall be as described in Annex E. A summary of the steps is provided in Annex A.

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## 6.2 In vitro measurement preparation

### 6.2.1 Blank reference PMMA plate

Prepare a "blank" reference PMMA plate by spreading a few microlitres of glycerine or petrolatum on the roughened side of the plate. Choose the amount of glycerine or petrolatum such that the entire surface is just completely covered (approximately 15 µl for a 50 mm × 50 mm plate. Any excess glycerine or petrolatum shall be avoided. Measurements shall be performed on the same type of plate as the one used for the product (moulded or sandblasted), from the same batch. Measure this pre-treated plate a "blank" reference before test formulations are measured.

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

### 6.2.2 Product application

Apply the sunscreen product to a new untreated PMMA plate (with the roughened side uppermost) by mass, at an application rate of 1,3 (±1,6 %) mg/cm$^2$ for moulded plates and 1,2 (±1,5 %) mg/cm$^2$ for sandblasted plates. The application area should not be less than 16 cm$^2$.

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

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

Apply the sunscreen as at least 12 small droplets of approximate equal volume, distributed evenly over the whole surface of the plate.

A bare finger shall be used to spread the product on the plate. Dip the finger used for spreading into the test product and then wipe it to remove excess product before spreading the test product on the plate. Clean the fingertip used to spread the product between applications of different test products.

If an automated application is used for spreading product on the plate, a finger cot shall be utilized. Dip the fingertip used for spreading into the product and then wipe to remove excess product before spreading the test product applied to the plate. Clean the mechanical fingertip used to spread the product between applications of different test products.

Deposit and weighing shall not take more than 30 s.

After the sunscreen product is deposited on the surface of the plate, spread it immediately over the whole surface using light strokes with the human fingertip or mechanical fingertip.

### 6.2.3 Product spreading

Spreading shall be completed in a two-phase process.

Spread the product 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, turn the plate 1/4 turn to alternate passages, with minimum pressure and repeat this movement three times at least (about 30 s).

Rub the sample 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 30 s with increased moderate pressure.

### 6.2.4 Spreading for alcoholic products

For alcoholic or oil products, application shall be adapted as follows.

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Spread the sample 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. Turn the plate at the end of the first pass, (1/4 turn) to alternate passages, with minimal pressure and repeat this movement two times at least (about 20 s to 25 s).

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

De-gas any spray products provided in a pressurized container by puncturing a very small pinhole in the container to relieve all the pressure, and then allowed to rest for at least 24 h at room temperature before accessing the liquid for testing.

Set the test plate aside in a dark environment at the ambient temperature (27 °C ± 2 °C to 32 °C ± 2 °C) of the UV exposure chamber to dry for at least 30 min at same temperature that it is experienced by the plates during the exposure.

## 6.3 In vitro measurement

Mount the test plate in the UV transmittance spectrophotometer as per manufacturer's instructions. Measure the absorbance spectrum of the test formulation from 290 nm to 400 nm in 1 nm increments and save it to a file. Transmittance measurements can be converted to absorbance by the Formula (8):

$$A_{\mathrm{vt0kl}}(\lambda) = -\log(T_{\mathrm{vt0kl}}(\lambda)) \tag{8}$$

where $T_{\mathrm{vt0kl}}(\lambda)$ is the transmittance at each wavelength for plate k=1-4, l=1-n spots per plate.

Scan one or more spots on each of at least four different plates. Record each individual spectrum for each spot on each plate. If the absorbance scan for any part of the spectrum exceeds the linear absorbance range limit of the spectrophotometer (determined according to Annex B, B.3 and B.4), a new plate shall be prepared with a lower amount of sunscreen (i.e. 0,75 mg/cm$^2$). A typical limit for several spectrophotometers is 2,2 OD.

## 6.4 Determination of $A_{\mathrm{vt0}}$

Calculate the arithmetic mean of the absorbance values for each plate (index l), then calculate the arithmetic mean of all the plates tested (index k), and record this absorbance spectrum, represented by $A_{\mathrm{vt0}}$ (λ) as shown in Formula (9).

$$A_{vt0}(\lambda) = \sum_{k=1}^{k=4} \sum_{l=1}^{l=n} \frac{1}{4 \times n} \times A_{vt0kl}(\lambda) \tag{9}$$

where

$A_{\mathrm{vt0kl}}(\lambda)$ is the absorbance at each wavelength for a spot l=1 to $n$ on a plate k=1 to 4 pre-irradiation (see ISO 24443);

$n$ is the number of spots.

This spectrum is the initial in vitro absorbance spectrum of the test.

## 6.5 Determination of the UV exposure dose

The output irradiance of the solar simulator used for photo-stability exposures of the PMMA sunscreen-treated plates shall be the same spectrum as described Annex E (UV-SSR source) and regular calibration specifications are described in Annex C.

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The output is determined with a calibrated UVA radiometer. The radiant exposure dose $D$ is 1,2 J/cm$^2$ of UVA radiation multiplied by UVA-PF$_{DRS}$ value determined in 5.5.11.2 and 5.5.11.3 for monochromatic and polychromatic systems respectively, Formula (10).

$$D(UVA) = 1{,}2 \times UVA - PF_{DRS} \tag{10}$$

where $UVA\text{-}PF_{DRS}$ is the initial UVA protection factor of a sunscreen product calculated in 5.5.11.2 (monochromatic system) or 5.5.11.3 (polychromatic system).

Pre-irradiation dose shall be limited to a maximum dose of 36 J/cm$^2$ (which corresponds to a $UVA\text{-}PF_{DRS}$ of 30). The samples are to be exposed to full spectrum radiation (as defined in Annex E) from the simulator but the irradiation dose is defined by the UVA content of that simulator. The temperature of the plates during the exposure shall be maintained in the range of 27 °C ± 2 °C to 32 °C ± 2 °C.

## 6.6 Measurement of in vitro sunscreen-treated plates post-irradiation

### 6.6.1 General

After the sunscreen-treated plates have been irradiated with the calculated exposure dose, the absorbance spectrum of the test product at each wavelength is measured and stored as described in step 6.3. The individual post-irradiation spectra of the sunscreen-treated plates are designated as $A_{vt1kl}(\lambda)$.

### 6.6.2 Calculation of the $A_{vt1}(\lambda)$ post irradiated spectrum

Calculate the arithmetic mean absorbance value for each plate (index l), take the arithmetic mean of all plates tested (index k) and record this absorbance spectrum, represented by $A_{vt1}$ (λ) as in Formula (11):

$$A_{vt1}(\lambda) = \sum_{k=1}^{k=4} \sum_{l=1}^{l=n} \frac{1}{4 \times n} \times A_{vt1kl}(\lambda) \tag{11}$$

where

$A_{vt1kl}(\lambda)$ is the absorbance at each wavelength for a spot l=1 to $n$ on a plate k=1 to 4 post-irradiation;

$n$ is the number of spots.

## 6.7 Determination of the hybridization wavelength

### 6.7.1 Monochromatic system

The hybridization wavelength (HW) is the wavelength where the in vivo determined absorbance curve is merged with the in vitro spectral absorbance curve to provide the full absorbance spectrum. It is determined by calculating where the shape of the in vivo determined spectrum starts to deviate from the shape of the in vitro measured absorbance spectrum. The hybridization wavelength shall be ≥322 nm, but no higher than 350 nm and it is calculated by Formula (13).

$A_{vt0}(\lambda)$ is adjusted to meet the level of the $A_{DRSi}$ (λ) at 350 nm by multiplying the $A_{vt0}(\lambda)$ spectrum by the scalar value $A_{DRSi}(350)/A_{vt0}(350)$. Moving towards shorter wavelengths from 350 nm, the first wavelength at which the values for $A_{vt0}(\lambda)$ deviates above the $A_{DRSi}(\lambda)$ by more than 2 % of the value is defined as the lower limit ($\lambda 1_i$) of the hybridization range. $\lambda_{HWi}$ is defined as $\lambda_{HW} = \lambda 1_i + 2$ nm. If the $\lambda_{HWi}$ is calculated as a

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wavelength <322 nm ($A_{DRSi}(\lambda)>A_{vt0}(\lambda)$ down to 320 nm), then 322 nm shall be used as the $\lambda_{HWi}$. If the $\lambda_{HWi}$ is higher than 349 nm the measurement shall be rejected.

$$s_{HW} = \frac{A_{DRS}(\lambda=350)}{A_{vt0}(\lambda=350)} \tag{12}$$

where $s_{HW}$ is the scalar to normalize the $A_{vt0}(\lambda)$ spectrum to the $A_{HDRSi}(\lambda)$ spectrum.

$$\text{If } (A_{DRSi}(\lambda) - A_{vt0}(\lambda) \times s_{HW}) > 0{,}02 \times A_{vt0}(\lambda) \times s_{HW} \text{ then } \lambda_{HWi} = (\lambda + 2) \tag{13}$$

$A_{DRSi}(\lambda)$ is the in vivo subject average DRS absorbance value at ($\lambda$) for a product;

$A_{vt0}$ is the average in vitro absorbance value at wavelength ($\lambda$) for a product;

$\lambda_{HWi}$ is the hybridization wavelength for an individual.

### 6.7.2 Polychromatic system

The hybridization wavelength ($\lambda_{HW}$) is defined as 345 nm for all spectra.

## 7 Spectral ratio of photo-degradation ($S_{RPD}$)

### 7.1 General

To account for the variability of the product photo-stability, UVA or UVB, a spectral ratio of photo-degradation [$S_{RPD}(\lambda)$] is defined by the ratio of the in vitro absorption curves post and pre UV exposure as function of wavelength from 290 nm to 400 nm.

### 7.2 Determination of $S_{RPD}(\lambda)$

Calculate $S_{RPD,UVB}$, $S_{RPD,UVA}$, and $S_{RPD,mean}$ according to Formulae (14), (15) and (16).

$$S_{RPD,UVB} = \frac{\sum_{290}^{320}(10^{A_{vt1}(\lambda)}/10^{A_{vt0}(\lambda)})}{31} \tag{14}$$

$$S_{RPD,UVA} = \frac{\sum_{320}^{400}(10^{A_{vt1}(\lambda)}/10^{A_{vt0}(\lambda)})}{81} \tag{15}$$

$$S_{RPD,mean} = \frac{(S_{RPD,UVA} + S_{RPD,UVB})}{2} \tag{16}$$

where

$A_{vt0}(\lambda)$ is in vitro UV absorbance spectrum pre irradiation, see in 6.4

$A_{vt1}(\lambda)$ is in vitro UV absorbance spectrum post irradiation see in 6.6.2

Select the lowest value from Formula (14), ($S_{RPD,UVB}$) or Formula (16), ($S_{RPD,mean}$) to determine the $S_{RPD}(\lambda)$ formulae below using Formula (17), Formula (18) or Formula (19):

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If the lowest value is ≥ 0,8

$$S_{\mathrm{RPD}}(\lambda)=\frac{10^{A_{\mathrm{vt1}}(\lambda)}}{10^{A_{\mathrm{vt0}}(\lambda)}} \tag{17}$$

where any individual $S_{\mathrm{RPD}}(\lambda)$ ≥ 1,0 then the $S_{\mathrm{RPD}}(\lambda)$=1,0.

If the lowest value is < 0,8 but ≥0,7

$$S_{\mathrm{RPD}}(\lambda)=\left[\frac{10^{A_{\mathrm{vt1}}(\lambda)}}{10^{A_{\mathrm{vt0}}(\lambda)}}+\frac{A_{\mathrm{vt1}}(\lambda)}{A_{\mathrm{vt0}}(\lambda)}\right]/2 \tag{18}$$

where any individual $S_{\mathrm{RPD}}(\lambda)$ ≥ 1,0 then the $S_{\mathrm{RPD}}(\lambda)$ = 1,0.

If the lowest value is <0,7

$$S_{\mathrm{RPD}}(\lambda)=\left[\frac{A_{\mathrm{vt1}}(\lambda)}{A_{\mathrm{vt0}}(\lambda)}\right] \tag{19}$$

where any individual $S_{\mathrm{RPD}}(\lambda)$ ≥ 1,0 then the $S_{\mathrm{RPD}}(\lambda)$=1,0.

The selected $S_{\mathrm{RPD}}(\lambda)$ function is used to multiply $A_{\mathrm{DRSi}}(\lambda)$ to take care for any photo-instability issue in following the formulae.

# 8 Calculations to estimate SPF and UVA-PF

## 8.1 Determination of $A_{\mathrm{HDRSi}}(\lambda)$

### 8.1.1 Determination of $A_{\mathrm{DRSi}}(\lambda)$ (monochromatic system)

The absorbance spectrum $A_{\mathrm{DRSi}}(\lambda)$ of a subject (i) is calculated as arithmetic mean over the absorbance spectra of the subsites (j), given in Formula (20):

$$A_{\mathrm{DRSi}}(\lambda)=\frac{1}{m}\times\sum_{j=1}^{j=m}A_{\mathrm{DRSj}}(\lambda) \tag{20}$$

where

$m$ is the number of subsites per test site

$A_{\mathrm{DRSj}}(\lambda)$ is the absorbance for a subsite j at each wavelength λ calculated in Formula (2).

### 8.1.2 Determination of the $A_{\mathrm{DRSi}}$ (polychromatic system)

When using the polychromatic system, the initial non-irradiated in vitro scan $A_{\mathrm{vt0}}$ shall be scaled according to the individual $UVA\text{-}PF_{\mathrm{DRSi}}$ values as calculated in 5.5.11.3. The in vitro scan $A_{\mathrm{vt0}}$ absorbance values are multiplied by a scalar value "$s_{\mathrm{i}}$" until the $UVA\text{-}PF_{\mathrm{vt0i}}$ = $UVA\text{-}PF_{\mathrm{DRSi}}$. This can be accomplished by the use of the "goal seek" function in a spreadsheet (or equivalent calculating process) by solving Formula (21) for $s_{\mathrm{i}}$ and $A_{\mathrm{DRSi}}$ is calculated by Formula (22).

$$UVA-PF_{\mathrm{DRSi}}=\frac{\int_{320}^{400}P(\lambda)\times S(\lambda)\,d\lambda}{\int_{320}^{400}P(\lambda)\times S(\lambda)\times 10^{-A_{\mathrm{vt0}}(\lambda)\times s_i}\times d\lambda} \tag{21}$$

$$A_{DRSi}(\lambda)=A_{vt0}(\lambda)\times s_i \tag{22}$$

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where

$P(\lambda)$ is the persistent pigment darkening (PPD) action spectrum (see Annex E);

$S(\lambda)$ is the spectral irradiance of a UVA clinical solar simulator source (see Annex E);

$A_{vt0}(\lambda)$ is the in vitro UV absorbance spectrum (290 nm to 400 nm) of a sunscreen product measured before sample UV exposure (Annex E);

$s_i$ is the scaling factor for individual subject determined in Formula (21);

$d(\lambda)$ is the 1 nm interval wavelength step.

From this point forward, all calculations are the same for monochromatic and polychromatic systems.

### 8.1.3 Determination of the individual hybridization scalar value – $C_{Ai}$

The hybridization scalar value $C_{Ai}$ is used to adjust the amplitude of the in vitro absorption spectrum to the level of the in vivo DRS spectrum within the hybridization wavelength range. $C_{Ai}$ is defined in Formula (23).

$$C_{Ai} = \frac{\sum_{\lambda 1}^{\lambda 2} (A_{DRSi}(\lambda) \times S_{RPD}(\lambda) / A_{vt1}(\lambda))}{5} \tag{23}$$

where

$\lambda_1$ is $\lambda_{HWi}$ – 2 nm;

$\lambda_2$ is $\lambda_{HWi}$ + 2 nm;

$S_{RPD}(\lambda)$ is the spectral ratio of photo-degradation ($\lambda$);

$A_{vt1}(\lambda)$ is the in vitro UV absorbance spectrum post irradiation ($\lambda$).

The value for $C_{Ai}$ should lie between 0,6 and 1,6, or new in vitro test plates shall be prepared (with less product if <0,6 and more product if >1,6).

### 8.1.4 Calculation of final hybrid absorbance spectrum

The individual $A_{HDRSi}(\lambda)$ is obtained by Formula (24) combining the $A_{vt1}(\lambda)$ spectrum from 290 nm to $\lambda_{HWi}$ - 1 nm with the $S_{RPD}(\lambda) \times A_{DRSi}(\lambda)$ values from $\lambda_{HWi}$ to 400 nm. To complete the absolute absorbance spectrum for the test material from 290 nm to 400 nm is calculated in Formula (25).

$$A_{HDRSi}(\lambda) = \begin{cases} A_{vt1}(\lambda) \times C_{Ai} & \text{for } \lambda < \lambda_{HWi} \\ A_{DRSi} \times S_{RPD}(\lambda) & \text{for } \lambda \geq \lambda_{HWi} \end{cases} \tag{24}$$

$$A_{HDRS}(\lambda) = \frac{1}{n} \times \sum_{i=1}^{i=n} A_{HDRSi}(\lambda) \tag{25}$$

where

$A_{vt1}(\lambda)$ is the in vitro UV absorbance spectrum post irradiation (6.6.2);

$A_{DRSi}$ is the absorbance spectrum for a subject $i$ obtained from DRS from Formula (19) (monochromatic) and Formula (21) (polychromatic);

$\lambda_{HWi}$ is the hybridization wavelength used to merge the spectra from skin and from the in vitro measurement;

$S_{RPD}(\lambda)$ is the spectral ratio of photo-degradation ($\lambda$);

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$C_{Ai}$ is the individual hybridization constant;

$n$ is the number of subjects.

## 8.2 Calculate test material $SPF_{HDRSi}$

Using $A_{HDRSi}(\lambda)$ absorbance spectrum 290 nm to 400 nm, calculate the test sample $SPF_{HDRSi}$ using Formula (26).

$$SPF_{HDRSi} = \left[ \frac{\int_{290}^{400} E(\lambda) \times S(\lambda) \times d\lambda}{\int_{290}^{400} E(\lambda) \times S(\lambda) \times 10^{-A_{HDRSi}(\lambda)} \times d\lambda} \right] \times C_{calSPF} \quad (26)$$

where

$E(\lambda)$ is the erythema action spectrum (CIE-1999) (see Annex E);

$S(\lambda)$ is the spectral irradiance received from UV clinical solar simulator source (Annex E);

$A_{HDRSi}(\lambda)$ is the absorbance spectrum (290 nm to 400 nm) calculated from the hybridized signals as a function of wavelength λ from Formula (24);

$d(\lambda)$ is the 1 nm interval wavelength step;

$C_{calSPF}$ is the manufacturer's calibration factor/function for SPF (as determined in clinical trials) from Annex I;

$SPF_{HDRSi}$ shall be expressed to one decimal point by truncation.

## 8.3 Calculate test material $UVA\text{-}PF_i$

Using $A_{HDRSi}(\lambda)$ absorbance spectrum 290 nm to 400 nm, calculate the test sample $UVA\text{-}PF_{HDRSi}$ by Formula (27).

$$UVA-PF_{HDRSi} = \left[ \frac{\int_{320}^{400} P(\lambda) \times S(\lambda) \times d\lambda}{\int_{320}^{400} P(\lambda) \times S(\lambda) \times 10^{-A_{HDRSi}(\lambda)} \times d\lambda} \right] \quad (27)$$

where

$P(\lambda)$ is the persistent pigment darkening (PPD) action spectrum (see Annex E);

$S(\lambda)$ is the spectral irradiance received from UVA clinical solar simulator source (see Annex E);

$A_{HDRSi}(\lambda)$ is the absorbance spectrum (290 nm to 400 nm) calculated from the hybridized signals as a function of wavelength λ from Formula (24);

$d(\lambda)$ is the 1 nm interval wavelength step.

$UVA\text{-}PF_{HDRSi}$ shall be expressed to one decimal point by truncation.

## 8.4 Critical wavelength calculation

The raw critical wavelength (before calibration) for the material is calculated by Formula (28) using the final hybrid absorbance spectrum as defined as $A_{HDRS}$ (λ) from 290 nm to 400 nm in Formula (25). The critical wavelength calculations shall be done by trapezoidal approximations to compute area under the curve.

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The raw critical wavelength "$\lambda_c$'" is the wavelength at which the area under the absorbance curve represents 90 % of the total area under the curve in the UV region as calculated by Formula (28).

$$\int_{\lambda=290}^{\lambda_{c'}} A_{\mathrm{HDRS}}(\lambda)\times d\lambda = 0{,}9\times\int_{\lambda=290}^{\lambda=400} A_{\mathrm{HDRS}}(\lambda)\times \mathrm{d}\lambda \tag{28}$$

where

$A_{\mathrm{HDRS}}(\lambda)$ is the mean absorbance at each wavelength after exposure;

$d(\lambda)$ is the wavelength interval between measurements;

$\lambda_{c'}$ is the raw critical wavelength calculated using $A_{\mathrm{HDRS}}(\lambda)$ by Formula (25).

The final critical wavelength for the material is calculated by Formula (29).

$$\lambda_c = \lambda_{c'} + C_{\mathrm{Wcal}} \tag{29}$$

$\lambda_c$ is the calibrated critical wavelength ($\lambda_{\mathrm{CHDRS}}$);

$C_{\mathrm{Wcal}}$ is the calibration factor for $\lambda_C$, see Annex J.

The critical wavelength is expressed as a whole number by truncation and with nanometre (nm) unit. Other protection parameters may be calculated from the final absorbance curve as desired.

## 8.5 Calculation of the mean and standard deviations for SPF and UVA-PF

The product mean SPF and UVA-PF will be the geometric mean values obtained from repeating the protocol in at least 10 subjects. Final SPF and UVA-PF values for the product are calculated according to Formula (30) and Formula (31), respectively. The product SPF and UVA-PF standard deviation are calculated by Formulae (32) and (33), respectively.

$$SPF_{HDRS} = \exp\left[\frac{\sum_{i=1}^{n}\ln(SPF_{HDRSi})}{n}\right] \tag{30}$$

$$UVA-PF_{HDRS} = \exp\left[\frac{\sum_{i=1}^{n}\ln(UVA-PF_{HDRSi})}{n}\right] \tag{31}$$

$$sd_{SPF_{HDRS}} = \left[\left(exp\left(\sigma_{SPF}{}^{2}\right)-1\right)\times\left(\exp\left(2*\mu_{SPF}+\left(\sigma_{SPF}{}^{2}\right)\right)\right)\right]^{1/2} \tag{32}$$

$$sd_{UVA-PF_{HDRS}} = \left[\left(exp\left(\sigma_{UVA}{}^{2}\right)-1\right)\times\left(\exp\left(2*\mu_{UVA}+\left(\sigma_{UVA}{}^{2}\right)\right)\right)\right]^{1/2} \tag{33}$$

where

$SPF_{\mathrm{HDRSi}}$ is the individual SPF obtained from the final individual HDRS absorption spectrum $A_{\mathrm{HDRSi}}(\lambda)$;

$UVA\text{-}PF_{\mathrm{HDRSi}}$ is the individual UVA-PF obtained from the final individual HDRS absorption spectrum $A_{\mathrm{HDRSi}}(\lambda)$;

$n$ is the number of subjects;

ln is the natural logarithm;

$\mu_{\mathrm{SPF}}$ is the arithmetic mean of the ln transformed $SPF_{\mathrm{HDRSi}}$ values;

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$\sigma_{SPF}$ is the standard deviation of the ln transformed $SPF_{HDRSi}$ values;

$\mu_{UVA}$ is the geometric mean of the ln transformed UVA-$PF_{HDRSi}$ values;

$\sigma_{UVA}$ is the standard deviation of the ln transformed UVA-$PF_{HDRSi}$ values.

$SPF_{HDRS}$ and UVA-$PF_{HDRS}$ are to be expressed as a whole number by truncation with no decimal.

## 8.6 Statistical criterion

The statistical test for variability is calculated on the $SPF_{HDRS}$ and UVA-$PF_{HDRS}$ values using Formula (34); a minimum of 10 subjects is required. If the "*c*" value is >0,17, the number of subjects shall be increased stepwise from 10 until the statistical criterion is met (up to a maximum of 20 valid results or a maximum of 25 subjects tested). If this statistical criterion is not reached after 20 valid results from a maximum of 25 subjects, the entire test is rejected, and a new test shall be initiated. Statistical definitions, sequential testing procedure and calculations shall be in accordance with Annex F.

$$c = \left[ \frac{t_{(0,05,n-1)} \times (\sigma)}{\sqrt{n}} \right] \leq 0,17 \qquad (34)$$

where

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

$\Sigma$ is the standard deviation of the ln transformed individual UVA-$PF_{HDRSi}$ and $SPF_{HDRSi}$ values;

$n$ is the number of valid test results.

## 8.7 Reference standards for SPF and UVA-PF

### 8.7.1 Establishment of SPF and UVA-PF for product claim:

One of the reference standards P5, P6, or P8 shall be used for simultaneous testing with the test product and the mean value for the $SPF_{HDRS}$ or UVA-$PF_{HDRS}$ shall fall within their acceptance ranges (as in Annex G) and the statistical criteria as defined as "c" Formula (34). Additional subjects may be added as necessary to achieve a mean for the reference standard that is within the acceptance range and the statistical criteria for the reference standard.

For validation purposes once every 3-month a SPF reference standard, and a UVA-PF and critical wavelength reference standard shall be tested. For SPF either P5, P6, or P8 may be used, for UVA-PF, P5, P8, or S2 may be tested, and for CW P5, P8 or S2 may be used. All reference standards values for SPF, UVA-PF and CW shall fall within the acceptance range as in Annex G.

### 8.7.2 Other calculations

Other types of comparative ratios (e.g. SPF/UVA, UVB/UVA, UVA1/UV) may be calculated using the $A_{HDRS}$ (λ) from 290 nm to 400 nm as additional information.

## 8.8 Data rejection criteria

### 8.8.1 Subject data rejection criterion

Up to 5 subjects may be rejected from a test based on calculation of the difference of the ln(UVA-$PF_{DRSi}$) value for a subject from the average of ln(UVA-$PF_{DRS}$). If the ln($UVA_{DRSi}$) (see Formula (4)) is more than two standard deviations from the mean ln($UVA_{DRS}$) (see Formula (5)) of all the subjects, then those values may be rejected and deleted from subsequent calculations. A recalculation of the standard deviation and of the mean ln($UVA_{DRS}$) shall be performed after each data rejection instance.

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### 8.8.2 Site-specific data rejection criterion

Individual subject site-specific data may only be rejected if the test site area has been touched or wiped after the sunscreen product has been applied and before the protected skin remittance measurements have been conducted on that site. If more than one site has been affected, the entire subject shall be rejected. Examples of technical failure of data that can be rejected are illustrated in Annex H.

## 8.9 Test failure criteria

The entire test shall be rejected as invalid if the statistical test criterion in 8.6 is not met after testing a maximum of 20 valid test subjects either for the test product or for the reference standard, or if more than 5 outlier ln(UVA-$PF_{DRSi}$) value were found. Additionally, if the average reference standard values for both $SPF_{HDRS}$ and UVA-$PF_{HDRS}$ determined during the test are outside of its acceptance range as stated in Annex G, the test shall be invalidated.

# 9 Test report

## 9.1 General

The test report on the determination of the absorbance spectrum of a sunscreen product should contain at least the following information:

— identification of the testing laboratory;

— the test method by reference to this document (including year of publication), i.e. ISO 23689:2024;

— product identifier;

— any deviations to the protocol;

— commencement and ending dates of the test;

— identification of the reference sunscreen used and evidence of compliance with the acceptance range for this sunscreen according to the limits described in Annex G;

— description of the instruments used: manufacturer and instrument model, reference to latest calibration and statement of compliance document (date and provider) of the clinical solar simulator and radiometer used for irradiation of PMMA plates (assessment of SRPD) as described in Annex E for the solar simulator;

— plate roughness quality (sandblasted or moulded), plate manufacturer and batch code as described in Annex D;

— the geometric mean $SPF_{HDRS}$ value expressed in one decimal place (truncated), standard deviation on the geometric mean, the geometric mean $SPF_{HDRS}$ value for the reference standards within their acceptance limits as described in Annex G, and c value less than 0,17;

— the geometric mean UVA-$PF_{HDRS}$ value expressed in one decimal place (truncated), standard deviation on the geometric mean, the geometric mean UVA-$PF_{HDRS}$ value for the reference standards within their acceptance limits as described in Annex G, and c value less than 0,17;

— final hybrid absorbance spectrum $A_{HDRS}(\lambda)$ and mean UV absorbance values at each 1 nm wavelength increment for the test sample;

— $A_{vt0}$ and $A_{vt1}$ absorbance spectrum and mean UV absorbance values at each 1 nm wavelength increment for the test sample;

— UVA irradiance (W/m$^2$) and mean UVA exposure dose used to irradiate the test sample in vitro;

— UVA-$PF_{DRS}$ by Formula (21), in vitro UVA-$PF_{vt0}$ and UVA-$PF_{vt1}$ calculated values;

— the critical wavelength (CW) given in Formula (28), in whole number of nm (no decimal).

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## 9.2 Data in tabular form for each test subject

The following information shall be provided in a table as shown in Annex K, Table K.1:

— subject number in sequence;

— identification, by code number, of each subject;

— subject ITA° value;

— identification, by subject, of the technicians conducting the test;

— individual $SPF_{HDRSi}$ values expressed in one decimal place (truncated), including all valid data and rejected data for the test product and for the reference sunscreen;

— individual $UVA\text{-}PF_{HDRSi}$ values expressed in one decimal place (truncated), including all valid data and rejected data for the test product and for the reference sunscreen;

— $SPF_{HDRS}$ calculated by Formula (30) and the c value of the $SPF_{HDRS}$ as calculated in Formula (34);

— $UVA\text{-}PF_{HDRS}$ calculated by Formula (31), and the c value of the $UVA\text{-}PF_{HDRS}$ calculated in Formula (34);

— $\lambda_C$ as calculated in Formula (29).

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# Annex A
(informative)

# Test flow chart monochromatic and polychromatic DRS

Table A.1 gives an overview of the DRS-Method and does not reflect all detailed requirements of this document.

**Table A.1 — Flow chart of the test method according to type of equipment**

| No. | Monochromatic procedure | Polychromatic procedure |
|---|---|---|
| **Instrument set up (Clause 5)** | | |
| 1 | Warm up DRS measurement equipment (minimum 20 min or manufacturer's specification) | |
| **Qualify panelist (5.5)** | | |
| 2 | Inspect test sites, measure subject's skin ITA°, clip or shave hair as needed and defined | |
| **Unprotected skin DRS measurements (5.5.8)** | | |
| 3 | Identify clear test sites of at least 30 $cm^2$. Mark the corners of the test sites with marker | |
| 4 | Set exit and/or entrance slits as needed. | |
| 5 | Set High Voltage of PMT to optimize signal gain to the test subject's skin darkness (reference scan) within the linear operating range of the PMT. | |
| 6 | Conduct a minimum of 3 unprotected skin remittance scans (5 are recommended). These spectral scans constitute $R_{uj}(\lambda)$. | Conduct unprotected skin remittance measurements at each of at least 9 subsites. These scans constitute $I_{uj}$. |
| 7 | Repeat unprotected skin remittance scans at remaining test sites. | |
| **Sunscreen application (5.5.10)** | | |
| 8 | Apply 2,00 mg/$cm^2$ ± 0,05 mg/$cm^2$ to the test area as defined by Annex J. Wait a minimum 15 min to dry. | |
| **DRS Measurements after product application (5.5.11)** | | |
| 9 | Conduct a minimum of 5 skin remittance scans at each subsite within the test site. Clean the end of the optical probe between each subsite. These spectral scans constitute $R_{pj}$ (λ). Repeat for other test areas. | Conduct a minimum of 9 skin remittance measurements at each subsite within the test site. Clean the end of the optical probe between each subsite. These spectral scans constitute $I_{pj}$. Repeat for other test areas. |
| 10 | Repeat skin remittance scans at remaining test sites. | |
| 11 | Calculate $T_{DRSj}(\lambda)$ [Formula (2)], $A_{DRSj}(\lambda)$ (Formula (3)), UVA-$PF_{DRSj}$ [Formula (4)]: for each subsite, and UVA-$PF_{DRSi}$ for each subject [Formula (5)] | Calculate UVA-$PF_{DRSj}$ for each subsite Formula (7), and $UVA_{DRSi}$ for each subject Formula (5). |
| 12 | Calculate average UVA-$PF_{DRS}$ for all test subjects Formula (6) | |
| **In vitro spectrophotometer measurements (Clause 6)** (steps below do not provide complete instructions and are provided strictly for convenience; all steps shall be in full compliance with procedures described in the Annexes. ) | | |
| 13 | Ensure compliance of instrumentation according to requirements specified in Annex A. | |
| 14 | Measure baseline for PMMA pre-treated plate. | |
| 15 | Apply test formulation on the plates and spread as described in 6.1. | |
| 16 | Dry plates as per 6.1. | |
| 17 | Scan sunscreen absorbance from 290 nm to 400 nm at 1 nm intervals, at least one observation per plate. These scans constitute $A_{vt0kl}(\lambda)$ according to Formula (8). Repeat for a minimum of 4 plates. | |
| 18 | Calculate average $A_{vt0}(\lambda)$ for all the plates according to Formula (9). | |
| 19 | Calculate the Exposure Dose according to Formula (9) (maximum dose of 36 J/$cm^2$). | |
| 20 | Expose plates to solar simulator with calculated dose. | |

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**Table A.1** *(continued)*

| No. | Monochromatic procedure | Polychromatic procedure |
|---|---|---|
| 21 | Rescan the plates after exposure as before (step 17). These measurements constitute $A_{vt1kl}(\lambda)$. | |
| 22 | Calculate the average $A_{vt1}(\lambda)$ for the plates using Formula (11) | |
| **Determination of the hybridization wavelength and $A_{DRSi}$ (λ) (6.7)** | | |
| 23 | Determine a scaling factor to adjust the $A_{vt0}$ (λ) spectrum to match the $A_{vt0}$ value at 350 nm to the $A_{DRSi}$ value at 350 nm.<br>Individual scaling factor = $A_{DRSi}(350)/A_{vt0}(350)$ | HW=345 nm |
| 24 | Multiply the $A_{vt0}(\lambda)$ spectrum by the Individual scaling factor for comparison with $A_{DRSi}$ (λ) | N/A |
| 25 | Determine the hybridization wavelength (HW) by comparing the scaled $A_{vt0}$ with $A_{DRSi}(\lambda)$ as per Formula (13). | N/A |
| **Calculations to address photo-instability (Clause 7)** | | |
| 26 | Calculate the spectral ratio of photo-degradation ($S_{RPD,UVB}$ and $S_{RPD,UVA}$) according to Formulae (14), (15) and (16). Depending on the SRPD values [Formula (14) or Formula (16)] is used the $S_{RPD}(\lambda)$ calculations in Formulae (17), (18) or (19). | |
| 27 | Calculate $A_{DRSi}$ according to Formula (20) | Calculate the Formulae (21) and (22) for $s_i$ using a goal-seek function until UVA-$PF_{vt0i}$ = UVA-$PF_{DRSi.}$ (see 8.1.2 and Formula (21)). Than calculate $A_{DRSi}$ according to Formula (22) |
| **Determination of SPF and UVA-PF (8.1 to 8.5)** | | |
| 28 | Determine the hybridization scalar value $C_{Ai}$ according to Formula (23) | |
| 29 | Calculate the final hybrid spectrum $A_{HDRSi}$ according to Formula (25) | |
| 30 | Calculate the $SPF_{HDRSi}$ for each test subject according to Formula (26) | |
| 31 | Calculate the UVA-$PF_{HDRSi}$ for each test subject according to Formula (27) | |
| 32 | Calculate the $\lambda_{c\,i}$ for each test subject according to Formula (29). | |
| 33 | Calculate the mean values for $SPF_{HDRS}$ ,UVA-$PF_{HDRS}$ by Formula (30) and Formula (31), respectively | |
| **Statistical test (8.5)** | | |
| 34 | Calculate the c values using the ln($SPF_{HDRSi}$) and ln(UVA-$PF_{HDRSi}$) values to ensure that the c values are less than 0,17 (Formula (34)). Add additional subjects as needed to have both c values ≤ 0,17. | |

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# Annex B
(normative)

# Calibration check of UV spectrophotometer and plate transmittance test (in vitro measurements)

## B.1 General

This procedure describes the requirements for wavelength accuracy, linearity and dynamic range of the UV spectrophotometer.

## B.2 Wavelength accuracy

### B.2.1 Holmium oxide filter

The filter thickness should not exceed 3 mm. For wavelength calibration, at least two absorption peaks shall be considered for the measurement range of PMMA plates, for example: 333,5 nm and 361,3 nm. A holmium perchlorate solution can be used as well to identify the absorbance peaks.

### B.2.2 Method

**B.2.2.1** Place the holmium oxide filter in the sample path and scan the absorbance in the range between 290 nm and 430 nm. Measure against air in the blank light path. Repeat the scan 3 times. Accumulate the data and transfer absorbance values to the "Holmium Wavelength Accuracy" tab in the spreadsheet "ISO 24443 UVSpectcalib.xls" (available from https://standards.iso.org/iso/23698/ed-1/en) in Columns B to D. Click on the macro button at cell "P28" to activate the peak check function. The results will automatically appear in the system calibration summary sheet in this document (see Table B.1 and Figure B.1).

**B.2.2.2** The deviations of the measured band from the reference value in the UV range of the instrument should not exceed 1 nm. An example of a measured calibration spectrum is shown in Figure B.1. The reported peak wavelength shall be either 360 nm, 361 nm or 362 nm, or else the instrument shall be recalibrated to achieve one of these wavelength values.

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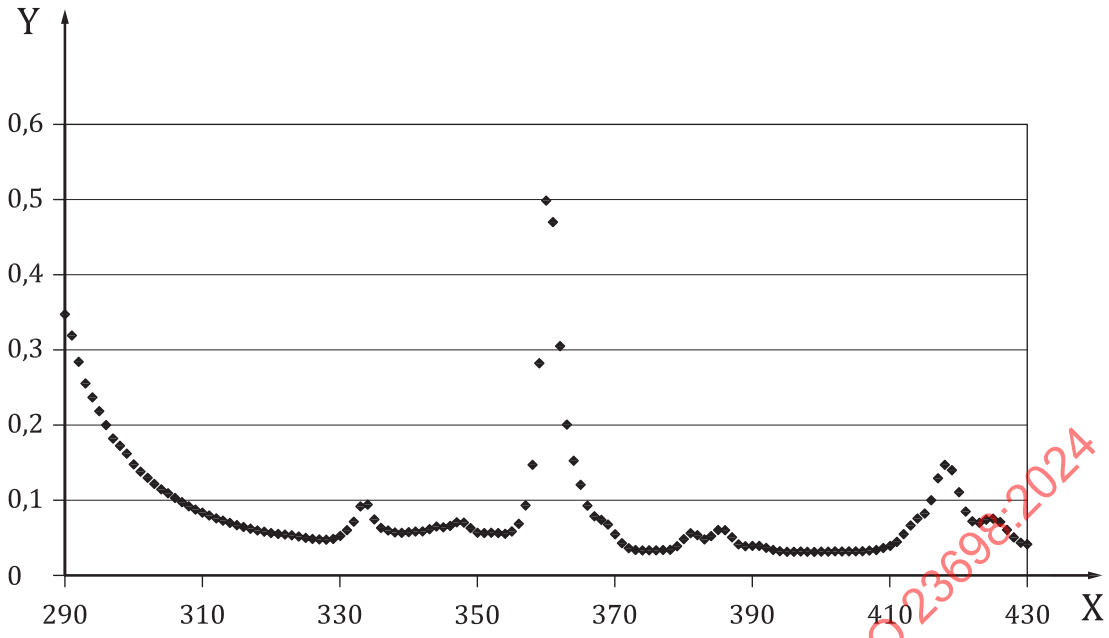


**Key**

X wavelength (nm)

Y absorbance

**Figure B.1 — Holmium oxide absorbance plot**

## B.3 Linearity

### B.3.1 Standard reference plates

The plates are cut from a large sheet of standard cast, UV-stabilized PMMA (helping ensure the same optical properties for each plate). The plates are made in a way as to match the absorbance spectra of a range of common sunscreens. The casting process enables a very homogeneous distribution of UV absorbing material, relative to a manually applied film of a test emulsion.

Because of their stable and standardized absorbance and diffuse-scattering properties, they are very suitable as "reference emulsions" to check and compare instruments used for in vitro determination of UV protection, for intra- as well as interlaboratory purposes.

### B.3.2 Linearity assessment

Select two of the transparent UV-stabilized PMMA reference plates. The absorbance peak of these reference plates at 340 nm shall be between 1,1 and 1,5 absorbance units (AU).

Designate the first plate as Slide A and place it in the light path of the UV spectrophotometer. Measure against air in the blank light path. Run a duplicate (290 nm to 380 nm) and transfer data to the "Linearity test" spreadsheet tab, cells B8:C98.

Designate the second plate as Slide B and place it in the light path of the UV spectrophotometer. Measure against air in the blank light path. Run in duplicate and transfer data to the "Linearity test" spreadsheet tab, cells D8:E98. Place both slides (A and B) on top of each other with their roughened sides towards one another into the light path and measure the combined absorbance (290 nm to 380 nm). Measure against air in the blank light path. Run 4 replicates and transfers data to the "Linearity test" spreadsheet tab, cells F8:I98. The results will automatically appear in the system calibration summary sheet in this document (see Table B.2).

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## B.4 Dynamic absorbance range limit determination

The spreadsheet will also calculate the maximum absorbance range limit of the UV spectrophotometer, based on deviation from additivity of the two plates. When the deviation exceeds 0,1 AU, the dynamic range limit is determined the results will automatically appear in the system calibration summary sheet in the spreadsheet (see Table B.2 and Figure B.2). The minimum range limit is 2,2 AU.

## B.5 Reporting

The results of the calibration check shall be recorded.

**Table B.1 — Wavelength accuracy example**

| Spectrophotometer wavelength accuracy (example) | | |
|---|---|---|
| | Peak 1 | Peak 2 |
| Reference wavelength: | 333,5 nm | 361,3 nm |
| Measured wavelength: | 333,5 nm | 361,3 nm |
| Peak value: | 0,1 | 0,433 |
| Limit ±1 | True | True |

**Table B.2 — Linearity test example**

| Spectrophotometer linearity test | | | |
|---|---|---|---|
| | | | Limit |
| Dynamic range limit | 2,41 | Pass | 2,2 |
| Linearity limit | 92,50 | Pass | 85 |

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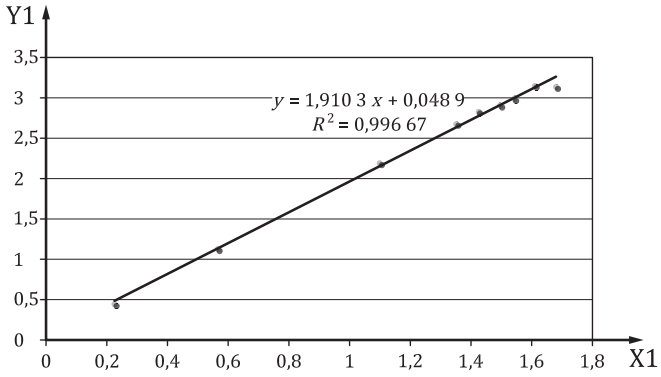
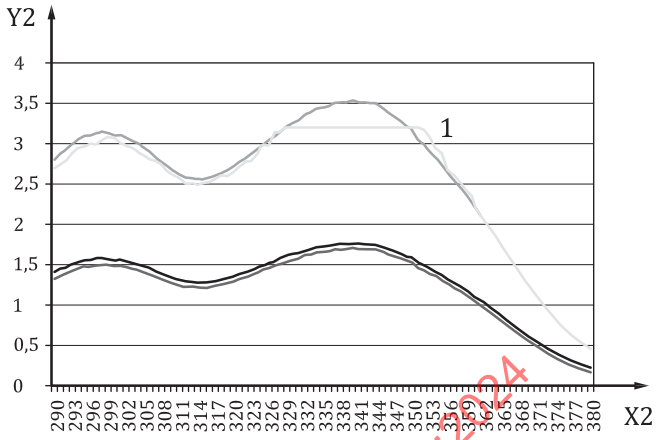



**a) One versus two PMMA calibration plates correlation**




**b) Dynamic range test**

**Key**

X1 one plate (mean) (absorbance)

Y1 two plates (stacked) (absorbance)

**Key**

X2 wavelength (nm)

Y2 absorbance calculated

1 dynamic range limit

Slide A

Slide B

Slide A + B (calc)

Slide A + B (obs)

**Figure B.2 — System calibration summary sheet**

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# Annex C
(normative)

# Calibration of solar simulator irradiance and radiometer procedure

## C.1 Purpose

The purpose is to calibrate the radiometer used to measure the UV exposure source for accurate dose exposures for the photo-stability challenge step in the in vitro UVA sunscreen testing protocol.

## C.2 Summary of procedure

A spectroradiometric irradiance measurement is first conducted on the UV exposure source over the UV range of 290 nm to 400 nm. The UVA radiometer probe being cross calibrated is placed in the same exposure position as the spectroradiometer and a measurement of the irradiance at the plane of exposure is conducted. Taking the spectroradiometric irradiance data, the energy at each wavelength, in 1 nm intervals, is integrated from 320 nm to 400 nm to yield the spectroradiometric UVA irradiance. The spectroradiometric UVA irradiance is divided by the irradiance measurement from the UVA radiometer to yield a calibration factor, *Y*, that is used to multiply all subsequent UVA radiometer measurements of the UVA source used in this exercise.

## C.3 Step-by-step procedure

The purpose is to calibrate the radiometer used to measure the UV exposure source for accurate dose exposures for the photo-stability challenge step in the in vitro part of the HDRS protocol.

**C.3.1** A spectroradiometer with current calibration traceable to a certified irradiance standard source over the range of 290 nm to 400 nm is required.

**C.3.2** Place the reference entrance optics of the spectroradiometer into position at the plane of exposure of the test PMMA plates.

**C.3.3** Turn on the UV exposure source and allow it to warm up for at least 20 min.

**C.3.4** Scan the spectral irradiance of the source with the spectroradiometer over the range of 290 nm to 400 nm in 1 nm increments.

**C.3.5** Integrate the spectral irradiance from 320 nm to 400 nm in order to determine the total UVA spectroradiometric irradiance of the source at the exposure plane of the PMMA plate samples. This is designated $IUVA_{spec}$.

**C.3.6** Move the spectroradiometer probe away from the source.

**C.3.7** Place the UVA radiometer that is to be calibrated in the same position as the spectroradiometer so that the calibration reference plane of the radiometer is in the same position as the spectroradiometer reference entrance optics being illuminated by the UV exposure source.

**C.3.8** Measure the irradiance of the source with the UVA radiometer. This is designated $IUVA_{rad}$.

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**C.3.9** Calculate the calibration factor using Formula (C.1):

$$Y = \frac{IUVA_{\text{spec}}}{IUVA_{\text{rad}}} \tag{C.1}$$

**C.3.10** Subsequent measurements of the UV exposure source by the UVA radiometer shall be multiplied by Y for calibrated UVA irradiance, as shown in Formula (C.2):

$$I_{\text{rad,UVA}} = I_{\text{UVArad}} \times \text{Y} \tag{C.2}$$

where $I_{\text{rad,UVA}}$ is the calibrated UVA irradiance.

**C.3.11** The calibration correction factor Y can be entered directly into the ISO in vitro UVA test spreadsheet. The raw radiometer value (without calibration correction) is also entered on this same tab to calculate the calibrated irradiance value for the UV exposure step.

## C.4 Solar simulator uniformity, monitoring and maintenance

The output from the solar UVR simulator shall be continuous, uniform, stable, with no gaps or extreme peaks of emission in the UVR region and suitably filtered to create a spectral quality that complies with the required acceptance limits (see Annex E).

To ensure that appropriate amounts of UVA radiation are included in the spectrum of the solar UV simulator, the total radiometric proportion of UVA-II irradiance of the simulator (320 nm to 340 nm) shall be ≥ 20,0 % of total UVR irradiance (290 nm to 400 nm) to be aligned with ISO 24444 which requires the same solar irradiance. Additionally, UVA-I region (340 nm to 400 nm) irradiance shall be ≥ 60 % of total UVR irradiance.

The source spectral specification is described in terms of cumulative erythemal effective irradiance by successive wavelength bands, 290 nm to 400 nm. The erythemal effective irradiance of each wavelength band is expressed as a percentage of total erythemal effective irradiance, 290 nm to 400 nm, or as percentage relative cumulative erythemal effectiveness (%RCEE).

The definition and calculation of %RCEE values is described in Table C.1 and acceptance limits are shown in Table C.2

Total irradiance shall not exceed 200 W/m$^2$. The output of the solar simulator shall be measured with a broad-spectrum sensor (capable of measuring between 280 nm and 1 600 nm) calibrated against a standard reference source over the range of 280 nm to 1 600 nm. Alternatively, the source may be measured with a calibrated spectroradiometer over this same wavelength range to determine the total irradiance.

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 ≥ 90 %, calculated using Formula (C.3):

$$U = (1\text{-}(\text{max-min})/(\bar{X})) \tag{C.3}$$

where

$U$ is the uniformity in percentage;

$\bar{X}$ is the average.

If the uniformity is less than 90 %, then optical components should be adjusted (and a new beam uniformity control shall be performed) or appropriate compensation for different irradiance shall be made in the exposure time on each plate.

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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 2 500 hours of lamp running time and after changing any significant physical (optical) component of the solar simulator (including the bulb only if the bulb was not already previously calibrated with the associated solar simulator).

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. Prior to the UV exposure of sample, the UV intensity of the exposure source output shall be measured and recorded with a spectroradiometer (as detailed in 6.5) or an UVA radiometer cross-calibrated against a spectroradiometric measurement of each assigned solar simulator output as detailed in 6.5.

**Table C.1 — Example of calculation — Xenon-arc UV source and RCEE values**

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|
| | UV Source | | | | | | | RCEE accept. range | |
| W.L. $\lambda$ | Irradiance | Normalized | Eryth. A.S. (CIE-1999) | Spectral eryth. eff. | Interval eryth. eff. | Cumulative eryth. eff. | Sol. Sim. % RCEE | Lower limit | Upper limit |
| nm | {E} $W \cdot m^{-2} \cdot nm^{-1}$ | to 320 nm | $\{E(\lambda)\}$ | $\{E \times E(\lambda)\}$ | $1/2\{E \times E(\lambda)\}$ dl | Sum$\{E \times E(\lambda)\}$ | Sum$\{E \times E(\lambda)\}/T$ | | |
| **280** | **1,523E−05** | **1,75E−06** | **1,00E+00** | **1,52E−05** | | | | | |
| 281 | 1,848E−05 | 2,12E−06 | 1,00E+00 | 1,85E−05 | 1,69E−05 | | | | |
| 282 | 2,904E−05 | 3,34E−06 | 1,00E+00 | 2,90E−05 | 2,38E−05 | | | | |
| 283 | 1,878E−05 | 2,16E−06 | 1,00E+00 | 1,88E−05 | 2,39E−05 | | | | |
| 284 | 2,139E−05 | 2,46E−06 | 1,00E+00 | 2,14E−05 | 2,01E−05 | | | | |
| 285 | 2,837E−05 | 3,26E−06 | 1,00E+00 | 2,84E−05 | 2,49E−05 | | | | |
| 286 | 2,935E−05 | 3,37E−06 | 1,00E+00 | 2,94E−05 | 2,89E−05 | | | | |
| 287 | 2,627E−05 | 3,02E−06 | 1,00E+00 | 2,63E−05 | 2,78E−05 | | | | |
| 288 | 2,927E−05 | 3,36E−06 | 1,00E+00 | 2,93E−05 | 2,78E−05 | | | | |
| 289 | 4,308E−05 | 4,95E−06 | 1,00E+00 | 4,31E−05 | 3,62E−05 | | | | |
| **290** | **4,405E−05** | **5,06E−06** | **1,00E+00** | **4,40E−05** | **4,36E−05** | **2,74E−04** | **0,00 %** | **—** | **< 0,1 %** |
| 291 | 5,500E−05 | 6,32E−06 | 1,00E+00 | 5,50E−5 | 4,95E−05 | | | | |
| 292 | 8,279E−05 | 9,52E−06 | 1,00E+00 | 8,28E−05 | 6,89E−05 | | | | |
| 293 | 2,379E−04 | 2,73E−05 | 1,00E+00 | 2,38E−04 | 1,60E−04 | | | | |
| 294 | 8,219E−04 | 9,45E−05 | 1,00E+00 | 8,22E−04 | 5,30E−04 | | | | |
| 295 | 2,685E−03 | 3,09E−04 | 1,00E+00 | 2,68E−03 | 1,75E−03 | | | | |
| 296 | 8,029E−03 | 9,23E−04 | 1,00E+00 | 8,03E−03 | 5,36E−03 | | | | |
| 297 | 2,102E−02 | 2,42E−03 | 1,00E+00 | 2,10E−02 | 1,45E−02 | | | | |
| 298 | 5,030E−02 | 5,78E−03 | 1,00E+00 | 5,03E−02 | 3,57E−02 | | | | |
| 299 | 1,041E−01 | 1,20E−02 | 8,05E−01 | 8,39E−02 | 6,71E−02 | | | | |
| **300** | **1,886E−01** | **2,17E−02** | **6,49E−01** | **1,22E−01** | **1,03E−01** | **2,29E−01** | **4,0 %** | **1 %** | **8,0 %** |
| 301 | 3,352E−01 | 3,85E−02 | 5,22E−01 | 1,75E−01 | 1,49E−01 | | | | |
| 302 | 5,358E−01 | 6,16E−02 | 4,21E−01 | 2,25E−01 | 2,00E-01 | | | | |
| 303 | 8,051E−01 | 9,25E−02 | 3,39E−01 | 2,73E−01 | 2,49E−01 | | | | |
| 304 | 1,126E+00 | 1,29E−01 | 2,73E−01 | 3,07E−01 | 2,90E−01 | | | | |
| 305 | 1,563E+00 | 1,80E−01 | 2,20E−01 | 3,43E−01 | 3,25E−01 | | | | |
| 306 | 2,009E+00 | 2,31E−01 | 1,77E−01 | 3,56E−01 | 3,50E−01 | | | | |
| 307 | 2,576E+00 | 2,96E−01 | 1,43E−01 | 3,67E−01 | 3,61E−01 | | | | |
| 308 | 3,081E+00 | 3,54E−01 | 1,15E−01 | 3,54E−01 | 3,60E−01 | | | | |
| 309 | 3,700E+00 | 4,25E−01 | 9,25E−02 | 3,42E−01 | 3,48E−01 | | | | |
| **310** | **4,248E+00** | **4,88E−01** | **7,45E−02** | **3,16E−01** | **3,29E−01** | **3,19E+00** | **55,7 %** | **49,0 %** | **65,0 %** |
| 311 | 4,769E+00 | 5,48E−01 | 6,00E−02 | 2,86E−01 | 3,01E−01 | | | | |

$E(\lambda)$ is the erythemal effectiveness.

$E$ is the source irradiance.

W.L. is the wavelength $\lambda$ of the source.

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**Table C.1** *(continued)*

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|
| | UV Source | | Eryth. A.S. (CIE-1999) | Spectral eryth. eff. | Interval eryth. eff. | Cumulative eryth. eff. | Sol. Sim. % RCEE | RCEE accept. range | |
| W.L. $\lambda$ | Irradiance | Normalized | | | | | | Lower limit | Upper limit |
| nm | {E} $W \cdot m^{-2} \cdot nm^{-1}$ | to 320 nm | $\{E(\lambda)\}$ | $\{E \times E(\lambda)\}$ | $1/2\{E \times E(\lambda)\}$ dl | Sum$\{E \times E(\lambda)\}$ | Sum$\{E \times E(\lambda)\}/T$ | | |
| 312 | 5,384E+00 | 6,19E−01 | 4,83E−02 | 2,60E−01 | 2,73E−01 | | | | |
| 313 | 5,978E+00 | 6,87E−01 | 3,89E−02 | 2,33E−01 | 2,46E−01 | | | | |
| 314 | 6,399E+00 | 7,36E−01 | 3,13E−02 | 2,01E−01 | 2,17E−01 | | | | |
| 315 | 6,896E+00 | 7,93E−01 | 2,52E−02 | 1,74E−01 | 1,87E−01 | | | | |
| 316 | 7,250E+00 | 8,33E−01 | 2,03E−02 | 1,47E−01 | 1,61E−01 | | | | |
| 317 | 7,731E+00 | 8,89E−01 | 1,64E−02 | 1,27E−01 | 1,37E−01 | | | | |
| 318 | 8,060E+00 | 9,26E−01 | 1,32E−02 | 1,06E−01 | 1,16E−01 | | | | |
| 319 | 8,338E+00 | 9,58E−01 | 1,06E−02 | 8,85E−02 | 9,74E−02 | | | | |
| **320** | **8,700E+00** | **1,00E+00** | **8,55E−03** | **7,44E−02** | **8,15E−02** | **5,01E+00** | **87,0 %** | **85,0 %** | **90,0 %** |
| 321 | 8,988E+00 | 1,03E+00 | 6,89E−03 | 6,19E−02 | 6,81E−02 | | | | |
| 322 | 9,320E+00 | 1,07E+00 | 5,55E−03 | 5,17E−02 | 5,68E−02 | | | | |
| 323 | 9,547E+00 | 1,10E+00 | 4,47E−03 | 4,26E−02 | 4,72E−02 | | | | |
| 324 | 9,755E+00 | 1,12E+00 | 3,60E−03 | 3,51E−02 | 3,89E−02 | | | | |
| 325 | 9,913E+00 | 1,14E+00 | 2,90E−03 | 2,87E−02 | 3,19E−02 | | | | |
| 326 | 1,015E+01 | 1,17E+00 | 2,33E−03 | 2,37E−02 | 2,62E−02 | | | | |
| 327 | 1,029E+01 | 1,18E+00 | 1,88E−03 | 1,93E−02 | 2,15E−02 | | | | |
| 328 | 1,042E+01 | 1,20E+00 | 1,51E-03 | 1,58E-02 | 1,76E-02 | | | | |
| 329 | 1,060E+01 | 1,22E+00 | 1,46E-03 | 1,55E-02 | 1,56E-02 | | | | |
| **330** | **1,071E+01** | **1,23E+00** | **1,41E-03** | **1,51E-02** | **1,53E-02** | **5,35E+00** | **92,9 %** | **91,5 %** | **95,5 %** |
| 331 | 1,085E+01 | 1,25E+00 | 1,36E-03 | 1,48E-02 | 1,50E-02 | | | | |
| 332 | 1,099E+01 | 1,26E+00 | 1,32E-03 | 1,45E-02 | 1,46E-02 | | | | |
| 333 | 1,108E+01 | 1,27E+00 | 1,27E-03 | 1,41E-02 | 1,43E-02 | | | | |
| 334 | 1,120E+01 | 1,29E+00 | 1,23E-03 | 1,38E-02 | 1,39E-02 | | | | |
| 335 | 1,127E+01 | 1,29E+00 | 1,19E-03 | 1,34E-02 | 1,36E-02 | | | | |
| 336 | 1,135E+01 | 1,30E+00 | 1,15E-03 | 1,30E-02 | 1,32E-02 | | | | |
| 337 | 1,143E+01 | 1,31E+00 | 1,11E-03 | 1,27E-02 | 1,29E-02 | | | | |
| 338 | 1,149E+01 | 1,32E+00 | 1,07E-03 | 1,23E-02 | 1,25E-02 | | | | |
| 339 | 1,160E+01 | 1,33E+00 | 1,04E-03 | 1,20E-02 | 1,22E-02 | | | | |
| **340** | **1,166E+01** | **1,34E+00** | **1,00E-03** | **1,17E-02** | **1,18E-02** | **5,48E+00** | **95,2 %** | **94 %** | **97,0 %** |
| 341 | 1,176E+01 | 1,35E+00 | 9,66E-04 | 1,14E-02 | 1,15E-02 | | | | |
| 342 | 1,185E+01 | 1,36E+00 | 9,33E-04 | 1,11E-02 | 1,12E-02 | | | | |
| 343 | 1,189E+01 | 1,37E+00 | 9,02E-04 | 1,07E-02 | 1,09E-02 | | | | |
| 344 | 1,194E+01 | 1,37E+00 | 8,71E-04 | 1,04E-02 | 1,06E-02 | | | | |
| 345 | 1,196E+01 | 1,37E+00 | 8,41E-04 | 1,01E-02 | 1,02E-02 | | | | |
| 346 | 1,200E+01 | 1,38E+00 | 8,13E-04 | 9,75E-03 | 9,91E-03 | | | | |
| 347 | 1,204E+01 | 1,38E+00 | 7,85E-04 | 9,45E-03 | 9,60E-03 | | | | |
| 348 | 1,212E+01 | 1,39E+00 | 7,59E-04 | 9,19E-03 | 9,32E-03 | | | | |
| 349 | 1,215E+01 | 1,40E+00 | 7,33E-04 | 8,90E-03 | 9,05E-03 | | | | |
| **350** | **1,220E+01** | **1,40E+00** | **7,08E-04** | **8,64E-03** | **8,77E-03** | **5,57E+00** | **97,2 %** | | |
| 351 | 1,224E+01 | 1,41E+00 | 6,84E-04 | 8,37E-03 | 8,50E-03 | | | | |
| 352 | 1,230E+01 | 1,41E+00 | 6,61E-04 | 8,13E-03 | 8,25E-03 | | | | |

$E(\lambda)$ is the erythemal effectiveness.

$E$ is the source irradiance.

W.L. is the wavelength $\lambda$ of the source.

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**Table C.1** *(continued)*

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|
| | UV Source | | Eryth. A.S. (CIE-1999) | Spectral eryth. eff. | Interval eryth. eff. | Cumulative eryth. eff. | Sol. Sim. % RCEE | RCEE accept. range | |
| W.L. $\lambda$ | Irradiance | Normalized | | | | | | Lower limit | Upper limit |
| nm | {E} $W \cdot m^{-2} \cdot nm^{-1}$ | to 320 nm | $\{E(\lambda)\}$ | $\{E \times E(\lambda)\}$ | $1/2\{E \times E(\lambda)\}$ dl | Sum$\{E \times E(\lambda)\}$ | Sum$\{E \times E(\lambda)\}/T$ | | |
| 353 | 1,231E+01 | 1,42E+00 | 6,38E-04 | 7,86E-03 | 7,99E-03 | | | | |
| 354 | 1,229E+01 | 1,41E+00 | 6,17E-04 | 7,58E-03 | 7,72E-03 | | | | |
| 355 | 1,234E+01 | 1,42E+00 | 5,96E-04 | 7,35E-03 | 7,46E-03 | | | | |
| 356 | 1,233E+01 | 1,42E+00 | 5,75E-04 | 7,10E-03 | 7,22E-03 | | | | |
| 357 | 1,232E+01 | 1,42E+00 | 5,56E-04 | 6,85E-03 | 6,97E-03 | | | | |
| 358 | 1,234E+01 | 1,42E+00 | 5,37E-04 | 6,63E-03 | 6,74E-03 | | | | |
| 359 | 1,234E+01 | 1,42E+00 | 5,19E-04 | 6,40E-03 | 6,51E-03 | | | | |
| **360** | **1,233E+01** | **1,42E+00** | **5,01E-04** | **6,18E-03** | **6,29E-03** | **5,64E+00** | **98,5 %** | | |
| 361 | 1,230E+01 | 1,41E+00 | 4,84E-04 | 5,96E-03 | 6,07E-03 | | | | |
| 362 | 1,225E+01 | 1,41E+00 | 4,68E-04 | 5,73E-03 | 5,84E-03 | | | | |
| 363 | 1,217E+01 | 1,40E+00 | 4,52E-04 | 5,50E-03 | 5,61E-03 | | | | |
| 364 | 1,212E+01 | 1,39E+00 | 4,37E-04 | 5,29E-03 | 5,39E-03 | | | | |
| 365 | 1,200E+01 | 1,38E+00 | 4,22E-04 | 5,06E-03 | 5,18E-03 | | | | |
| 366 | 1,183E+01 | 1,36E+00 | 4,07E-04 | 4,82E-03 | 4,94E-03 | | | | |
| 367 | 1,171E+01 | 1,35E+00 | 3,94E-04 | 4,61E-03 | 4,71E-03 | | | | |
| 368 | 1,153E+01 | 1,33E+00 | 3,80E-04 | 4,38E-03 | 4,50E-03 | | | | |
| 369 | 1,130E+01 | 1,30E+00 | 3,67E-04 | 4,15E-03 | 4,27E-03 | | | | |
| **370** | **1,102E+01** | **1,27E+00** | **3,55E-04** | **3,91E-03** | **4,03E-03** | **5,69E+00** | **99,3 %** | | |
| 371 | 1,073E+01 | 1,23E+00 | 3,43E-04 | 3,68E-03 | 3,79E-03 | | | | |
| 372 | 1,042E+01 | 1,20E+00 | 3,31E-04 | 3,45E-03 | 3,56E-03 | | | | |
| 373 | 1,005E+01 | 1,16E+00 | 3,20E-04 | 3,21E-03 | 3,33E-03 | | | | |
| 374 | 9,649E+00 | 1,11E+00 | 3,09E-04 | 2,98E-03 | 3,10E-03 | | | | |
| 375 | 9,370E+00 | 1,08E+00 | 2,99E-04 | 2,80E-03 | 2,89E-03 | | | | |
| 376 | 8,977E+00 | 1,03E+00 | 2,88E-04 | 2,59E-03 | 2,69E-03 | | | | |
| 377 | 8,597E+00 | 9,88E−01 | 2,79E-04 | 2,40E-03 | 2,49E-03 | | | | |
| 378 | 8,195E+00 | 9,42E−01 | 2,69E-04 | 2,21E-03 | 2,30E-03 | | | | |
| 379 | 7,707E+00 | 8,86E−01 | 2,60E-04 | 2,00E-03 | 2,10E-03 | | | | |
| **380** | **7,176E+00** | **8,25E−01** | **2,51E-04** | **1,80E-03** | **1,90E-03** | **5,72E+00** | **99,8 %** | | |
| 381 | 6,703E+00 | 7,70E−01 | 2,43E-04 | 1,63E-03 | 1,71E-03 | | | | |
| 382 | 6,147E+00 | 7,07E−01 | 2,34E-04 | 1,44E-03 | 1,53E-03 | | | | |
| 383 | 5,577E+00 | 6,41E−01 | 2,26E-04 | 1,26E-03 | 1,35E-03 | | | | |
| 384 | 4,994E+00 | 5,74E−01 | 2,19E-04 | 1,09E-03 | 1,18E-03 | | | | |
| 385 | 4,423E+00 | 5,08E−01 | 2,11E-04 | 9,35E-04 | 1,01E-03 | | | | |
| 386 | 3,860E+00 | 4,44E−01 | 2,04E-04 | 7,88E-04 | 8,61E-04 | | | | |
| 387 | 3,348E+00 | 3,85E−01 | 1,97E-04 | 6,60E-04 | 7,24E-04 | | | | |
| 388 | 2,846E+00 | 3,27E−01 | 1,91E-04 | 5,42E-04 | 6,01E-04 | | | | |
| 389 | 2,389E+00 | 2,75E−01 | 1,84E-04 | 4,40E-04 | 4,91E-04 | | | | |
| **390** | **1,996E+00** | **2,29E−01** | **1,78E-04** | **3,55E-04** | **3,97E-04** | **5,73E+00** | **100,0 %** | | |
| 391 | 1,626E+00 | 1,87E−01 | 1,72E-04 | 2,79E-04 | 3,17E-04 | | | | |
| 392 | 1,297E+00 | 1,49E−01 | 1,66E-04 | 2,15E-04 | 2,47E-04 | | | | |
| 393 | 1,016E+00 | 1,17E−01 | 1,60E-04 | 1,63E-04 | 1,89E-04 | | | | |

$E(\lambda)$ is the erythemal effectiveness.

$E$ is the source irradiance.

W.L. is the wavelength $\lambda$ of the source.

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**Table C.1** *(continued)*

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|
| | UV Source | | Eryth. A.S. (CIE-1999) | Spectral eryth. eff. | Interval eryth. eff. | Cumulative eryth. eff. | Sol. Sim. % RCEE | RCEE accept. range | |
| W.L. $\lambda$ | Irradiance | Normalized | | | | | | Lower limit | Upper limit |
| nm | {E} $W \cdot m^{-2} \cdot nm^{-1}$ | to 320 nm | $\{E(\lambda)\}$ | $\{E \times E(\lambda)\}$ | $1/2\{E \times E(\lambda)\}$ dl | Sum$\{E \times E(\lambda)\}$ | Sum$\{E \times E(\lambda)\}/T$ | | |
| 394 | 7,810E−01 | 8,98E−02 | 1,55E-04 | 1,21E-04 | 1,42E-04 | | | | |
| 395 | 5,916E−01 | 6,80E−02 | 1,50E-04 | 8,85E-05 | 1,05E-04 | | | | |
| 396 | 4,438E−01 | 5,10E−02 | 1,45E-04 | 6,41E-05 | 7,63E-05 | | | | |
| 397 | 3,247E−01 | 3,73E−02 | 1,40E-04 | 4,53E-05 | 5,47E-05 | | | | |
| 398 | 2,312E−01 | 2,66E−02 | 1,35E-04 | 3,12E-05 | 3,83E-05 | | | | |
| 399 | 1,593E−01 | 1,83E−02 | 1,30E-04 | 2,08E-05 | 2,60E-05 | | | | |
| **400** | **1,073E−01** | **1,23E−02** | **1,26E-04** | **1,35E-05** | **1,71E-05** | **5,73E+00** | **100,0 %** | **99,9** | **100,0 %** |
| | UV irrad ($W \cdot m^{-2}$): 8,03*E*+02 | | UVe irrad. ($W \cdot m^{-2} \cdot$ery), *T* : **5,76*E*+00** | | | **Conclusion:** Complies | | | |

$E(\lambda)$ is the erythemal effectiveness.

$E$ is the source irradiance.

W.L. is the wavelength $\lambda$ of the source.

**Table C.2 — % RCEE acceptance limits for the UV solar simulator output**

| Spectral range | Measured % RCEE | |
|---|---|---|
| nm | Lower limit | Lower limit |
| <290 | | <0,1 |
| 290 to 300 | 1,0 | 8,0 |
| 290 to 310 | 49,0 | 65,0 |
| 290 to 320 | 85,0 | 90,0 |
| 290 to 330 | 91,5 | 95,5 |
| 290 to 340 | 94,0 | 97,0 |
| 290 to 400 | 99,9 | 100,0 |

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# Annex D
(normative)

# Test plate and surface specifications

## D.1 Test plate type

PMMA plates with a moulded or sandblasted (recommended) surface texture shall be used for the in vitro part of HDRS.

## D.2 Test plate surface parameter

The surface profile characteristics of the substrates were measured based on several batches under specific criteria as recommended here below by using non-contact surface topographic analysis consisting of an optical sensor, a motion controller, an x-y translation stage, and microtopography software[15]. The PMMA plate is defined by covering at least a surface area of 10 mm × 5 mm in 15 µm intervals, measured by non-contact surface topographic analysis. A sensor based on a white light chromatic aberration principle is recommended, which allows for a high resolution: 10 nm vertically and 1 µm horizontally. Gaussian filters of 0,8 mm or 2,5 mm are used according to profilometer characteristics.

The profile parameters are as follows:

— A1: Upper area

— Ra: Arithmetic mean deviation of the roughness profile

— Rdq: Root-mean-square slope of the roughness profile

— Rv: Maximum valley depth of the roughness profile

— Ssc: Arithmetic mean summit curvature

— Vvv: Pit void volume

The plates utilized in testing shall conform with the topographic parameters described in the control chart in Table D.1. Alternative specifications of topographic parameters may be obtained by using the same technology principle of the profilometer non-contact surface topographic analysis) but with other

a) optical sensor,

b) measurement conditions,

c) analysis operators or

d) microtopography software.

These alternative control charts can be considered as valid only after the user has demonstrated, based on several batches, that the alternative is suitable and produces equivalent and correlated measurement results to those achieved using original specifications.

The surface profile parameters of the PMMA plate shall fall within the limits given in in Table D.1.

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**Table D.1 — Target and upper and lower limits for PMMA plates**

| Parameter | Target | Limits |
|---|---|---|
| Ra [µm] | 4,2 | ±0,5 |
| Rv [µm] | 11,4 | ±2,5 |
| Rdq [°] | 12,0 | ±2,5 |
| A1 [µm²/mm] | 230,0 | ±75,0 |
| Ssc [1/µm] | 0,03 | ±0,015 |
| Vvv [mm³/mm²] | 0,000 8 | ±0,000 3 |

## D.3 Test plate transmittance specifications

Representative samples of each lot of PMMA plates are to be tested for transmittance properties to ensure compliance. The profiled surface of the test plate is to be treated with pure glycerine or a modified glycerine solution as shown in Table D.2.

**Table D.2 — Modified glycerine solution**

| Ingredient | % |
|---|---|
| Glycerine BP/USP/JP | 90,0 |
| 1 % Sodium lauryl sulphate (SLS) solution in water | 10,0 |

Prepare a standard PMMA blank plate by applying approximately 15 mg of pure glycerine or modified glycerine solution as a thin continuous film to the rough side of the plate. The slide shall be transparent after treatment. Wipe away any excess glycerine material with a bare fingertip. Place the plate in the light path of the UV spectrophotometer. Measure transmittance (290 nm to 400 nm) against an air baseline (with no plate) as the reference light path.

Transmittance values of the treated plate shall fulfil the limits Table D.3.

**Table D.3 — Transmittance limits**

| Wavelength (nm) | Transmittance (%) |
|---|---|
| 290 | >60 |
| 300 | >69 |
| 320 | >81 |

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# Annex E
(normative)

# Computation values — PPD and erythema action spectra and UVA and UV-SSR spectral irradiances

**Table E.1 — PPD and erythema action spectra and UVA and UV-SSR spectral irradiances**

| Wavelength nm | PPD action spectrum[17] (scalar) $P(\lambda)$ | Erythema action spectrum[4] (scalar) $E(\lambda)$ | UV-SSR source Relative irradiance (normalized to peak @ 355 nm) $S(\lambda)$ | UVA radiation source Relative irradiance (normalized to peak @ 364 nm) |
|---|---|---|---|---|
| 290 | — | 1,0000E+00 | 8,36E-06 | — |
| 291 | — | 1,0000E+00 | 1,39E-05 | — |
| 292 | — | 1,0000E+00 | 2,54E-05 | — |
| 293 | — | 1,0000E+00 | 4,37E-05 | — |
| 294 | — | 1,0000E+00 | 9,62E-05 | — |
| 295 | — | 1,0000E+00 | 2,48E-04 | — |
| 296 | — | 1,0000E+00 | 6,73E-04 | — |
| 297 | — | 1,0000E+00 | 1,60E-03 | — |
| 298 | — | 1,0000E+00 | 3,56E-03 | — |
| 299 | — | 8,0538E-01 | 7,59E-03 | — |
| 300 | — | 6,4863E-01 | 1,41E-02 | — |
| 301 | — | 5,2240E-01 | 2,40E-02 | — |
| 302 | — | 4,2073E-01 | 3,99E-02 | — |
| 303 | — | 3,3884E-01 | 5,95E-02 | — |
| 304 | — | 2,7290E-01 | 8,31E-02 | — |
| 305 | — | 2,1979E-01 | 1,16E-01 | — |
| 306 | — | 1,7701E-01 | 1,54E-01 | — |
| 307 | — | 1,4256E-01 | 1,90E-01 | — |
| 308 | — | 1,1482E-01 | 2,37E-01 | — |
| 309 | — | 9,2470E-02 | 2,77E-01 | — |
| 310 | — | 7,4473E-02 | 3,21E-01 | — |
| 311 | — | 5,9979E-02 | 3,70E-01 | — |
| 312 | — | 4,8306E-02 | 4,12E-01 | — |
| 313 | — | 3,8905E-02 | 4,67E-01 | — |
| 314 | — | 3,1333E-02 | 4,90E-01 | — |
| 315 | — | 2,5235E-02 | 5,32E-01 | — |
| 316 | — | 2,0324E-02 | 5,70E-01 | — |
| 317 | — | 1,6368E-02 | 5,98E-01 | — |
| 318 | — | 1,3183E-02 | 6,28E-01 | — |
| 319 | — | 1,0617E-02 | 6,58E-01 | — |
| 320 | 1,000E+00 | 8,5507E-03 | 6,92E-01 | 4,40E-03 |
| 321 | 9,750E-01 | 6,8865E-03 | 7,05E-01 | 7,70E-03 |
| 322 | 9,500E-01 | 5,5463E-03 | 7,34E-01 | 1,23E-02 |
| 323 | 9,250E-01 | 4,4668E-03 | 7,61E-01 | 1,89E-02 |
| 324 | 9,000E-01 | 3,5975E-03 | 7,64E-01 | 2,76E-02 |
| 325 | 8,750E-01 | 2,8973E-03 | 7,93E-01 | 3,90E-02 |

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**Table E.1** *(continued)*

| Wavelength nm | PPD action spectrum[17] (scalar) $P(\lambda)$ | Erythema action spectrum[4] (scalar) $E(\lambda)$ | UV-SSR source Relative irradiance (normalized to peak @ 355 nm) $S(\lambda)$ | UVA radiation source Relative irradiance (normalized to peak @ 364 nm) |
|---|---|---|---|---|
| 326 | 8,500E-01 | 2,3335E-03 | 8,06E-01 | 5,22E-02 |
| 327 | 8,250E-01 | 1,8793E-03 | 8,18E-01 | 6,91E-02 |
| 328 | 8,000E-01 | 1,5136E-03 | 8,40E-01 | 8,95E-02 |
| 329 | 7,750E-01 | 1,4125E-03 | 8,56E-01 | 1,10E-01 |
| 330 | 7,500E-01 | 1,3646E-03 | 8,61E-01 | 1,37E-01 |
| 331 | 7,250E-01 | 1,3183E-03 | 8,76E-01 | 1,65E-01 |
| 332 | 7,000E-01 | 1,2735E-03 | 9,02E-01 | 1,94E-01 |
| 333 | 6,750E-01 | 1,2303E-03 | 9,03E-01 | 2,22E-01 |
| 334 | 6,500E-01 | 1,1885E-03 | 9,02E-01 | 2,58E-01 |
| 335 | 6,250E-01 | 1,1482E-03 | 9,15E-01 | 2,90E-01 |
| 336 | 6,000E-01 | 1,1092E-03 | 9,24E-01 | 3,26E-01 |
| 337 | 5,750E-01 | 1,0715E-03 | 9,34E-01 | 3,62E-01 |
| 338 | 5,500E-01 | 1,0351E-03 | 9,34E-01 | 3,99E-01 |
| 339 | 5,250E-01 | 1,0000E-03 | 9,53E-01 | 4,34E-01 |
| 340 | 5,000E-01 | 9,6605E-04 | 9,50E-01 | 4,73E-01 |
| 341 | 4,938E-01 | 9,3325E-04 | 9,63E-01 | 5,10E-01 |
| 342 | 4,876E-01 | 9,0157E-04 | 9,67E-01 | 5,45E-01 |
| 343 | 4,814E-01 | 8,7096E-04 | 9,67E-01 | 5,80E-01 |
| 344 | 4,752E-01 | 8,4140E-04 | 9,76E-01 | 6,13E-01 |
| 345 | 4,690E-01 | 8,1283E-04 | 9,80E-01 | 6,48E-01 |
| 346 | 4,628E-01 | 7,8524E-04 | 9,88E-01 | 6,79E-01 |
| 347 | 4,566E-01 | 7,5858E-04 | 9,89E-01 | 7,08E-01 |
| 348 | 4,504E-01 | 7,3282E-04 | 9,94E-01 | 7,44E-01 |
| 349 | 4,442E-01 | 7,0795E-04 | 9,82E-01 | 7,66E-01 |
| 350 | 4,380E-01 | 6,8391E-04 | 9,99E-01 | 7,96E-01 |
| 351 | 4,318E-01 | 6,6069E-04 | 9,96E-01 | 8,22E-01 |
| 352 | 4,256E-01 | 6,3826E-04 | 9,94E-01 | 8,44E-01 |
| 353 | 4,194E-01 | 6,1660E-04 | 9,93E-01 | 8,62E-01 |
| 354 | 4,132E-01 | 5,9566E-04 | 9,97E-01 | 8,85E-01 |
| 355 | 4,070E-01 | 5,7544E-04 | 1,00E+00 | 8,97E-01 |
| 356 | 4,008E-01 | 5,5590E-04 | 9,89E-01 | 9,17E-01 |
| 357 | 3,946E-01 | 5,3703E-04 | 9,93E-01 | 9,35E-01 |
| 358 | 3,884E-01 | 5,1880E-04 | 9,82E-01 | 9,50E-01 |
| 359 | 3,822E-01 | 5,0119E-04 | 9,89E-01 | 9,65E-01 |
| 360 | 3,760E-01 | 4,8417E-04 | 9,91E-01 | 9,80E-01 |
| 361 | 3,698E-01 | 4,6774E-04 | 9,80E-01 | 9,87E-01 |
| 362 | 3,636E-01 | 4,5186E-04 | 9,78E-01 | 9,98E-01 |
| 363 | 3,574E-01 | 4,3652E-04 | 9,71E-01 | 9,95E-01 |
| 364 | 3,512E-01 | 4,2170E-04 | 9,54E-01 | 1,00E+00 |
| 365 | 3,450E-01 | 4,0738E-04 | 9,52E-01 | 1,00E+00 |
| 366 | 3,388E-01 | 3,9355E-04 | 9,25E-01 | 9,94E-01 |
| 367 | 3,326E-01 | 3,8019E-04 | 9,22E-01 | 9,88E-01 |
| 368 | 3,264E-01 | 3,6728E-04 | 8,98E-01 | 9,84E-01 |
| 369 | 3,202E-01 | 3,5481E-04 | 8,79E-01 | 9,74E-01 |
| 370 | 3,140E-01 | 3,4277E-04 | 8,58E-01 | 9,53E-01 |
| 371 | 3,078E-01 | 3,3113E-04 | 8,34E-01 | 9,33E-01 |

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**Table E.1** *(continued)*

| Wavelength nm | PPD action spectrum[17] (scalar) $P(\lambda)$ | Erythema action spectrum[4] (scalar) $E(\lambda)$ | UV-SSR source Relative irradiance (normalized to peak @ 355 nm) $S(\lambda)$ | UVA radiation source Relative irradiance (normalized to peak @ 364 nm) |
|---|---|---|---|---|
| 372 | 3,016E-01 | 3,1989E-04 | 8,10E-01 | 9,05E-01 |
| 373 | 2,954E-01 | 3,0903E-04 | 7,77E-01 | 8,82E-01 |
| 374 | 2,892E-01 | 2,9854E-04 | 7,50E-01 | 8,52E-01 |
| 375 | 2,830E-01 | 2,8840E-04 | 7,09E-01 | 8,23E-01 |
| 376 | 2,768E-01 | 2,7861E-04 | 6,83E-01 | 7,96E-01 |
| 377 | 2,706E-01 | 2,6915E-04 | 6,39E-01 | 7,66E-01 |
| 378 | 2,644E-01 | 2,6002E-04 | 6,00E-01 | 7,33E-01 |
| 379 | 2,582E-01 | 2,5119E-04 | 5,61E-01 | 6,92E-01 |
| 380 | 2,520E-01 | 2,4266E-04 | 5,11E-01 | 6,46E-01 |
| 381 | 2,458E-01 | 2,3442E-04 | 4,71E-01 | 6,05E-01 |
| 382 | 2,396E-01 | 2,2646E-04 | 4,28E-01 | 5,56E-01 |
| 383 | 2,334E-01 | 2,1878E-04 | 3,76E-01 | 5,06E-01 |
| 384 | 2,272E-01 | 2,1135E-04 | 3,28E-01 | 4,54E-01 |
| 385 | 2,210E-01 | 2,0417E-04 | 2,85E-01 | 4,03E-01 |
| 386 | 2,148E-01 | 1,9724E-04 | 2,45E-01 | 3,52E-01 |
| 387 | 2,086E-01 | 1,9055E-04 | 2,05E-01 | 3,06E-01 |
| 388 | 2,024E-01 | 1,8408E-04 | 1,72E-01 | 2,61E-01 |
| 389 | 1,962E-01 | 1,7783E-04 | 1,42E-01 | 2,19E-01 |
| 390 | 1,900E-01 | 1,7179E-04 | 1,14E-01 | 1,83E-01 |
| 391 | 1,838E-01 | 1,6596E-04 | 8,99E-02 | 1,49E-01 |
| 392 | 1,776E-01 | 1,6032E-04 | 6,95E-02 | 1,19E-01 |
| 393 | 1,714E-01 | 1,5488E-04 | 5,29E-02 | 9,35E-02 |
| 394 | 1,652E-01 | 1,4962E-04 | 3,83E-02 | 7,18E-02 |
| 395 | 1,590E-01 | 1,4454E-04 | 2,76E-02 | 5,43E-02 |
| 396 | 1,528E-01 | 1,3964E-04 | 1,98E-02 | 4,05E-02 |
| 397 | 1,466E-01 | 1,3490E-04 | 1,34E-02 | 2,96E-02 |
| 398 | 1,404E-01 | 1,3032E-04 | 9,09E-03 | 2,09E-02 |
| 399 | 1,342E-01 | 1,2589E-04 | 5,92E-03 | 1,44E-02 |
| 400 | 1,280E-01 | 1,2162E-04 | 3,99E-03 | 9,50E-03 |

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# Annex F
(normative)

# Statistics and calculations

## F.1 $SPF_{HDRSi}$ and UVA-$PF_{HDRSi}$

### F.1.1 General

The individual $SPF_{HDRSi}$ and UVA-$PF_{HDRSi}$ of each product on each subject are calculated according to 8.2 and 8.3.

### F.1.2 Calculation of the $SPF_{HDRS}$ and standard deviation of the $SPF_{HDRS}$

The SPF of the product is the arithmetical mean of the ln-transformed individual $SPF_{HDRSi}$ values obtained from the total number, *n*, of subjects used, expressed to one decimal point as shown in Formula (F.1):

$$SPF_{HDRS} = exp\left[\frac{\sum_{i=1}^{n} \ln(SPF_{HDRSi})}{n}\right] \quad \text{(F.1)}$$

Its standard deviation of the *ln*- transformed data is given by Formula (F.2):

$$\sigma_{SPF} = \sqrt{\frac{\left[\sum_{i=1}^{n} \ln(SPF_{HDRSi})^2\right] - \left[\frac{(\sum(\ln(SPF_{HDRSi}))^2}{n}\right]}{(n-1)}} \quad \text{(F.2)}$$

where

$\sigma_{SPF}$ is the standard deviation of the ln-transformed individual UVA-$PF_{HDRSi}$ values;

$n$ is the total number of valid test results;

$t$ is the two tail Student's $t$ -distribution 95 % quantile (two-sided $t$ -value for $p$=0,05), with $n$-1 degrees of freedom.

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### F.1.3 Calculation of the UVA-PF$_{HDRS}$ and standard deviation of the UVA-PF$_{HDRS}$

The UVA-PF$_{HDRS}$ of the product is the arithmetical mean of the ln-transformed individual UVA-PF$_{HDRSi}$ values obtained from the total number, *n*, of subjects used, expressed to one decimal point:

$$UVA-PF_{HDRS} = exp\left[\frac{\sum_{i=1}^{n} \ln(UVA-PF_{HDRSi})}{n}\right] \quad \text{(F.3)}$$

The standard deviation of the *ln*-transformed data is given by Formula (F.4):

$$\sigma_{UVA-PF} = \sqrt{\frac{\left[\sum_{i=1}^{n} \ln(UVA-PF_{HDRSi})^2\right] - \left[\frac{(\sum \ln(UVA-PF_{HDRSi}))^2}{n}\right]}{(n-1)}} \quad \text{(F.4)}$$

Calculate "*c*" as shown in Formula (F.5):

$$c = \left(\frac{t_{0,05,n-1} \times \sigma}{\sqrt{n}}\right) \leq 0{,}17 \quad \text{(F.5)}$$

where

$\sigma_{UVA-PF}$ is the standard deviation of the ln-transformed individual UVA-PF$_{HDRSi}$ values;

n is the total number of valid test results;

$t$ is the two tail Student's $t$ -distribution 95 % quantile (two-sided $t$ -value for $p$=0,05), with $n$-1 degrees of freedom.

**Table F.1 — Two-sided student-*t* distribution table**

| *n* | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *t* value | 2,262 | 2,228 | 2,201 | 2,179 | 2,160 | 2,145 | 2,131 | 2,120 | 2,110 | 2,101 | 2,093 |

NOTE For spreadsheet calculation, the *t* value can be modelled by $t = 2{,}03 + \frac{12{,}7}{n^{1{,}75}}$ ( *for* $n \geq 4$ ).

If the calculated provisional c is greater than 0,17 then testing of the product shall continue on additional subjects until the c value is less than or equal to 0,17.

## F.2 Predicted number of subjects, *n**

If the c value on the SPF$_{HDRS}$ or UVA-PF$_{HDRS}$ is greater than 0,17 of SPF$_{n'}$ then the predicted likely total number of subjects, *n**, necessary to meet the statistical criterion can be estimated according to Formula (F.5) and rounded up to the nearest integer, as shown in Formula (F.6):

$$n^* = \left(\frac{t_{n'} \times \text{stdev}_n}{0{,}17}\right)^2 \quad \text{(F.6)}$$

where

$t_{n'}$ is the *t* statistic from Student-*t* table or Formula (F.1), with *n'* results;

stdev' is the best estimate of population standard deviation (i.e. from the n results).

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## F.3 Rejected data

Up to 5 UVA-$PF_{HDRSi}$ results may be rejected for a test based on calculation of the difference of the ln(UVA-$PF_{HDRSi}$) value for a subject from the logarithm of the geometric mean. If the ln(UVA-$PF_{HDRSi}$ ) is more than 2 standard deviations from the mean ln(UVA-$PF_{HDRS}$) of all the subjects, then those values may be rejected and deleted from calculation of the geometric mean of the UVA-$PF_{HDRS}$ and from the calculations of the c value see [Formula (34)].

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