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Cosmetics — Sun protection test methods — Review and evaluation of methods to assess the photoprotection of sun protection products

Cosmétiques — Méthodes d'essai de protection solaire — Revue systématique et évaluation des méthodes usuelles de mesure de la protection solaire fournie par les produits de protection solaire

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 26369 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

Cosmetics — Sun protection test methods — Review and evaluation of methods to assess the photoprotection of sun protection products

1 Scope

This Technical Report reviews and evaluates the methods which are currently used to assess, for regulatory or self-regulatory purposes, the photoprotection of sun protection products applied on the human body.

It is applicable to SPF and UVA protection, and both *in vivo* and *in vitro* methods.

This Technical Report does not include the aspects of labelling in a wide sense.

2 Terms and definitions

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

2.1
ultraviolet
UV
electromagnetic radiation with a wavelength shorter than that of visible light, but longer than soft X-rays and so named because the spectrum consists of electromagnetic waves with frequencies higher than those that humans identify as the color violet (purple)

NOTE In this Technical Report the following wavelengths are considered: UVA: 320 nm to 400 nm; UVB: 290 nm to 320 nm.

2.2
sun protection factor
SPF
〈of a sunscreen〉 laboratory measurement to assess the effectiveness of sunscreens against UV erythema

NOTE 1 The higher the SPF, the more protection a sunscreen offers.

NOTE 2 The SPF is a ratio between the ultraviolet dose required to produce minimal erythema reaction (redness) in protected skin (skin with sunscreen) compared to unprotected skin (skin without any sunscreen).

3 Principle

This systematic review and evaluation of the methods are conducted for development of those ISO Standards which assess the photoprotection provided by sun protection products applied on the human body. It will serve as a technical/scientific framework to identify the most suitable methods for standardization.

The key parameters and elements are listed in Tables 1 to 6 in order to enable an easy comparison of the methods.

4 Sun protection test methods

4.1 SPF *in vivo*

The SPF *in vivo* methods currently used are given in Table 1.

4.2 SPF *in vitro*

The SPF *in vitro* methods based on transmittance evolved from the Diffey proposal and new methods based on measurement of free radicals or use of skin biopsies are given in Tables 2 and 3. The relevant parameters of methods based on transmittance are given in Table 4.

4.3 UVA *in vivo*

The methods reviewed by ISO/TC 217 are given in Tables 5 and 6.

Table 1 — SPF *in vivo* methods currently used

Parameters	International 2006 [1] [a]	FDA 1999 [2]	Australia 1998 [3]
UV definition (UVB, UVA)	UVB: 290 nm to 320 nm UVA: 320 nm to 400 nm UVAII 320 nm to 340 nm UVAI 340 nm to 400 nm	UVB: 290 nm to 320 nm UVA: 320 nm to 400 nm	Solar UVR: 290 nm to 400 nm UVB: 290 nm to 320 nm UVA: 320 nm to 400 nm
Volunteers selection			
Ethical considerations	Helsinki, national regulations, medical status	Not defined	Medical questionnaire
Age limitation	Yes, excluded below age of consent	Not defined	Not defined
Informed consent	Yes, with signatures	Yes	Yes
Exclusion criteria	Pregnant, lactating women Photosensitizing medication Dermatological problems, history of abnormal response to sun Tanning beds No sun damage, marks, blemishes or nevi	Skin disease, abnormal responses to UV, phototoxic or photo-allergic response, medication (topical or systemic) known to produce abnormal sunlight responses Sunburn, scars, active dermal lesions and uneven skin tones on the areas to be tested	Abnormal response to medication, UV radiation, allergies to topically applied cosmetics Phototoxic or photosensitizing medication
Test subjects			
Skin phototype and skin colour	Fitzpatrick skin type (s) I, II, III or skin colour (ITA° value > 28° very fair, fair-skin and intermediate skin colour) and untanned on the test area	Phototypes I, II, III Fair skin colour	Phototypes I, II, III Fair skin colour
Test area	Back, between scapula line and waist Skeletal protrusions and extreme areas of curvature should be avoided	The back between the beltline and the shoulder blade (scapulae) and lateral to the midline	Back, clean dry skin, without any suntan or sunburn, active dermal lesions, excessive hair, uneven skin tones
Time, interval between two tests	No less than 2 months, sufficient interval for reversal of skin tanning until the site is clear	Not defined	Not defined

[a] The numbers in brackets refer to the Bibliographic references.

Table 1 (*continued*)

Parameters	International 2006 [1]	FDA 1999 [2]	Australia 1998 [3]
Source of UV radiation			
Solar simulator Filtration	Continuous emission spectrum with no gaps or extreme peaks Stable output Xenon Arc lamp recommended with dichroic mirror and WG320 + UG11/1 mm	Continuous emission spectrum 290 nm to 400 nm, similar to sunlight at sea level, 10° zenith angle < 1 % energy < 290 nm ⩽ 5 % energy > 400 nm Stable output after appropriate warm-up time	Xenon arc is preferred No peak in UVB; continuation in the UVA WG320 filter, dichroic mirror or heat absorbing filter
Acceptance limits %RCEE UVA2/UVA1	% RCEE defined in different bands W.L. range: RCEE%: ⩽ 290 nm < 0,1 % 290 nm to 300 nm 1,0 % to 8,0 % 290 nm to 310 nm 49,0 % to 65,0 % 290 nm to 320 nm 85,0 % to 90,0 % 290 nm to 330 nm 91,5 % to 95,5 % 290 nm to 340 nm 94 % to 97 % 290 nm to 400 nm 99,9 % to 100 % UVAII ⩾ 20 % UVAI ⩾ 60 % of the total UV irradiance to ensure that appropriate amounts of UVA radiation are included	Not defined	< 0,01 % < 290 nm “Red” & “blue” acceptance limits (± 4 nm): graph
Irradiance uniformity	As uniform as possible, no more than 10 % for large beam	Within 10 %	Uniformity of spot appearance (no half-moon shape)
Total irradiance	Lower than 160 mW/cm^2	Not defined	Not defined

Table 1 (*continued*)

Parameters	International 2006 [1]	FDA 1999 [2]	Australia 1998 [3]
(Spectro) radiometry			
Checking of UV source emission spectrum by spectroradiometry	Spectroradiometric check at least once a year by an independent expert or each time a significant physical (optical) component is changed Colipa guidelines “monitoring of UV light sources”	Measured periodically with an accurately-calibrated spectroradiometer system or equivalent instrument	Not defined
Radiometry	Before exposure of each test site, checking with a calibrated radiometer	Not defined	Before and after each test series, variations kept to a minimum; UV monitor response restricted to UV range recommended
Test site description			
Mode of delineation	Skin marker and/or template made from a non-absorbent material	Outlined with ink	Means which do not interfere with the test or harm the subject
Application surface	Between 30 cm^2 and 60 cm^2	Minimum 50 cm^2, e.g. 5×10 cm	Minimum of 30 cm^2, maximum not defined
Space between test sites	Minimum distance of 1 cm	Not defined	Not defined
Test site pre-treatment	Possible with dry cotton pad	Not defined	Warm water and toweling

Table 1 (*continued*)

Parameters	International 2006 [1]	FDA 1999 [2]	Australia 1998 [3]
Product quantity and application			
Quantity applied	2 mg/cm^2 ± 2,5 % Sensitivity of the balance, at least 0,1 mg Method of weighing by loss	2 mg/cm^2	2 ± 0,1 mg/cm^2
Position of volunteers	Position in a way to ensure that the complete amount of test product is evenly applied and remains on skin, seated or prone position, excepted for powder products tested only in prone position	No indication, same position as delineation?	Not defined
Mode of delivery	Lotion, liquid, milk, cream, spray: syringe/pipette droplets on the whole test site Spreading time in the range of 20 s to 50 s, low pressure of application Powders: spatula, finger, Applicator puff. + water CD-ROM for application procedure training for emulsions and powders	Volumetric syringe Pastes and ointments shall be weighed	Weighing boat or weighed syringe Spreading according to the sponsor instructions Product film lightly and evenly applied with uniform thickness Validation of the method by the test facility
Room temperature, air conditioning	Room temperature between 18 °C and 26 °C	Not defined	Air-conditioned, 20 °C and 25 °C
Drying time	15 min to 30 min	At least 15 min	At least 15 min
Finger cot	If appropriate	Yes	Yes recommended, other appropriate means may be used
Randomization	Yes	Yes	Not defined
Blinded application	Not defined	Yes	Not defined

Table 1 (*continued*)

Parameters	International 2006 [1]	FDA 1999 [2]	Australia 1998 [3]
UV exposures			
Position of volunteers	Position shall be the same for product applications, for UV exposure and for MED assessment	Upright or prone position	Seated or prone position
Exposure sub-site surface	At least 0,5 cm^2, recommended 1 cm^2 Distance between sub-sites at least 0.8 cm	$\geqslant$ 1 cm^2	Approximately 1 cm^2 Distance between sub-sites at least 1 cm and 1 cm from any edge of the test site
Number of sub-sites	Minimum of 5 for MEDu and MEDp	5 for the unprotected area 7 for the protected areas	Minimum of 5 for MEDu and MEDp
Provisional individual MEDu	The day prior to the product testing, determined again on the same day as the test sunscreens or estimation of the MEDu by colorimetry (ITA°)	Usually the day prior to testing a product Determined again on the same day as the test sunscreens	Prediction by experienced tester or provisional MEDu the day before
Progression of UV dose	Geometric progression of either ($1{,}25^n$) or ($1{,}12^n$) for the unprotected area. For the protected areas, a minimum of five sub-sites centered on the expected SPF $\times$ MEDu shall be exposed with a geometric progression of either ($1{,}25^n$) or ($1{,}12^n$) A maximum progression of 1,12 must be used for expected SPF > 25	Geometric progression ($1{,}25^n$) for the unprotected area For the protected areas geometric series of five exposure where the middle exposure is placed to yield the expected SPF plus two other exposures placed around the middle exposure According to the expected SPF (X) SPF < 8: 0,64, 0,8, 0,9, 1,1 .1, 1.25, 1,56X SPF 8 to 15: 0,69, .83, 0,91, 1, 1,09, 1,2, 1.44X SPF > 15: 0,76, 0,87, 0,93,1, 1,07,1,15, 1,32X	Unprotected MED re-determined with a dose range of ca 0,6 to 1,5 provisional MEDu For protected skin the dose range is multiplied by the expected SPF Increments between sub-sites no more than 1,25 $\leqslant$ 1.118 for SPF $\geqslant$ 25
Randomized UV exposure	Not defined	Yes if only one product is being tested	Not defined
Product removal	Products may be removed gently using a cotton pad and mild lotion	Not defined	Not defined
Ambient conditions	18 °C to 26 °C	Not defined	Not defined

Table 1 (*continued*)

Parameters	International 2006 [1]	FDA 1999 [2]	Australia 1998 [3]
Response description			
Definition of response	The MED is the lowest UV dose that produces the first perceptible unambiguous erythema with defined borders appearing over most of the field, 16 h to 24 h after UV exposure	The MED is the quantity of erythema-effective energy required to produce the first perceptible unambiguous redness reaction with clearly defined borders at 22 h to 24 h post-exposure	Minimum quantity of radiant energy to produce a perceptible reddening of human skin. The first subsite to show a minimal redness perceptible to the eye, (with normal vision)
Units	J/m^2 or mJ/cm^2 or MED units or time (seconds) if the flux is constant throughout the test	J/m^2	Energy or time (if flux constant)
Time of assessment	16 h to 24 h post-exposure MEDu and MEDp on same day	22 h to 24 h post-exposure	16 h to 24 h post-exposure
Conditions of observation	Sufficient and uniform illumination: at least 450 lx	Illumination: tungsten or warm white fluorescent light bulb 450 lx to 550 lx (at the test site)	Full daylight, or a tungsten filament light providing adequate illumination; matt neutral wall colours
Position of volunteers	Same position used for the UV exposure	Same position used for the UV exposure	Seated or prone position
Biological endpoint	Erythema	Erythema	Erythema
Evaluator	Normal colour and acuity vision different from the person who applied the sunscreen or administered the UV doses	Different from the person who applied the sunscreen or administered the UV doses	Normal vision, colour vision checked
Data rejection criteria on individual test site	All sites visible or no site visible, responses on the treated sites randomly absent Rejection of the subject if MEDu or MEDp of standard product not determined	All sites visible or no site visible, responses on the treated sites randomly absent (indication of uneven spreading)	If the result obtained using the reference product on a subject varies by > 25 % of the average value of that test series the results of the subject are excluded If more than two subjects return SPFs for the test product which vary by > 25 % of the mean SPF, a new sample should obtained

Table 1 (*continued*)

Parameters	International 2006 [1]	FDA 1999 [2]	Australia 1998 [3]
Reference sunscreen formulations			
Reference sunscreen formulations used	Expected SPF < SPF 20 P2 or P3 or P7 Expected SPF ⩾ SPF 20 P2 or P3 The same has to be tested on every subject in the same series of at least ten subjects	Homosalate 8 % SPF 4,47 (S.D.: 1,279)	On each test subject either: *Homosalate 8 % SPF 4,47 *P3 SPF 15,5 or values derived from the laboratory's historical record on its test results
Acceptance limits (ranges)	Mean SPF ± 2 SE P2: 16,6 (14,2 to 19,0) P3: 16,2 (13,8 to 18,7) P7: 5,1 (4,4 to 5,9)	The SPF must fall within the range 4,47 ± 1,279 and the 95 % CI of the mean SPF must contain the value four	* Homosalate 8 % SPF ± 2 SD ∈ [4 to 5] * P3 SPF ± 2 SD ∈ [12.5 to 18.5]
Calculation and results			
Number of test subjects	Minimum of ten, maximum of twenty five	No more than twenty five, at least twenty valid data	Minimum of ten, maximum not defined
Calculation of mean SPF	Arithmetic mean, minimum of ten valid results and a maximum of twenty shall be used for the calculation of SPF A maximum of five results may be excluded from the calculation of the mean SPF; each exclusion has to be justified	Mean, SD, t value at 5 % with $n - 1$, SEM	Arithmetical mean, expressed to one decimal point
Statistical criterion	95 % confidence interval should fall within the range of ± 17 % of the mean SPF A minimum of ten valid results is only sufficient if the criterion is fulfilled, otherwise the number of subjects is increased stepwise from ten until the statistical criterion is met up to a maximum of twenty valid results	No	SEM ⩽ 7 % of mean SPF for valid result

Table 1 (*continued*)

Parameters	Canada 2002 [4]	Korea 2004 [5]	China 2002 [6]
UV definition (UVB, UVA)	Not defined	UVB: 290 nm to 320 nm UVA: 320 nm to 400 nm	UVB: 290 nm to 320 nm UVA: 320 nm to 400 nm
Selection of volunteers			
Ethical considerations	Medical history	Medical status checked	Not defined
Age limitation	Not defined	18 y to 60 y	18 y to 60 y
Informed consent	Not defined	Not defined	Not defined
Exclusion criteria	Standard criteria	Standard criteria	Standard criteria
Test subjects			
Skin phototype	Burns readily, tans slowly	I, II, III Example of questionnaire is given	Individuals with skin type I, II, III sensitive to the sunlight or UV exposure, burns easily and tans minimally
Skin colour	Light	Not defined (uniform colour without pigmentation)	Not defined
Test area	The back between the waist and the shoulder blades and to either side of the mid-line	The back without any skin damage or extreme hair	Back or other body site
Time, interval between two tests	Not defined	Not defined	Not defined
Source of UV radiation			
Solar simulator Filtration	Sun or solar simulator Solar simulator is preferred and xenon arc is recommended with a WG-320/1 mm filter + dichroic mirror + IR filter	Light source similar to the sunlight Xenon arc with a continuous emission spectrum with no gap or extreme peaks, or similar devices Stable intensity	Only xenon arc Continuous emission of UV from 290 nm to 400 nm < 290 nm < 1 % > 400 nm < 5 % Constant output
Acceptance limits %RCEE UVA2/UVA1	Not defined	Not defined λ < 290 nm should be removed	Not defined
Irradiance uniformity	Not defined	Not defined	Within 10 %
Total irradiance	Not defined	Not defined	Not defined

Table 1 (*continued*)

Parameters	Canada 2002 [4]	Korea 2004 [5]	China 2002 [6]
Spectroradiometry			
Checking of UV source emission spectrum by spectroradiometry	Calibration and periodic checking	Not defined	Not defined
Radiometry	Robertson Berger meter Calibration is needed, able to measure the output to within 1 % of the absolute value	Not defined	Not defined
Test site description			
Mode of delineation	Suitable and lasting marker	Not defined, however two examples of irradiation area demarcation are given	Not defined
Application surface	Approximately 50 cm^2	Minimum 24 cm^2 or larger	Minimum 30 cm^2
Space between test sites	Not defined	Not defined	Not defined
Test site pre-treatment	Not defined	Clean and dry	Not defined
Position of volunteers	Prone or upright, the same as for the exposure	Not defined	Not defined
Product quantity and application			
Quantity applied	2 mg/cm^2 or 2 $\mu l/cm^2$	2,0 mg/cm^2 or 2,0 $\mu l/cm^2$	2 mg/cm^2
Position of volunteers	No indication	No indication	No indication
Mode of delivery	No indication	No indication	Weighing, application as uniformly as possible
Room temperature, air conditioning	No indication	No indication	No indication
Drying time	At least 15 min	15 min	15 min
Finger cot	No indication	Rubber thimble	Emulsion glove
Randomization	Not specified	Not defined	Not defined
Blinded application	Not specified	Not defined	Not defined

Table 1 (*continued*)

Parameters	Canada 2002 [4]	Korea 2004 [5]	China 2002 [6]
UV exposures			
Position of volunteers	Prone or upright position	Comfortable position	Bent forward position or recumbent prostrate position
Exposure sub-site surface	At least 1 cm^2	0,5 cm^2 or larger, 1 cm between each sub-site, 0,5 cm from the borders of the site	Not defined
Number of sub-sites	Five for the unprotected area and for the protected areas	Six for the unprotected and protected areas	Five for the unprotected area Five to seven for the protected areas
Provisional individual MEDu	Predetermination of the unprotected MED the day before the testing phase	Expected MED is determined based on the skin type the day before	Predetermination of the unprotected MED 24 h prior to the testing phase
MEDu on the same day as the tested products	Determined again on the same day as the MED with test sunscreens	No	Determined again on the same day as the MED with test sunscreens
Progression of UV dose	Geometric progression ($1,25^n$)	25 % or lower when the expected SPF < 20 15 % when the SPF is ⩾ 20 and < 30 10 % or lower when the SPF is ⩾ 30	Geometric progression ($1,25^n$) for the unprotected area When the expected SPF < 15 the dose increase rate is 25 %: 0,64, 0,8, 0,9, 1,00,1 .1, 1,25, 1,56X When the expected SPF >15, the dose increase rate is 15 %: 0,76, 0,87, 0,93, 1,00, 1,07, 1,15, 1,32X Two doses are added around the 1,00X dose X (expected SPF × MEDu)
Randomized UV exposure	Not defined	Not defined	Not defined
Product removal	Not defined	Not defined	Not defined
Ambient conditions	Not defined	Not defined	Not defined

Table 1 (*continued*)

Parameters	Canada 2002 [4]	Korea 2004 [5]	China 2002 [6]
Response description			
Definition of response	The amount of solar radiation or solar simulated radiation needed to produce a barely noticeable erythema (redness) on human skin	The minimum erythema dose is defined as the lowest dose that produces the first perceptible unambiguous erythema with defined borders appearing over most of the field of UV exposure, 16 h to 24 h after UV exposure	The smallest UV dose (Joules per square metre) or the shortest time (seconds) required to produce defined skin erythema in the test site and its boundaries
Units	Using constant irradiation conditions MED is proportional to the duration of exposure (seconds)	Not defined	Joules per square metre or seconds
Time of assessment	16 h to 24 h post exposure	16 h to 24 h post exposure	24 h post exposure
Conditions of observation (light)	Consistent conditions of illumination, background colour	Sufficient light source	Not defined
Position of volunteers	Not defined	Not defined	Not defined
Biological endpoint	Erythema	Erythema	Erythema
Evaluator	Human eye or reflectometer, at least one evaluator	By two or more trained evaluators MEDu and MEDp shall be determined by the same person in same conditions	No indication
Data rejection criteria	All sub-sites visible or no sub-site visible, responses randomly absent	Not defined	All sites visible or no site visible, responses randomly absent

Table 1 (*continued*)

Parameters	Canada 2002 [4]	Korea 2004 [5]	China 2002 [6]
Reference sunscreen formulations			
Reference sunscreen formulations used	Homosalate 8 % or for high SPF values a standard with a comparably high SPF should be used	Homosalate 8 % for SPF < 20 High SPF standard for SPF ⩾ 20	Homosalate 8 % SPF 4,47 (S.D.: 1,279)
Acceptance limits (ranges)	4,11 ± 0,103	Homosalate 8 % The SPF must fall within the range 4,47 ± 1,279 High SPF standard The SPF must fall within the range 15,5 ± 3,0	The SPF must fall within the range 4,47 ± 1,279 and the 95 % CI of the mean SPF must contain the value four
Calculation and results			
Number of test subjects	Minimum of twenty, males and females	⩾ 10; maximum number not defined	> 10 (minimum 11)
Calculation of mean SPF	Arithmetic mean, SE	Arithmetic mean 95 % confidence interval	Arithmetic Mean, SD, SE SPF is the integer part
Statistical criterion	SE should be ⩽ 5 % of the mean	95 % CI should be within the range of ± 20 % of the mean; if the statistical criteria is not met, the number of subjects is increased gradually or reset the testing conditions and then test repeatedly to reach the criterion	SE must range within 10 % of the arithmetic mean, otherwise more subjects should be added until the final result matches the criteria

Table 2 — Methods based on spectral transmittance (Diffey)

Method Parameters	I [18]	II	III [19]	IV [20]	VI [22]
Spectra analyser					
Spectra analyser system	Optronics 742, single monochromator with bandwidth of 1,5 nm	Optometrics SPF-290S, single monochromator, collection of transmitted and most of the diffracted light by an integrating sphere	Sunscreen tester equipped with a sensor having a spectral sensitivity adjusted to $s(\lambda)_{er}$ for determining SPF and a spectral radiometer 320 nm to 400 nm for determining PF's in UVA	Four different spectra analysers (OL754, Uvikon 933, Labsphere UV1000S and sunscreen tester), double or single monochromator, dual diode array and integrating detector, integrating sphere behind or before sample – scattering dome	Labsphere UV1000S, dual diode array, integrating sphere d/0° geometry
Instrument calibration	Low pressure mercury discharge lamp at 253,7 and 435,8 nm	Neutral density filters (ND 1,0 and ND 1,5) should be scanned to check the optical performance of the system. The observed data should agree with the supplied data by optometrics within 20 %	N/A	PMMA standard plate	PMMA standard plate
Instrument sensitivity	N/A	N/A	N/A	N/A	N/A
UV source for spectral measurement	Unfiltered 75 W xenon arc lamp, continuous	125 W CW xenon arc lamp, continuous	Xenon lamp with appropriate filters excluding VIS and IR, continuous	Xenon lamp depending instrument continuous or flash	Pulsed xenon Lamp 10 W, 3 flashes per second
Sample beam diameter	10 mm	10 mm, focal length 74 mm, resolution 1,66 mm with 3 µm slit	12 mm	Depending on appliance	10 mm

Table 2 (*continued*)

Method Parameters	I [18]	II	III [19]	IV [20]	VI [22]
Measurement interval	5 nm	1 nm, 2 nm or 5 nm	1 nm	1 nm	1 nm
Wavelength accuracy		— System specifications ± 0,2 % — Using Transpore™ tape and the light level at approximately 3 850 counts, is the system calibrated — The measured wavelength should be between 355 nm and 375 nm — Maximum voltage should be observed between 355 nm and 375 nm and should be at least 8,5 V — The y-axis value should be at least 0,8 V at 290 nm	Not specified		± 2 nm + 1 holmium oxide filter
Range of measurement	290 nm to 400 nm	290 nm to 400 nm	290 nm $\leqslant \lambda \leqslant$ 400 nm for SPF sensor 320 nm $\leqslant \lambda \leqslant$ 400 nm for PF's in UVA	290 nm to 400 nm	290 nm to 400 nm
Measurement scale calibration	N/A	Neutral densities (ND), ND 1,0 and ND 1,5	N/A	Standard PMMA plate, 3 electrolytically perforated screens	Standard PMMA plate, 3 electrolytically perforated screens
Scan time (one spot)	N/A	N/A	N/A	From seconds to minutes depending on spectra-analyser	1 s
Environmental laboratory conditions	22 °C to 24 °C	Temperature range 22 °C to 24 °C, relative humidity range 30 % to 40 %	Regular laboratory conditions, not controlled	22 °C to 24 °C	22 °C to 24 °C

Table 2 (*continued*)

Method Parameters	I [18]	II	III [19]	IV [20]	VI [22]
Substrate					
Plate (substrate) definition	Transpore™ tape	Quartz sample plate covered with Transpore™ surgical tape	PMMA roughened without UV-absorber	PMMA roughened	PMMA roughened, frost
Plate size	40 mm × 40 mm or 75 mm × 25 mm	Plate 80 mm × 120 mm, Transpore™ surgical tape 75 mm ×120 mm	75 mm × 25 mm × 1 mm	50 mm × 50 mm or 75 mm × 25 mm	50 mm × 50 mm × 2,5 mm and 50 mm × 50 mm × 3 mm
Plate roughness	N/A	N/A	DGK standard, checked by BDF	Sa close to 5 µm to be checked by the user	1,9 µm to 6,9 µm (different samples)
Plate cleaning	N/A	Using clean piece of Transpore™ tape for each sample	No cleaning, new plates used for every experiment	Ethanol	Ethanol
UV source for sample exposure					
UV source for sample exposure	Xenon lamp, continuous	Xenon lamp, continuous	Xenon lamp, continuous, with appropriate filters	Xenon lamp, depending on instrument – continuous or flash	Xenon lamp, flash
UV source spectra for sample exposure	N/A	Colour compensating filter	According to Int. SPF Test Method (1994)	N/A	N/A
Total irradiance for sample exposure	N/A	N/A	Sample is permanently irradiated during the measurement of SPF and PF's in UVA up to 1 MED behind sample for checking photo aging of the sunscreen	N/A	N/A
Doses of UV exposure of the sample	N/A	N/A	Permanent measurement of SPF and PFs in UVA up to 1 MED behind the sample as used for *in vivo* SPF testing	N/A	N/A
Total UV (pre-) exposure dose	N/A	N/A	10 × irradiance of solar radiation in UV as used for *in vivo* SPF testing	N/A	N/A

Table 2 (*continued*)

Method Parameters	I [18]	II	III [19]	IV [20]	VI [22]
Spectra radiometry					
Checking of UV source emission spectrum by spectra radiometry	N/A	N/A	Permanently checked automatically	N/A	N/A
Radiometry for UV dose application	N/A	N/A	Permanently checked automatically	N/A	N/A
Product application					
Application mode	Gloved finger	Gloved finger	Saturated glove	Saturated glove	Saturated glove
Quantity applied	24 µl/cm^2 or 32 µl/cm^2 to achieve 1,5 µl/cm^2 or 2 µl/cm^2 (depending on products)	135 µl corresponding to 134,5 mg to 139,9 mg of sample, 1,5 mg/cm^2	1 mg/cm^2 (cream, milk), 0,5 mg/cm^2 (oil, spray)	1,2 mg/cm^2	1 mg/cm^2
Weighting the applied quantity	Supposes before and after deposition	After the sample is applied the empty syringe is weighed to determine the weight of applied sample	PMMA plate weighted before and after applying sample	Before and after deposition, pipette weighted	Before and after deposition, pipette weighted
Pressure of the finger when applying the product	N/A	Light pressure	Medium	Medium	Medium
Deposition tool	Pipette for spotting	Pipette for spotting	No	Pipette for spotting	Pipette for spotting
Way of spreading	Circular light rubbing motion	Circular light rubbing motion	Finger	Finger	Light strokes followed by rubbing using stronger pressure
Duration of spreading	About 10 s	Range: 10 s to 15 s	Some minutes	About 60 s	About 60 s
Drying time	0 min	0 min	15 min	15 min	15 min
Conditions of stocking plates during drying time	N/A	N/A	N/A	Dark room, room temperature	Dark room, room temperature

Table 2 (*continued*)

Method Parameters	I [18]	II	III [19]	IV [20]	VI [22]
Measurement					
Number of plates per products	3	1	3	5	3
Number of spectral measurements per plate	1	12	3	1 to 9 depending on spectra-analyser	9
Measurement of the blank plates	Measurement of Transpore™ tape without sunscreen applied	Only at beginning of a sequence of measurements due to the use of Transpore™ tape	Permanently checked automatically	1 PMMA plate with transparent glycerine	1 PMMA plate with transparent glycerine
Noise measurement (black)	N/A	N/A	Automatically checked prior to every experiment	N/A	N/A
Calculation and results					
Calculation	SPF, weighting of transmission data	SPF, weighting of transmission data	Direct measurement of SPF as a function of irradiation time. Calculation of a mean value of SPF during the irradiation time which includes photo aging of the sunscreen. For PFs in UVA: measurement of spectral transmittance depending on irradiation time and calculation of PFs including change of PFs (photo aging)	SPF, weighting of transmission data and direct measurement of erythema effective irradiance	SPF, UVAPF, UVA/UVB ratio, critical wavelength, weighting of transmission data
Sources spectra	Midway midsummer sunlight from southern Europe 40°N solar zenith angle 20° ozone layer thickness 0,305 cm	Midway midsummer sunlight from southern Europe 40°N solar zenith angle 20° ozone layer thickness 0,305 cm	Sun simulation according to Colipa specifications	Midway midsummer sunlight from southern Europe 40°N solar zenith angle 20° ozone layer thickness, 0,305 cm	Midway midsummer sunlight from southern Europe 40°N solar zenith angle 20° ozone layer thickness 0,305 cm
Action spectra	Erythema action spectrum CIE (1987)	Erythema action spectrum CIE (1987)	$s(\lambda)_{er}$ according to CIE, $s(\lambda)_{PPD}$ according to DIN 67502	Erythema action spectrum CIE (1987)	Erythema action spectrum CIE (1987) and PPD action spectrum
Result	*In vitro* SPF	SPF, UVA/UVB ratio, average UVA PF, erythemal UVA PF and critical wavelength, graph of MPF versus wavelength	*In vitro* SPF depending on irradiation (photostability), PFs in UVA depending on irradiation (photostability)	*In vitro* SPF	Roughness: strong influence on absolute indices like SPF or UVAPF, moderate influence on relative indices

Table 3 — New methods

Method Parameters	V [21]	VII [23]
Spectra analyser		
Spectra analyser system	ESR spectrophotometer, ESR X-Band (ZWG, Germany), microwave frequency: 9,52 GHz, microwave power: 20 mW, modulation frequency: 100 KHz, modulation amplitude: 0,2 mT, magnetic field: 20 mT	Lambda 5 spectrometer, Perkin Elmer, collection of transmitted light by an integrating sphere
Instrument calibration	Mn + reference marker	N/A
Instrument sensitivity	Five density filters to attenuate the UV irradiance (2, 5, 10, 20 and 30)	N/A
UV source for spectral measurement	N/A	N/A
Sample beam diameter	N/A	N/A
Measurement interval	N/A	N/A
Wavelength accuracy	N/A	N/A
Range of measurement	N/A	240 nm to 500 nm
Measurement scale calibration	Neutral density filters	N/A
Scan time (one spot)	60 s	N/A
Environmental laboratory conditions	22 °C to 24 °C	N/A
Substrate		
Plate (substrate) definition	Human skin biopsies impregnated with spin trap PBN (0.4M)	Adhesive tape (Tesa film No. 5529)
Plate size	10 mm × 10 mm reduced to diameter Φ = 6 mm in the sample holder ESR	60 mm × 19 mm
Plate roughness	N/A	N/A
Plate cleaning	N/A	N/A

Table 3 (*continued*)

Method Parameters	V [21]	VII [23]
UV source for sample exposure		
UV source for sample exposure	Xenon lamp	N/A
UV source spectra for sample exposure	PCR Krockmann replaced recently by Oriel 1 000 W with filter WG320	N/A
Total irradiance for sample exposure	17,9 mW/cm^2 (UVB+UVA)	N/A
Doses of UV exposure of the sample	0,5 J/cm^2 to 10,7 J/cm^2	N/A
Total UV (pre-) exposure dose	N/A	N/A
Spectra radiometry		
Checking of UV source emission spectrum by spectra radiometry	Yes	N/A
Radiometry for UV dose application	Yes	N/A
Product application		
Application mode	Saturated glove	Fingers
Quantity applied	2 mg/cm^2	2 mg/cm^2 on to a skin area of 80 cm^2
Weighing the applied quantity	Before and after deposition pipette weighed	N/A
Pressure of the finger when applying the product	Moderate	Light pressure
Deposition tool	Pipette 1ml	Fingers
Way of spreading	Finger	N/A
Duration of spreading	60 s	N/A
Waiting drying time	10 min	One hour before tape stripping is performed, measurement 1 min after removal
Conditions of stocking plates during drying time	Dark room, room temperature	N/A

Table 3 (*continued*)

Method Parameters	V [21]	VII [23]
Measurement		
Number of plates per products	Four biopsies	Ten strips per product per volunteer
Number of spectral measurements per plate	One	One
Measurement of the blank plates	Two biopsies	One measurement per volunteer
Noise measurement (black)	N/A	N/A
Calculation and results		
Calculation	Dose ratio skin protected and unprotected for a same amount of free radicals	SPF, weighting of transmission data
Sources spectra	N/A	N/A
Action spectra	N/A	N/A
Result	Global protection factor (UVA + UVB)	SPF

Table 4 — Relevant parameters of methods based on transmittance

Publication	Authors	Date	Spectro analyser	Sample beam diameter	Interval measurement	Substrate	Roughness	Quantity applied	UV source for analyser	Total UV pre exposure dose	Product application
I) A new substrate to measure sunscreen protection factors	B Diffey J Robson	1989	Any radiation source providing continual spectral power between 290 nm and 400 nm (Optronic 742)	10 mm	5 nm	Transpore™ tape	Unknown and not regular	1,5 mg/cm^2 to 2 mg/cm^2	Xe lamp continuous	No	Finger movement, measurement immediately after application
II) Screening of the SPF	The Netherlands	1997	Optometrics SPF 290S single monochromator/ integrating sphere	10 mm	1,2 nm or 5 nm	Quartz covered with Transpore™	Unknown and not regular	Around 1,5 mg/cm^2	Xe lamp continuous	No	Finger movement, measurement immediately after application
III) Testing of sunscreen based on measuring both erythema effective irradiance and spectral transmittance	Germany	1998	New sunscreen tester with sensor having a spectral sensitivity adjustment for determining SPF (290 nm to 400 nm) and spectral radiometer for determining PFs in UVA	12 mm	1 nm	PMMA plates single use	DGK standard checked by BDF (2 µm to 3 µm)	1 mg/cm^2	Xe lamp continuous	10X irradiance of solar radiation in UV as used for *in vivo* SPF testing	Finger movement, measurement 15 min after application
IV) Determination of the *in vitro* SPF	France/ Germany/ Italy	2003	Four different spectro analysers which specification or appliances included those previously mentioned, integrating sphere	depending on appliance	1 nm	PMMA plates single use	5 µm checked by micro-topography	1,2 mg/cm^2	Xe lamp depending instrument continuous or flash	No	Finger movement, measurement 15 min after application
V) Importance of the substrate roughness	France	2006	Labsphere UV 1 000 (one of the appliances of previous publication), integrating sphere	10 mm	1 nm	PMMA plates single use	Specific topic of the paper to focus its importance. Roughness range: 1,88 µm to 6,76 µm	1 mg/cm^2	Xe lamp flash	No	Finger movement, measurement 15 min after application

Table 5 — UVA *in vivo* test methods currently published

Name of methods	PFA	Stanfield	PPD - JCIA	PPD - EU	PPF	IPD
Parameters			**UVA PF (1)JCIA, KFDA**	**UVA PF (2) EU**		**UVA PF**
			PPD Persistent pigment darkening	PPD Persistent pigment darkening		IPD Immediate pigment darkening
References	[7]	[8]	[9]	[10]	[11]	[12]
Selection of test subjects						
Ethical considerations		IRB approved	Informed consent	Informed consent	Informed consent	Informed consent
Age limitation	18 y to 65 y	Not Specified	M and F > 18 y; < 60 y	M and F > 18 y; < 60 y	M and F > 18 y	M and F 18 y to 50 y
Informed consent	Yes	Yes	Yes	Yes	Yes	Yes
Exclusion criteria	No photosensitizing or anti-inflammatory drugs	Not Specified	Photodermatitis or taking medicine relating to photosensitivity	Pregnant or lactating, past history allergy, photo allergy, other abnormal responses; latex allergy, used self-tanners; taking medication with photosensitization potential, etc.	History of photosensitivity diseases, atopy, or skin cancer, or taking photosensitizing medications, women with childbearing potential, subjects with sun exposure to the back or had applied sunscreens, or those with visible tanning in the test area	Pregnant or lactating, past history allergy, photo allergy, skin cancer, other abnormal responses; taking medication with photosensitivity potential, etc., Fitzpatrick skin types I, II, and VI
Skin type	I, II, III	II	II, III or IV	II, III, IV (ITA value > = 20 and < = 41°)	Skin Type I and II	III, IV or V
Test area	Back, 5 cm × 10 cm	Mid-back	Back, having almost uniform color without pigmentation	Back between scapula line and waist	Lower part of the back	Mid or lower back, lateral to the midline
Interval between two tests	Not specified	Not specified	Not specified but after winter with no sun exposure	Two months (study or sun exposure)	Not recently	Not specified

Table 5 (*continued*)

Name of methods	PFA	Stanfield	PPD - JCIA	PPD - EU	PPF	IPD
Source of UV radiation						
Solar simulator filtration	3 mm WG-335 filtered xenon arc; 1 mm UG-11	2 mm WG-345, 1 mm UG-11 dichroic, water filter, wire mesh	Must emit continuous 320 nm to 400 nm. Excluding below 320 nm	Typical: multiport 601 solar simulator; filters: Schott WG 335 (3mm) and UG 11 (1mm) infrared eliminated by dichroic filter	UVA fluorescent bulbs (Elder Pharmaceuticals) F36-T12-BL peak emission at 366nm, < 1 % UVB	150 W xenon arc solar simulator with 3 mm WG 335 and 1 mm UG 11 filters
Acceptance limits		Not specified	UVAII/UV A tot. = 8 % to 20 %	UVA II/UV A tot. = 8 % to 20 %	Not specified	Not specified
Irradiance uniformity	Same as for SPF	Not specified	Not specified			
Checking of the output flux			JCIA: checking of the output flux by a UVA sensitive radiometer and skin responses observed after UVA exposure KFDA: monitoring is necessary, but the method is not specified	Checking of the output flux before exposure with radiometer with a photosensitive cell with an optimal sensitivity in UVA expressed as mW/cm^2		
Total irradiance		50 mw/cm^2; 100 mw/cm^2	Not specified	Not specified	4,9 mW/cm^2 to 5,1 mW/cm^2 UVA	Irradiance < 150 mw/cm^2
(Spectro) radiometry						
Checking of UV source emission spectrum by spectroradiometry	Yes	IL790 double grating spectroradiometer	Monitoring and maintenance to ensure acceptance limits are maintained	Calibrated annually		Yes
Radiometry for UV dose application	Yes	IL UVA297; UVB66	Calibration at least once a year recommended	Checking of the output flux before each exposure site expressed as mW/cm^2	IL442A; IL700 with UVA probe	Yes

Table 5 (*continued*)

Name of methods	PFA	Stanfield	PPD - JCIA	PPD - EU	PPF	IPD
Test site						
Mode of delineation	Outlined with permanent marker	Not specified	Marker	Template and special skin marker	Not specified	Outlined with permanent marker
Application surface	50 cm^2 (5 cm × 10 cm site)	100 cm^2	> 20 cm^2 or > 24 cm^2	30 cm^2 to 60 cm^2	Five 2 × 10 cm^2 sunscreen test sites plus additional site for unprotected site	50 cm^2 (5 × 10 cm site) designated area
Space between test sites	1 cm	Not specified	> 1 cm	1 cm between each site Limited to six sites	Not specified	Not specified
Test site pre-treatment		None	Not specified	Not specified	Pre treatment requires oral dosing of the subjects with 0,6 mg/kg of 8-methoxypsoralen 1,5 hours prior to phototesting to sensitize the entire body skin surface. (subjects used eye protection for 24 hours after 8-MOP ingestion)	None

Table 5 (*continued*)

Name of methods	PFA	Stanfield	PPD - JCIA	PPD - EU	PPF	IPD
Product quantity and application						
Quantity applied	100 mg/50 cm^2 (= 2 mg/cm^2)	200 µl/100 cm^2	2 mg/cm^2 or 2 $µl/cm^2$	2 mg/cm^2 ± 2,5 %	2$µl/cm^2$	2mg/cm^2
Position of test subjects	Seated or prone	Not specified	Not specified	Consistent throughout the test Prone recommended		Not specified
Mode of delivery	Not specified	Not specified	Uniformly with finger tip or Uniformly with fingers wearing a rubber thimble	Finger cot Time 20 s to 50 s Without finger cot in case of uneven application	Spread evenly with the use of the tip of the pipette	Applied with a positive displacement pipette or tuberculin syringe and spread evenly using un-powdered finger cot
Conditions of application (room temperature, air conditioning)	Same as for SPF	Not specified	Room temperature	Room temperature between 18 °C and 26 °C		Not specified
Drying time	20 min minimum	15 min	>15 min	15 min to 30 min	15 min	15 min

Table 5 (*continued*)

Name of methods	PFA	Stanfield	PPD - JCIA	PPD - EU	PPF	IPD
UV exposure						
Position of test subjects	Seated or prone	Not specified	Not specified	Consistent throughout the test. Prone recommended	Not specified	Not specified
Exposure sub-site surface	1 cm^2	1 cm diameter circle	> 0,5 cm^2 (8 mm diameter)	Not defined	Two hours after 8-MOP ingestion. 1 cm × 1 cm	1 cm diameter circle
Number of sub-sites	Five exposures	Three to four	Not specified	Six	Ten	Minimum 5 exposures
Exposure of the test site protected and unprotected		On the same day	Not specified	On the same day		On the same day
Provisional individual response unprotected (timing)	One day before test procedure	Not specified	Not specified	Not needed	One day before test procedure	
Progression of UV dose	25 %	Not specified	Geometrically with maximum 25 % or smaller increments if high accuracy desired	25 % geometric progression	40 % geometric progression starting at 1 J/cm^2 to 21 J/cm^2	Geometric progression represented by 1,25^n increments
Product removal		Not specified	Not specified	Cotton or cellulose pad with neutral lotion	Not specified	
Skin response assessment						
Definition of end point/response	Erythema or tanning response graded on scale 0, 0,5, 1,0, 1,5, 2,0 (0,5 = MRD)	Minimally perceptible erythema without well-defined borders Grade ⩾ 1 on a 0 to 3 scale	Minimal persistent pigment darkening dose	Minimal persistent pigment darkening dose expressed as J/cm^2	Minimal phototoxic dose Joules per square centimetre	Minimum pigmentation dose (IPD)
Time of assessment	16 h to 24 h post exposure	6 h and 24 h	2 h to 4 h after exposure	2 h to 4 h after exposure	48 h, 72 h: evaluate erythema responses and 2 weeks: evaluate pigmentation responses	Immediately after UVA exposure that persists for at least 45 s

Table 5 (*continued*)

Name of methods	PFA	Stanfield	PPD - JCIA	PPD - EU	PPF	IPD
Conditions of observation (light)	Same as for SPF; grading readers blinded to product ID	Not specified	Under a sufficient light source	White lamps, industrial type, at least 500 lx	Not specified	Standardized lighting conditions. Grading readers blinded to product identification
Position of test subjects	Same as for testing	Not specified	Not specified	Consistent throughout the test. Prone recommended	Not specified	Same as for testing
Response assessment (visual)	Visual grading, see scale above	Visual erythema grade and photography	Visual, two observers recommended (shall be decided by two or more trained evaluators)	Visual, one qualified observer	Visual, observers not specified (not staff member who applied treatment)	Visual grading by the investigator or designated trained technician
Data rejection criteria	All sites or no sites respond or random sites	Not specified	No pigmentation or pigmentation in all sites on the protected or unprotected sites	No pigmentation on any spot; all spots marked; Pigmenting dose does not follow logical sequence	Inadequate photosensitization of subjects (no response on the unprotected skin site)	No response; an exposure series that fails to achieve a progression
Number of test subjects	10	15	> 10	Minimum 10 but no more than 20	40 (as few as 15 for one test compound – as many as 40 for one compound)	8
References formulations						
Reference products used	5 % oxybenzone	None	5 % BMDM, 3 % EH cinnamate	5 % BMDM, 3 % EH cinnamate. May require another standard if PFA > 8	Not specified	Not specified
Acceptance limits (ranges)	mean = 3,97 ± 0,84	None	PFA 3,75 (SD 1,01)	3,75 (SD 1,01)/4,5 (SD 0,5) typical		

Table 5 (*continued*)

Name of methods	PFA	Stanfield	PPD - JCIA	PPD - EU	PPF	IPD
Calculation and results						
Number of test subjects	10	6 to 7	10 minimum	10 but not more than 20	Minimum 15 (not cited)	8
Calculation of mean UVA PF	Yes	Mean ± SD	Arithmetic mean for individual PFA, rounding down to lower integer	MPD protected/MPD unprotected	Arithmetic mean of $MPD_{protected}$/ $MPD_{unprotected}$	UVA-PF = IPD threshold dose in protected skin/IPD threshold dose in unprotected skin
Statistical criteria		ANOVA $p \leqslant 0{,}05$	SEM must lie within 10 % of the measured (PFA) value	SEM must lie within 10 % of protection factor UVA (PFA)	2-way ANOVA with pair wise comparisons; 95 % confidence interval	Mean ± standard error
Results	Mean PFA	1. No significant difference between irradiance of 50 mw/cm^2 and 100 mw/cm^2	Mean PFA	Mean UVA PF	PPF (the phototoxic protecting factor) MPF(the melanogenic protection factor)	Mean UVA-PF
		2. No significant difference between evaluation at 4,3 h to 6,0 h and 22,6 h to 26,2 h.				
		3. Demonstrated feasibility of method				
Reporting data	PFA (mean)		Reported as PA+ (PFA 2 to < 4), PA++ (PFA 4 to < 8) or PA+++ (PFA > 8)	Individual results, colorimetric info recorded and validated. Individual data & means available for easy consultation		IPD mean

Table 6 — UVA-*In vitro* test methods currently published

Name of method Parameters	COLIPA UVAPF/PPD	German DIN UVA balance	UVA/UVB ratio	Australian/ New Zealand	Critical wavelength	APP
References	[13]	[14]	[15a), 15b)]	[3]	[15]	[16]
Spectro-analyser						
Spectro-analyser system	Spectrophotometer with optical density sensitivity range exceeding absorbance of test samples (typically ⩾ 2,2 absorbance units) as tested with standard methacrylate plates. Spectroradiometers with diffuse reflectance sphere/optical integrators can also be utilized	The spectroradiometer can be any device comprised of: scanning monochromator or diode array and a detector. Photomultiplier	The spectroradiometer can be any device comprised of: scanning monochromator or diode array and a detector	Not defined; integrating sphere with suitable matt white compound (method 3)	The spectroradiometer can be any device comprised of: scanning monochromator or diode array and a detector.	UV-Vis spectrophotometer fitted with an integrating sphere to collect forward scattering absorbance
Instrument validation	Dynamic range to be validated by use of standard PMMA plate testing. Instrument calibration as per manufacturer specified methods	Per manufacturer Every 3 months by measurement of a reference material with known and constant UV absorbance (DIN 5031-11)		Not defined	Per manufacturer	Not described
Instrument sensitivity and noise level	⩾ 2,2 absorbance units	2 to 3 absorbance units	2 to 3 absorbance units Low noise/signal ratio	Peak responsivity: 340 nm to 370 nm; (method 3) spectral responsivity at ⩽ 310 nm: ⩽ 0,01 maximum spectral responsivity at ⩾ 400 nm: 0,01 maximum	2 to 3 absorbance units	Not described