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SOUTH AFRICAN NATIONAL STANDARD

Sunscreen products

WARNING
This document references other documents normatively.

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Table of changes

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Acknowledgement

The South African Bureau of Standards wishes to acknowledge the valuable assistance derived from publications of the following organizations:

a) The Cosmetic, Toiletry and Fragrance Association of South Africa (CTFA);

b) The European Cosmetic, Toiletry and Perfumery Association (Cosmetics Europe);

c) The International Organization for Standardization;

d) The Japan Cosmetic Industry Association (JCIA); and

e) The Personal Care Products Council of the United States of America.

Foreword

This South African standard was prepared by National Committee SABS/TC 217, *Cosmetics*, in accordance with procedures of the South African Bureau of Standards, in compliance with annex 3 of the WTO/TBT agreement.

This document was approved for publication in February 2019.

This document supersedes SANS 1557:2014 (edition 3.3).

Reference is made in 4.1 to the "relevant national legislation". In South Africa this means the Legal Metrology Act, 2014 (Act No. 9 of 2014).

Annexes A, C, D and E form an integral part of this document. Annex B is for information only.

Compliance with this document cannot confer immunity from legal obligations.

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Sunscreen products

1 Scope

This standard specifies requirements for topically applied cosmetic products claiming sun protection properties, and provides a basis for the evaluation of such products in accordance with performance criteria. It also specifies requirements for the advertising and labelling of sunscreen products.

2 Normative references

The following referenced documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For date references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. Information on currently valid national and international standards can be obtained from the South African Bureau of Standards.

2.1 Standards

ISO 24442, *Cosmetics – Sun protection test methods – In vivo determination of sunscreen UVA protection.*

ISO 24444, *Cosmetics – Sun protection test methods – In vivo determination of the sun protection factor (SPF).*

SANS 98, *Ingredient labelling of cosmetic products*.

SANS 241-1, *Drinking water – Part 1: Microbiological, physical, aesthetic and chemical determinands.*

SANS 289, *Labelling requirements for prepackaged products (prepackages) and general requirements for the sale of goods subject to legal metrology control*.

SANS 22716, *Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices.*

SANS 24443/ISO 24443, *Cosmetics – Sun protection methods – Determination of sunscreen UVA photoprotection in vitro.*

SATR 24475/ISOTR 24475, *Cosmetics – Good manufacturing practices – General training document.*

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2.2 Other publications

CTFA Cosmetic Guideline[1)].

OTC Monograph: 21 CFR 201.327 (i) and (j).

The Code of Advertising Practice (ASA).

3 Definitions and abbreviations

3.1
broad spectrum
minimum SPF 15 and the mean critical wavelength of 370 nm or greater after irradiation determined using OTC Monograph: 21 CFR 201.327 (i) and (j): or any other equivalent method (see 5.3.5)

3.2
erythema
reddening of the skin caused by ultraviolet (UV) radiation

3.3
equivalent method
any test method which has been published and is internationally accepted to be an acceptable alternative test method and has been demonstrated to achieve the same outcomes

3.4
health professional
someone who works in the medical profession, for example, a doctor or nurse

3.5
minimum erythemal dose
MED

3.5.1
MEDps
MEDp
lowest UV 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 on test product-protected skin

3.5.2
MEDpw
lowest UV 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 on test product-protected skin after immersion in water

3.5.3
MEDus
MEDu
lowest UV 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 on unprotected skin

1) The *CTFA Cosmetic Guideline* is available from the CTFA, PO Box 721, Randpark Ridge, 2156. Tel.: (011) 795 4272. Fax: (011) 794 3039. E-mail: technical@ctfa.co.za. Worldwide web: www.ctfa.co.za.

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3.5.4
MEDuw
lowest UV 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 on unprotected skin after immersion in water

3.6
primary container
container which is in direct contact with the cosmetic

3.7
secondary container
container which is not in direct contact with the cosmetic

3.8
sunscreen
sun protection product

3.8.1
primary sunscreen
cosmetic product with the main purpose of protecting the skin from the effects of the sun

3.8.2
secondary sunscreen
cosmetic product with sun protection as an additional benefit and not as the main purpose

3.9
sun protection factor
SPF

3.9.1
SPFi
individual sun protection factor which is the ratio of the MED on test product-protected skin (MEDp) to the MED on unprotected skin (MEDu) of the same subject

$$SPFi = \frac{MED_p}{MED_u}$$

NOTE SPFi is expressed to one decimal place.

3.9.2
SPFis
individual dry arithmetic mean of all valid individual sun protection factor (SPFi) values obtained from all subjects in the test before immersion in water

3.9.3
SPFiw
individual wet arithmetic mean of all valid individual sun protection factor (SPFi) values obtained from all subjects in the test after immersion in water

3.10
technician
trained scientist
expert or person trained in the practical application of science in the laboratory

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3.11
ultraviolet (UV) radiation

3.11.1
UVA
ultraviolet radiation of wavelengths in the range 320 nm to 400 nm

3.11.2
UVB
ultraviolet radiation of wavelengths in the range 290 nm to 320 nm

4 General requirements

4.1 Statutory requirements

The sunscreen product shall comply with the relevant national legislation (see foreword), SANS 98, SANS 289, SATR 24475, the *CTFA Cosmetic Guideline* and *The Code of Advertising Practice (ASA)*.

4.2 Documented test results

Documented *in vivo* and *in vitro* test results for a specific sunscreen product shall be retained as proof of claimed results, until any changes in formulation or method of manufacture for that specific product are introduced.

NOTE Raw material source changes can affect the test results.

4.3 Classification

Sunscreen products shall be classified in accordance with their tested Sun Protection Factor (SPF), as specified in table 1.

Table 1 — Classification of sunscreen products

1	2
SPF	**Classification of protection**
6 to 14,9	Low
15 to 29,9	Medium
30 to 59,9	High
60 and more	Very high
NOTE A product with an SPF lower than 6 is not considered to be a sunscreen product.	

4.4 Good Manufacturing Practices (GMP)

Products shall be manufactured in accordance with the Good Manufacturing Practices (GMP) requirements as specified in the *CTFA Cosmetic Guideline*, SANS 22716 and SATR 24475.

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5 Requirements for the sunscreen products

5.1 Ingredient requirements

Sunscreen products shall comply with the requirements in annexes of the latest edition of the *CTFA Cosmetic Guideline*.

5.2 UV filters

5.2.1 Only UV filters listed in annex A shall be used in the product.

5.2.2 The maximum concentration of an individual UV filter in the sunscreen product shall not exceed the approved concentration for that UV filter given in annex A.

5.3 Performance requirements

5.3.1 SPF requirements

The SPF stated on the label shall be based on the mean SPF, shall be labelled in accordance with 6.2.2, and shall be determined in accordance with clause 8, ISO 24444 or any other equivalent method.

5.3.2 UVA requirements

5.3.2.1 Products bearing the UVA symbol shall be required to comply with either 5.3.2.2 or 5.3.2.3.

5.3.2.2 In *vitro* UVA requirements shall be specified as the UVA Protection Factor of at least 1/3 that of the labelled SPF measured above the critical wavelength of 370 nm after irradiation, determined using SANS 24443 or any other equivalent method.

5.3.2.3 In *vivo* UVA requirements shall be specified as the UVA Protection Factor of at least 1/3 that of the labelled SPF, determined using ISO 24442 or any other equivalent method.

5.3.4 Broad spectrum

In view of the high levels of UVA and UVB prevalent in South Africa, it is recommended as a best practice that for sunscreen products, protection for both UVA and UVB should be related. It is further recommended that for sunscreen products, UVA or Broad-spectrum compliance be considered as determined in 5.3.2.

5.3.5 Requirements for products for which "broad spectrum" is claimed

A product shall be considered to provide broad spectrum protection if the minimum SPF 15 and mean critical wavelength is 370 nm or greater after irradiation as determined using OTC Monograph: 21 CFR –201.327 (i) and (j) or any other equivalent method.

5.3.6 Requirements for products for which "water resistant" is claimed

A product shall be considered water resistant if after two periods of 20 min of activity in water, as described in clause 9,

a) the value for the 90 % lower unilateral confidence limit (such as Water Resistant Retention [mean %WRR-*d*]) is greater than or equal to 50 % of the mean dry SPF), and

b) the 95 % confidence interval (CI) on the mean dry SPF is within ± 17 % of the mean dry SPF.

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5.3.7 Requirements for products for which "very water resistant" is claimed

A product shall be considered very water resistant if after four periods of 20 min of activity in water, as described in clause 9,

a) the value for the 90 % lower unilateral confidence limit ([mean %WRR-*d*]) is greater than or equal to 50 % of the mean dry SPF, and

b) the 95 % CI on the mean dry SPF is within ± 17 % of the mean dry SPF.

6 Advertising and labelling of sunscreen products

6.1 Advertising of sunscreen products

6.1.1 General

6.1.1.1 The category of protection (see table 1) shall be accurately portrayed in claims for or in the visual advertising of a sunscreen product.

6.1.1.2 When specific protection claims are made or the inclusion of UV filters is stated or implied, the SPF number shall be stated on the container or label of the product, and shall be clearly indicated[2)].

6.1.2 "Sun Protection Factor" (SPF) claims

The advertising of primary sunscreen products and secondary sunscreen products shall not bear claims or implications of sun protection or of an SPF number unless documented *in vivo* test results that prove compliance with the requirements of this standard can be supplied to substantiate the claim (see 5.3.1).

6.1.3 "Water resistant" claims

The advertising of sunscreen products shall not bear claims or implications of "water resistance" unless documented test results that prove compliance with the requirements of this standard can be supplied to substantiate the claim (see 5.3.6). Such a claim shall only be advertised and labelled as "water resistant". Any other variants of "water resistant" shall not be accepted.

6.1.4 "Very water resistant" claims

The advertising of sunscreen products shall not bear claims or implications of "very water resistant" unless documented test results that prove compliance with the requirements of this standard can be supplied to substantiate the claim (see 5.3.7). Such a claim shall only be advertised and labelled as "very water resistant". Any other variants of "very water resistant" shall not be accepted.

6.1.5 "UVA protection" claims/ UVA symbol

For a product for which UVA protection is claimed, documented test results shall be made available to substantiate the claim (see 5.3.2).

6.1.6 "Block-out" or similar claims

Claims shall not be made for or to imply 100 % protection from UV radiation (for example, block, sunblock, sunblocker, or total protection).

2) Exclusion of ingredients listing.

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6.1.7 "All day protection and extended protection" claims

A sunscreen product shall not claim or imply that a single application can provide all day protection or similar.

6.1.8 "Classification" claims

Classification claims shall only be made in accordance with table 1, for example, low, medium, high, or very high.

6.1.9 "Non-irritation" claims

If irritation related claims are made, adequate substantiation shall be provided in the form of documented test results.

6.1.10 "UV protection" claims (also known as sun protection claims)

Products for which UV protection or sun protection is claimed or implied shall bear the SPF number for which an *in vivo* test report is available.

6.1.11 "Broad spectrum" claims

Products for which broad spectrum is claimed or implied shall comply with the requirements in 5.3.5.

6.1.12 "Sweat resistant" claims

A sunscreen product shall not claim to be "sweat resistant".

6.1.13 "Waterproof" claims

A sunscreen product shall not claim to be "waterproof".

6.1.14 "Very high SPF value" claims

The maximum SPF number that may be claimed shall be 50+ (see 6.2.2).

6.1.15 "Low SPF value" claims

No SPF value less than 6 shall be claimed.

6.2 Labelling of sunscreen products

6.2.1 General

The labelling of sunscreen products shall appear in visible, legible and indelible marking on the container, or on a label securely affixed to the container. The labelling of sunscreen products shall be in accordance with the requirements in tables 2 to 5 (inclusive).

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Table 2 — General labelling requirements (primary containers)

1	2	3
General labelling requirement	**Primary container**	**Additional comments and information**
Name of the product	√	Shall be an appropriate descriptive name whereby the intended use of the product is made clear.
Name of the person responsible for placing the product on the market in South Africa	√	Responsible person can be the manufacturer, packer, importer or seller or person on whose behalf the cosmetic is packed.
The local physical business address of the person responsible for placing the product on the market in South Africa	√	Shall include the street number and street name, town or suburb, and the postal code.
Precautions and warning statements	√	In accordance with column 6 of annexes III, VI and VII of the *CTFA Cosmetic Guideline*.
Date of minimum durability	When appropriate	Only if the durability is less than 30 months.
Nominal quantity	√	In accordance with SANS 289.
Manufacturing batch number	√	Where applicable.
List of ingredients in INCI nomenclature	√	In accordance with SANS 98.
SPF	√	Shall be labelled in accordance with table 6.
Directions for use	√	Shall indicate the following for primary sunscreen products: – "apply before exposure"; – "apply generously"; and – "re-apply frequently".
NOTE √ means that the labelling requirement should be stated on the container.		

Table 3 — Specific labelling claims (primary containers)

1	2	3
Specific labelling claim	**Primary container**	**Additional comments and information**
UVA protection	UVA symbol if claimed. (see annex B)	Shall be substantiated according to 5.3.2.
Broad Spectrum	When Appropriate	Shall be substantiated according to 5.3.5
"Water resistant" or "Very water resistant"	When appropriate	"Water resistant" or "very water resistant" claims shall be accompanied by the following: "re-apply after perspiring, swimming or towel drying ".
Sunscreen wipes	√	Shall have a statement: "contains an SPF (number) sunscreen".
NOTE √ means that the specific labelling claim should be stated on the container.		

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Table 4 — General labelling requirements (primary and secondary containers)

1	2	3	4
General labelling requirement	**Primary container**	**Secondary container**	**Additional comments and information**
Name of the product	√	√	Shall be an appropriate descriptive name whereby the intended use of the product is made clear.
Name of the person responsible for placing the product on the market in South Africa	–	√	Responsible person can be the manufacturer, packer, importer or seller or person on whose behalf the cosmetic is packed.
The local physical business address of the person responsible for placing the product on the market in South Africa	–	√	Shall include the street number and street name, town or suburb, and the postal code.
Precautions and warning statements	√	√	In accordance with column 6 of annexes III, VI and VII of the *CTFA Cosmetic Guideline*.
Date of minimum durability	–	When appropriate	Only if the durability is less than 30 months.
Nominal quantity	√	√	In accordance with SANS 289.
Manufacturing batch number	√	–	Where applicable.
List of ingredients in INCI nomenclature	–	√	In accordance with SANS 98.
SPF	√	√	Shall be labelled in accordance with table 6.
Directions for use	√	–	Shall indicate the following for primary sunscreen products: – "apply before exposure"; – "apply generously"; and – "re-apply frequently".
NOTE √ means that the labelling requirement should be stated on the specified container.			

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Table 5 — Specific labelling claims (primary and secondary containers)

1	2	3	4
Specific labelling claim	**Primary container**	**Secondary container**	**Additional comments and information**
"Water resistant" or "Very water resistant"	When appropriate	When appropriate	"Water resistant" or "very water resistant" claims shall be accompanied by the following: "re-apply after perspiring, swimming or towel drying".
UVA protection	UVA symbol if claimed. (see annex B)	UVA symbol if claimed. (see annex B)	Shall be substantiated according to 5.3.2
Broad Spectrum	When Appropriate	When Appropriate	Shall be substantiated according to 5.3.5
Sunscreen wipes	√	√	Shall have statement: "contains an SPF (number) sunscreen".
NOTE √ means that the specific labelling claim should be stated on the specified container.			

6.2.2 Labelled SPF

For the purposes of labelling, the mean arithmetical SPF shall be rounded down to the lower integer and shall be labelled in accordance with the integer in column 2 of table 6.

Table 6 — Labelled SPF

1	2
Labelled SPF	**Measured mean arithmetical SPF**
6	6 to 9,9
10	10 to 14,9
15	15 to 19,9
20	20 to 24,9
25	25 to 29,9
30	30 to 39,9
40	40 to 49,9
50	50 to 59,9
50+	$\geq$ 60

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6.2.3 Optional labelling

The following information may appear on the primary container or on a label securely affixed to the primary container:

a) the classification (see 4.3);

b) where appropriate, the UVA symbol;

c) the warning "avoid contact with eyes and in case of contact, flush eyes with water";

d) warnings, for example,:

1) "do not stay too long in the sun, even when using a sunscreen product",

2) "keep babies and young children out of direct sunlight",

3) "over-exposure to the sun is a serious health threat", or

4) "reducing the quantity and the number of applications will lower the level of protection significantly"; and

e) storage directions.

7 Test methods for determination of SPF and UVA

7.1 Principle

The SPF test method is a laboratory method that uses a xenon arc lamp solar simulator (or equivalent) of defined and known output to determine the protection provided by sunscreen products on human skin against erythema or sunburn induced by solar ultraviolet rays in accordance with ISO 24444 and SANS 24443.

7.2 Selection criteria for test subjects

7.2.1 Skin phototypes

The skin phototype of test subjects included in the SPF test shall be phototypes I, II, or III in accordance with Fitzpatrick (see table 7), or the skin phototype shall have an Individual Typology Angle (ITA°) value (see table 8) greater than 28° by colorimetric methods and shall be untanned on the test area.

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Table 7 — Fitzpatrick skin phototypes

1	2	3
Type	**Description**	**Characteristic**
I	Always burns easily	Never tans
II	Always burns easily	Tans minimally
III	Burns moderately	Tans gradually
IV	Burns minimally	Always tans well
V	Rarely burns	Tans profusely
VI	Never burns	Deeply pigmented
NOTE The Fitzpatrick skin phototypes are based on the first 30 min to 45 min of sun exposure after a Winter season of no sun exposure.		

Table 8 — Colorimetric Individual Typology Angle (ITA°) values

1	2
Skin colour	**ITA° value range**
Very light	> 55°
Light	> 41° to 55°
Intermediate	> 28° to 41°
Tan (or matt)	> 10° to 28°
Brown	> −30° to 10°
Black	≤ −30

NOTE 1 $ITA° = \left[\text{Arc Tangent}\left(\frac{L^* - 50}{b^*}\right)\right]\left(\frac{180}{3{,}1416}\right)$

where

L^* is the luminance; and

b^* is the blue-green axis.

NOTE 2 Colorimetric ITA° values and skin colour categories are defined by the colorimetric descriptors of Chardon, using the CIE L^*, b^* colour space.

7.2.2 Medical and ethical considerations

7.2.2.1 It is recommended that new test subjects first be interviewed by a health professional to establish their medical status and suitability before being included into the test subject panel.

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7.2.2.2 Test subjects shall be visually examined by a technician before participation in the study. The skin colour shall be uniform over the whole test area without pigmentation, nevi or similar, and erythema shall not be present. Test subjects shall not have any sun exposure on the test area (see 7.4) for at least four weeks before SPF testing.

7.2.2.3 Test subjects shall be informed of the aims and the potential risks (direct or secondary effects) of the study, and of any discomfort they might experience.

7.2.2.4 Informed, written consent shall be obtained from the test subject before entering the study in accordance with the Declaration of Helsinki for medical research involving human subjects.

7.2.2.5 If there is uncertainty regarding the provisional SPF value of the sunscreen product to be tested, then a screening shall first be performed on a maximum number of five test subjects. The range of UV doses on test product-protected skin is then progressively increased on consecutive subjects until an MED (minimum erythemal dose) response is achieved.

7.2.3 Non-inclusion criteria

The following groups shall not be used as test subjects:

a) children and persons below the age of consent;

b) persons older than 70 years;

c) pregnant or lactating women;

d) persons that use medication with photosensitizing potential;

e) persons that use anti-inflammatory medication;

f) persons with dermatological conditions;

g) persons with a history of abnormal response to the sun;

h) persons that are accustomed to using tanning beds; and

i) persons with marks, blemishes, nevi, or existing sun damage in the test area.

7.2.4 Frequency of test subject participation

There shall be a sufficient interval between two successive UV exposures of the same test site to allow for reversal of skin tanning from previous tests, for example, not less than two months.

7.3 Number of test subjects

7.3.1 The minimum number of valid SPFi results shall be 10, and the maximum number of valid SPFi results shall be 20 (see 8.6.4.2). In order to achieve between 10 and 20 valid results, a maximum of five individual invalid test results may be excluded from the calculation of the mean SPF.

7.3.2 Consequently, the actual number of test subjects used will fall between a minimum of 10 and a maximum of 25 subjects (for example, a maximum of 20 valid results plus 5 rejected invalid results).

7.3.3 Results may only be declared invalid and excluded from the calculation of the mean SPF in accordance with 8.5.4 or because of non-compliance with the test protocol.

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7.3.4 In order to determine the number of test subjects, the 95 % CI on the mean SPF shall be taken into account. The 95 % CI shall be within ± 17 % of the mean SPF determined from a minimum of 10 volunteers. Alternatively, the number of test subjects shall be increased stepwise from 10 until the statistical criterion is met (up to a maximum of 20 valid results from a maximum of 25 test subjects).

7.3.5 If the statistical criterion has not been met after 20 valid results from a maximum of 25 test subjects, then the test shall be rejected in accordance with annex C.

7.4 Test areas

7.4.1 The back shall be the chosen anatomical region for the test area.

7.4.2 The individual product test sites within the test area shall be delineated within the region between the scapula line and the waist.

7.4.3 Skeletal protrusions and extreme areas of curvature should be avoided.

8 Test method for the determination of *in vivo* SPF

8.1 Apparatus and materials

8.1.1 Source of ultraviolet radiation

8.1.1.1 General

An artificial light source shall be used, and shall comply with the requirements of this standard. A xenon arc solar simulator with appropriate filters is recommended.

8.1.1.2 Quality of ultraviolet radiation

8.1.1.2.1 The solar UV simulator shall emit a continuous spectrum with no gaps or extreme peaks of emission in the UV region. The output from the solar UV simulator shall be stable, uniform across the whole output beam, and suitably filtered to create a spectral quality that complies with the required acceptance limits.

8.1.1.2.2 To ensure that appropriate amounts of UVA radiation are included in the spectrum of the solar UV simulator throughout the entire UVA range, the total radiometric proportion of the UVA II (320 nm to 340 nm) irradiance of the simulator shall equal or exceed 20 % of the total UV irradiance. The UVA I (340 nm to 400 nm) irradiance shall equal or exceed 60 % of the total UV irradiance.

8.1.1.2.3 The source spectral specification is described in terms of cumulative erythemal effectiveness by successive wavelength bands from < 290 nm up to 400 nm. The erythemal effectiveness of each wavelength band is expressed as a percentage of the total erythemal effectiveness from < 290 nm to 400 nm, or as the Relative Cumulative Erythemal Effectiveness (% RCEE) (see table 9).

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Table 9 — % RCEE acceptance limits for the UV solar simulator output

1	2	3
Spectral range nm	**Measured % RCEE**	
	Lower limit	**Upper 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

8.1.1.3 Total irradiance (UV rays, visible rays and near infrared rays)

If total irradiance is strong, an excessive feeling of heat or pain can be induced in the irradiated skin of test subjects. The total irradiance shall not exceed 1 600 W/m^2. When total irradiance is less than 1 600 W/m^2, before conducting an SPF test, it shall be confirmed that the irradiance to be used (UV rays, visible rays and near-infrared rays) will not induce an excessive feeling of heat in the skin.

8.1.1.4 Uniformity of beam

8.1.1.4.1 When a large-beam UV source is used to simultaneously expose several subsites (for example, at least two subsites) within an irradiation series by varying the exposure time, the intensity of the beam shall be as uniform as possible. The minimum beam irradiance shall not be more than 10 % lower than the maximum beam irradiance at any point. If the variation exceeds 10 %, then appropriate compensation for different irradiance should be made in the exposure time on each subsite.

8.1.1.4.2 For a small-beam UV source which exposes subsites individually, the erythema generated following exposure shall be as uniform as possible. An uneven erythema (for example, a half-moon shape) indicates that the irradiance is not uniform and the delivery system shall be corrected.

8.1.1.5 Maintenance and monitoring of the UV solar simulator output

8.1.1.5.1 Radiometry

Before UV exposure of each test site, the UV irradiance should be checked with a radiometer calibrated against a spectroradiometric measurement of the solar simulator output.

8.1.1.5.2 Spectroradiometry

8.1.1.5.2.1 It is recommended that a complete spectroradiometric check (for example, UVA and UVB) of output spectrum and intensity be made by the laboratory at least once every 18 months or after 3 000 h of running and each time a significant physical component is changed, and that an independent expert conducts this inspection.

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8.1.1.5.2.2 The simple use of specific filters is not adequate assurance that the UV output is of correct quality.

8.1.2 Reference sunscreen formulations

8.1.2.1 General

8.1.2.1.1 One of the prescribed reference sunscreen formulations in annex D shall be measured on the same day as products are tested. The use of a low SPF reference sunscreen formulation or a high SPF reference sunscreen formulation depends on the expected SPF of the test products.

8.1.2.1.2 The formula and preparation of the reference sunscreen formulations shall be in accordance with annex D.

8.1.2.2 Expected SPF below SPF 20

8.1.2.2.1 One of the following reference sunscreen formulations shall be used:

a) P2;

b) P3; or

c) P7.

8.1.2.2.2 If a high SPF reference sunscreen formulation is used, it is not necessary to include a low SPF reference sunscreen formulation in the test even though there might be low SPF test products.

8.1.2.3 Expected SPF equal to or greater than SPF 20

8.1.2.3.1 One of the following reference sunscreen formulations shall be used:

a) P2; or

b) P3.

8.1.2.3.2 If a high SPF reference sunscreen formulation is used, it is not necessary to include a low SPF reference sunscreen formulation in the test even though there might be low SPF test products.

8.1.2.4 Acceptance SPF limits for the reference sunscreen formulations

If the mean SPF obtained in any test does not fall within the indicative range of the reference values, then the test shall be rejected (for example, all the test products shall be rejected). The acceptance of SPF ranges for the reference sunscreen formulations shall be as given in annex D.

8.2 Test procedure

8.2.1 Main steps

The main steps for the determination of *in vivo* SPF are as follows:

a) selection of test subjects;

b) delineation of test sites on the back of the subject;

c) weighing of the product;

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d) application of the test product;

e) drying time before UV exposure;

f) UV exposure;

g) MED assessment; and

h) calculations and reporting.

8.2.2 Test conditions

Product application, UV exposures and MED assessment shall be conducted in a room maintained at a temperature between 18 °C and 26 °C.

8.2.3 Position of the test subjects

All steps in the test procedure shall be performed in the same position (for example, an upright position, a seated position or a prone position).

8.2.4 Procedure for product application

8.2.4.1 General

The amount of product applied and the uniformity of spreading on the test sites affect the magnitude and variability of the test results. It is, therefore, very important to follow the requirements in 8.2.4.2 to 8.2.6 (inclusive).

8.2.4.2 Test sites and product application

8.2.4.2.1 The test sites intended for UV exposure shall be free from blemishes and shall have an even colour tone.

8.2.4.2.2 The minimum area for a test site for product application shall be 30 cm^2, and the maximum shall be 60 cm^2.

8.2.4.2.3 Randomly distribute the test sites for the test products and the reference sunscreen on the back over the whole group of test subjects in order to reduce systematic error arising from anatomical differences in skin. The unprotected MED should be randomized as one of the test sites across the test area and across volunteers.

8.2.4.2.4 There shall be a minimum distance of 1 cm between the borders of adjacent test sites.

8.2.4.2.5 Before product application, the test area may be cleaned with a dry cotton pad or equivalent.

8.2.4.2.6 The test sites shall be delineated using a method which does not interfere with the test or harm the test subject (for example, a skin marker or a template made from non-absorbent material (or both)).

8.2.4.3 Amount of product applied

8.2.4.3.1 The amount of the test product and the reference sunscreen formulation applied to the skin before spreading shall be 2,00 mg/cm^2 ± 0,05 mg/cm^2.

8.2.4.3.2 Use a balance with an accuracy of at least four decimal places (for example, 0,0001 g).

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8.2.4.3.3 Care shall be taken to prevent evaporative loss of volatile components when the product is being weighed and before application to the skin. It is important that the total quantity of weighed product is transferred to the product application site.

8.2.4.3.4 The amount of product to be applied may be weighed in a syringe or in another device such as a watch glass. A method of weighing by loss is recommended.

8.2.4.3.5 All products should be homogeneous and should be shaken if necessary, before weighing, to ensure uniform dispersion.

8.2.5 Mode of delivery

8.2.5.1 General

8.2.5.1.1 The use of a finger cot is recommended. If used, a new finger cot shall be used for each new application of the test product and shall not be pre-saturated with the test product.

8.2.5.1.2 If a naked finger is used, the finger shall be cleaned between applications of the test product.

8.2.5.2 Lotions, liquids, milks, creams and sprays

8.2.5.2.1 To aid uniform coverage, droplets of the product (approximately 15 drops/30 cm^2 or 30 drops/60 cm^2) should be deposited within the test site using a syringe or a pipette, then spread over the whole test site using light pressure.

8.2.5.2.2 The spreading time should be between 20 s and 50 s, depending on the test surface and ease of spreading of the test product.

8.2.5.3 Powders

8.2.5.3.1 For powdered sunscreen products, aliquots should be transferred to the skin in a grid-like manner, using a spatula or a finger.

8.2.5.3.2 The accumulated powder is tapped and then spread over the whole test site using a finger, with or without a finger cot.

8.2.5.3.3 Alternatively, the tip of a pre-loaded cosmetic applicator puff may be used instead of a finger. In this case, the amount of powder 2,00 mg/cm^2 ± 0,05 mg/cm^2 on the test site after application should be verified by weighing the remaining powder left on the tip of the applicator puff.

8.2.5.3.4 Purified water, or another suitable solvent that has no UV protection properties, may be applied on the test site before application of the powder to aid with the adhesion of the test product.

8.2.6 Drying time between application and UV exposure

Exposure of the test site to the sequence of UV doses shall start 15 min to 30 min after the application of the test product(s). Any extraneous exposure of the test sites to UV light (artificial or natural) shall be avoided during this period and for 24 h after exposure.

8.3 Procedure for UV exposure

8.3.1 Exposure subsites or skin-exposed spots

8.3.1.1 A non-absorbent template should be used to demarcate the exposure subsites (skin-exposed spots) for exposure to UV (large-beam UV solar simulator).

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8.3.1.2 The minimum area for each exposure subsite shall be 0,5 cm^2.

8.3.1.3 The minimum distance between the borders of each exposure subsite shall be at least 0,8 cm and each subsite shall be of the same area.

8.3.1.4 The distance between any subsite and any edge of the test site shall be at least 1 cm.

8.3.1.5 The minimum number of subsites used shall be five for unprotected MED (MEDu) and five for protected MED (MEDp).

8.3.2 Provisional individual MEDu

A provisional individual MEDu can be determined before the start of the main test in order to centre the UV dose ranges for the exposures of MEDu and MEDp. This is a pre-test in which the MEDu of a subject is determined before establishing the test MEDu, and it is performed by applying a preliminary series of UV exposures up to one week before the test.

8.3.3 Estimated or anticipated MEDu

The MEDu can be estimated by a colorimetric technique without UV exposure or it can be predicted by an experienced tester (for example, history of the volunteers, anticipated MEDu).

8.3.4 Individual MEDu

The individual MEDu shall be determined on the same day as the test products.

8.3.5 Incremental progression of UV doses

8.3.5.1 For the unprotected test sites, the centre of the range of UV doses applied shall be established using the provisional MEDu of the test subject, the estimated MEDu or the anticipated MEDu. A minimum of five subsites centred on the provisional or estimated MEDu shall be exposed with incremental UV doses, using a recommended geometric progression of 1,25x. Other geometric progressions of less than 1,25x may be used (for example, 1,2; 1,12; or 1,15), but shall be consistent throughout the test.

8.3.5.2 For the test product-protected sites, the centre of the UV dose range is that of the provisional, estimated or anticipated MED multiplied by the expected SPF of the sunscreen product. A minimum of five subsites centred on the expected MEDp shall be exposed with incremental UV doses, using a recommended geometric progression of 1,25x. Other geometric progressions of less than 1,25x may be used (for example, 1,2; 1,12; 1,15). A maximum geometric progression of 1,15 shall be used for expected SPF greater than 25 (> 25). Smaller geometric progressions (for example 1,12) may be used, but shall also be consistent throughout the exposure sequence.

8.4 Product removal

After UV exposures, the reference sunscreen formulations and the test products shall be removed gently, using appropriate means.

8.5 Procedure for MED assessments

8.5.1 General

The minimal erythemal dose for unprotected skin (MEDu), the test product-protected skin (MEDp), and the MEDp for the reference sunscreen formulation shall be determined on the same day.

8.5.2 Time of assessment of MED

The MED shall be assessed when the erythemal response is optimal, for example 20 h ± 4 h after UV exposure (between 16 h and 24 h). During the time interval between UV exposure and MED assessment, the test subject shall avoid any extra UV exposure (artificial UV light or sunlight) to the exposed area. Any additional exposure to the test area will invalidate the whole test.

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8.5.3 MED assessment

8.5.3.1 The MED shall be assessed visually. The observer's eyesight should be checked for normal colour vision. A yearly check of acuity of vision is recommended.

8.5.3.2 Visual assessment should be performed in sufficient and uniform illumination. At least 450 lux is recommended.

8.5.3.3 The determination of MED shall be carried out in a room with a matt neutral wall colour.

8.5.3.4 Erythemal responses shall be observed in a " blind manner ". The observers of erythemal responses should not be the same persons that performed the application of the product and the UV exposure on the test subjects. The observers shall not be aware of the test design (randomization of test sites and UV doses) on a test subject.

8.5.4 Data rejection criteria

8.5.4.1 Test data shall be deemed invalid and shall be rejected if

a) the series of UV exposures on a test subject fails to elicit an erythemal response on any subsite 20 h ± 4 h after exposure,

b) erythemal responses within an exposure series are randomly absent 20 h ± 4 h after exposure, and

c) all subsites in the exposure series show an erythemal response 20 h ± 4 h after exposure.

8.5.4.2 When one of the criteria in 8.5.4.1 applies to the exposure series on unprotected skin or to the reference sunscreen formulation exposure test sites, then all data for all test products on a test subject are invalid and shall be rejected.

8.5.4.3 When one of the criteria in 8.5.4.1 applies to a test product-treated exposure series, then all data for that test product on the test subject is invalid and shall be rejected.

8.5.4.4 If invalid data has to be rejected for any one product on more than five test subjects, then the whole test for that product is invalid and shall be rejected.

8.5.4.5 If invalid data has to be rejected for the reference sunscreen formulation on more than five test subjects, then the whole test is invalid and shall be rejected.

8.5.5 Expression of MED

8.5.5.1 MED shall be expressed in terms of energy ($J.m^{-2}$ or $mJ.cm^{-2}$), MED units or time (seconds). Units of time shall only be used where the flux rate of the solar simulator is constant throughout the test and has been recorded in units of radiant flux.

8.5.5.2 All irradiance measurements made for a specific study shall be made using the same radiometer, previously calibrated against a spectroradiometric measurement.

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8.6 Calculation of the sun protection factor (SPF) and statistics

8.6.1 Calculation of the individual SPF (SPFi)

The SPFi of both the reference sunscreen formulation and the test product for each test subject shall be calculated using the following equation:

$$SPFi = \frac{MED_p}{MED_u}$$

where

MED_p is the minimal erythemal dose on test product-protected skin; and

MED_u is the minimal erythemal dose on unprotected skin.

8.6.2 Calculation of the SPF

8.6.2.1 The SPF results for the test product and the reference sunscreen formulation shall be calculated as the arithmetical mean of all valid SPFi values.

8.6.2.2 The minimum number of valid SPFi values shall be 10 and the maximum number shall be 20. A maximum of five results may be excluded from the calculation of the mean SPF, but each exclusion shall be justified. A sixth invalid result automatically invalidates the whole test for that test product and the SPF shall not be calculated for it.

8.6.3 Statistical criterion

For all SPF measurements, the 95 % CI on the mean SPF measured shall fall within a range of ± 17 % of the measured mean SPF. This applies to the test products and the reference sunscreen formulations (see C.1.4).

8.6.4 Acceptance criteria

8.6.4.1 Consequently, the actual number of subjects tested is defined as

a) the number required to produce a mean test product SPF with a 95 % CI, which falls within a range of ± 17 % of the measured mean SPF for the tested product, and

b) a mean reference sunscreen formulation SPF which has a 95 % CI, which falls within the range of ± 17 % of the measured mean SPF for the reference sunscreen formulation (see table C.1).

8.6.4.2 A minimum of 10 valid results is sufficient only if the statistical criterion is fulfilled, otherwise the number of subjects is increased from 10 until the statistical criterion is fulfilled up to a maximum of 20 valid results. The calculation for the statistical procedure shall be as in annex C.

8.6.5 Validation of the test

The mean SPF of the reference sunscreen formulation used in the test shall fall within the acceptance limits.

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8.7 Test reports

The test report shall contain at least the following information:

a) product identifier and expected SPF;

b) test subject information (number, name or identification code, skin phototype or ITA° value, age and gender);

c) characterization of the UV source (% RCEE compliance and intensity in units of radiant flux);

d) reference sunscreen formulation used;

e) individual MED for unprotected skin, test product-protected skin and reference sunscreen-protected skin;

f) SPFi values expressed to one decimal place, including all valid data and rejected data for the test product and for the reference sunscreen formulation;

g) mean SPF values, standard deviation on the mean and 95 % CI;

h) protocol deviations, if any;

i) identification, by test subject, of the technician who conducted the test; and

j) date of the test.

9 Test methods for the determination of "water resistant" and "very water resistant" properties of sunscreen products

9.1 Apparatus and materials

9.1.1 Source of ultraviolet radiation

The ultraviolet radiation source shall be in accordance with the requirements in 8.1.1.

9.1.2 Spa bath

9.1.2.1 The spa bath shall be equipped with

a) water jets for moderate circulation of the water,

b) sufficient capacity to allow complete immersion of the test sites, without touching the sides of the spa bath, and

c) a temperature control device.

9.1.2.2 Air jets shall not be used to circulate the water.

9.1.2.3 It is recommended that the water used in the spa bath complies with the requirements in SANS 241-1.

9.1.2.4 The water temperature during the test procedure shall be 29 °C ± 2 °C.

9.1.2.5 The spa bath shall be cleaned and refilled after the completion of the test procedure for each test subject.

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9.1.3 Reference sunscreen formulations

9.1.3.1 The reference sunscreen formulations shall be as in annex D.

9.1.3.2 The reference sunscreen formulation shall be P3.

9.1.3.3 P2 shall be used to perform a water resistance procedure check every four months.

9.1.3.4 The expected "water resistant" for P2 shall be > 50 %.

9.1.3.5 The reference sunscreen formulations P2 and P3 shall not be older than 12 months.

9.2 Test method for the determination of "water resistant"

NOTE "Water resistant" and water resistance are synonymous.

9.2.1 Main steps

The main steps for the determination of "water resistance" are:

a) selection of test subjects;

b) delineation of test sites on the back of the subject;

c) weighing of the product for dry testing (static testing);

d) application of the test product for dry testing (static testing);

e) drying time before UV exposure for dry testing (static testing);

f) UV exposure for dry testing (static testing);

g) weighing of the test product for water resistance testing;

h) application of the test product for water resistance testing;

i) drying time before water resistance testing;

j) immersion of test sites;

k) air drying;

l) second immersion of test sites;

m) air drying;

n) UV exposure after second immersion;

o) MED assessment; and

p) calculations and reporting.

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9.2.2 Test subjects

9.2.2.1 Selection of test subjects

Follow the requirements in 7.2.

9.2.2.2 Position of the test subjects

All steps in the test procedure shall be performed in the same position, for example, an upright position or a seated position.

9.2.3 Procedure for product application

Follow the procedure in 8.2.4.

9.2.4 Mode of delivery

Follow the procedure in 8.2.5.1 to 8.2.5.2 (inclusive).

9.2.5 Test procedure and chronology

Follow the procedure in annex E.

9.2.6 Calculation of water resistance

9.2.6.1 Determination of the mean dry SPF or static SPF

NOTE SPFs means dry SPF or static SPF.

9.2.6.1.1 The SPFs shall be calculated as the mean of the total individual dry SPF values for both the reference sunscreen formulation and the test product using the following equation:

$$SPFs = \frac{MED_p}{MED_u}$$

where

MED_p is the minimal erythemal dose on test product-protected skin; and

MED_u is the minimal erythemal dose on unprotected skin.

9.2.6.1.2 The 95 % CI of both the test product and the reference sunscreen formulation shall be determined.

9.2.6.1.3 The 95 % CI of the test product shall be within ± 17 % of the mean SPF is measured for the test product, and the 95 % CI of the reference sunscreen formulation shall be within ± 17 % of the mean SPFs measured for the reference sunscreen formulation (see table C.1).

9.2.6.2 Determination of post-immersion SPF

An individual percentage water resistance retention (% WRRi) value shall be calculated for each test subject using the following equation:

$$\%\ WRRi = \frac{(SPFiw - 1)}{(SPFis - 1)} \times 100$$

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where

SPFiw is the individual wet SPF after water immersion; and

SPFis is the individual dry SPF before water immersion.

9.2.6.3 Determination of the mean percentage water resistance retention

The mean percentage water resistance retention shall be expressed as the arithmetic mean of the "*n*" individual % WRR values (% WRRi):

% WRRi = [mean % WRR − *d*]

where the difference between the mean and CI (*d*) is calculated as follows:

$$d = \frac{t_u \times s}{\sqrt{n}}$$

where

t_u is the t value from the "one-sided" student-*t* distribution table at a probability level $p = 0{,}10$ with *n*-1 degrees of freedom (see table 10);

s is the standard deviation; and

n is the total number of test subjects in the test.

Table 10 — Student-*t* distribution

1	2
Total number of volunteers *n*	**t_u value**
10	1,383
11	1,372
12	1,363
13	1,356
14	1,350
15	1,345
16	1,341
17	1,337
18	1,333
19	1,1330
20	1,328

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9.2.7 Acceptance criteria

A product will be considered "water resistant" if

a) the value for the 90 % lower unilateral confidence limit [mean % WRR-*d*] is greater than or equal to 50 % of the mean dry SPF, and

b) the 95 % CI on the mean dry SPF is within ± 17 % of the mean dry SPF.

NOTE It is recommended that a laboratory checks its procedures at least every four months by testing the reference sunscreen formulation (P2) with nominal SPF 12 to SPF 15 (inclusive). A fresh sample of P2, not older than 12 months, should be used. The expected level of water resistance should be greater than 50 %.

9.3 Test method for the determination of "very water resistant"

9.3.1 Main steps

The main steps for the determination of "very water resistant" are as follows:

a) selection of test subjects;

b) delineation of test sites on the back of the subject;

c) weighing of the product for dry testing (static testing);

d) application of the test product for dry testing (static testing);

e) drying time before UV exposure for dry testing (static testing);

f) UV exposure for dry testing (static testing);

g) weighing of the test product for "very water resistant" testing;

h) application of the test product for "very water resistant" testing;

i) drying time before "very water resistant" testing;

j) immersion of test sites;

k) air drying;

l) second immersion of test sites;

m) air drying;

n) third immersion of test sites;

o) air drying;

p) fourth immersion of test sites;

q) UV exposure after fourth immersion;

r) MED assessment; and

s) calculations and reporting.

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9.3.2 Procedure

9.3.2.1 Follow the procedure described in 9.2.2 to 9.2.5 (inclusive).

9.3.2.2 After 20 min, allow the test subject to exit the spa bath and allow the test sites to air dry for 15 min.

9.3.2.3 Allow the test subject to re-enter the spa bath and immerse the test sites for a third time.

9.3.2.4 After 20 min, allow the test subject to exit the spa bath and allow the test sites to air dry for 15 min.

9.3.2.5 Allow the test subject to re-enter the spa bath and immerse the test sites for a fourth time.

9.3.2.6 After 20 min, allow the test subject to exit the spa bath and allow the test sites to air dry for 15 min or until completely dry.

9.3.2.7 Expose the test sites to UV radiation.

9.3.2.8 Assess the erythemal responses of the test sites using the equation given in 8.6.1.

9.3.3 Calculation of "very water resistant"

The determination of "very water resistant" shall be in accordance with 9.2.6.

9.3.4 Acceptance criteria

A product will be considered "very water resistant" if

a) the value for the 90 % lower unilateral confidence limit [mean % WRR-*d*] is greater than or equal to 50 % of the mean dry SPF, and

b) the 95 % CI on the mean dry SPF is within ± 17 % of the mean dry SPF.

NOTE It is recommended that a laboratory checks its procedures at least every four months by testing the reference sunscreen formulation (P2) with nominal SPF 12 to SPF 15 (inclusive). A fresh sample of P2, not older than 12 months, should be used. The expected level of "very water resistant" should be greater than 50 %.

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Annex A
(normative)

Permitted UV filters

Sunscreen products shall comply with the list of permitted UV filters as listed in table A.1.

Table A.1 — List of permitted UV filters that a sunscreen product may contain

1	2				3			4
Reference number	**Substance identification**				**Conditions**			**Wording of conditions of use and warnings**
	Chemical name/INN/XAN	**Name of common ingredients glossary**	**CAS number**	**EC number**	**Product type, body parts**	**Maximum concentration in ready for use preparation**	**Other**	
A	B	C	D	E	F	G	H	I
2	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidenemethyl) anilinium methyl sulfate	Camphor Benzalkonium Methosulfate	52793-97-2	258-19 -8	–	6 %	–	–
3	Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester/Homosalate	Homosalate	118-56-9	204-260-8	–	10 %	–	–
4	2-Hydroxy-4-methoxybenzophenone/ Oxybenzone	Benzophenone-3	131-57-7	205-031-5	–	6 %	Not more than 0,5 % to protect product formulation	Contains Benzophenone-3[a]
5	Moved or deleted							

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Table A.1 *(continued)*

1	2				3			4
Reference number	**Substance identification**				**Conditions**			**Wording of conditions of use and warnings**
	Chemical name/INN/XAN	**Name of common ingredients glossary**	**CAS number**	**EC number**	**Product type, body parts**	**Maximum concentration in ready for use preparation**	**Other**	
A	B	C	D	E	F	G	H	I
6	2-Phenylbenzimidazole-5-sulfonic acid and its potassium, sodium and triethanolamine salts/Ensulizole	Phenylbenzimidazole Sulfonic Acid	27503-81-7	248-502-0	–	8 % (as acid)	–	–
7	3,3'-(1,4-Phenylenedimethylene) bis(7, 7-dimethyl-2- oxobicyclo-[2.2.1]hept-1-yl-methanesufonic acid) and its salts/Ecamsule	Terephthalylidene Dicamphor Sulfonic Acid	92761-26-7, 90457-82-2	410-960-6	–	10 % (as acid)	–	–
8	1-(4-tert-Butylphenyl)-3-(4-methoxyphenyl)propane-1,3-dione/Avobenzone	Butyl Methoxydibenzoylmethane	70356-09-1	274-581-6	–	5 %	–	–
9	alpha-(2-Oxoborn-3-ylidene)-toluene-4-sulphonic acid and its salts	Benzylidene Camphor Sulfonic Acid	56039-58-8	–	–	6 % (as acid)	–	–
10	2-Cyano-3,3-diphenyl acrylic acid, 2-ethylhexyl ester/Octocrilene	Octocrylene	6197-30-4	228-250-8	–	10 % (as acid)	–	–
11	Polymer of N-{(2 and 4)-[(2-oxoborn-3-ylidene)methyl-]benzyl} acrylamide	Polyacrylamidomethyl Benzylidene Camphor	113783-61-2	–	–	6 %	–	–
12	2-Ethylhexyl 4-methoxycinnamate/Octinoxate	Ethylhexyl Methoxycinnamate	5466-77-3	0 226-775-7	–	10 %	–	–
13	Ethoxylated ethyl-4-aminobenzoate	PEG-25 PABA	116242-27-4	–	–	10 %	–	–

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Table A.1 *(continued)*

1	2				3			4
Reference number	**Substance identification**				**Conditions**			**Wording of conditions of use and warnings**
	Chemical name/INN/XAN	**Name of common ingredients glossary**	**CAS number**	**EC number**	**Product type, body parts**	**Maximum concentration in ready for use preparation**	**Other**	
A	B	C	D	E	F	G	H	I
14	Isopentyl-4-methoxycinnamate/Amiloxate	Isoamyl p-Methoxycinnamate	71617-10-2	275-702-5	–	10 %	–	–
15	2,4,6-Trianilino-(p-carbo-2'-ethylhexyl-1'-oxy)-1,3,5- triazine	Ethylhexyl Triazone	88122-99-0	402-070-1	–	5 %	–	–
16	Phenol,2-(2H-benzotriazol-2-yl)-4-methyl-6-(2-methyl-3- (1,3,3,3-tetramethyl-1-(trimethylsilyl)oxy)-disiloxanyl)propyl)	Drometrizole Trisiloxane	155633-54-8	–	–	15 %	–	–
17	Benzoic acid, 4,4-((6-((4-(((1,1-dimethylethyl)amino)carbonyl)phenyl)amino)-1,3,5-triazine-2,4-diyl)diimino)bis-, bis (2-ethylhexyl) ester/Iscotrizinol (USAN)	Diethylhexyl Butamido Triazone	154702-15-5	–	–	10 %	–	–
18	3-(4-Methylbenzylidene)-d1 camphor/Enzacamene	4-Methylbenzylidene Camphor	38102-62-4/ 36861-47-9	- / 253-242-6	–	4 %	–	–
20	2-Ethyl hexyl salicylate/Octisalate	Ethylhexyl Salicylate	118-60-5	204-263-4	–	5 %	–	–
21	2-Ethylhexyl 4-(dimethylamino)benzoate/ Padimate O (USAN:BAN)	Ethylhexyl Dimethyl PABA	21245-02-3	244-289-3	–	8 %	–	–
22	2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid and its sodium salt/Sulisobenzone	Be nzophenone-4, Benzophenone-5	4065-45-6/ 6628-37-1	223-772-2/ -	–	5 % (as acid)	–	–

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Table A.1 *(continued)*

1	2				3			4
Reference number	**Substance identification**				**Conditions**			**Wording of conditions of use and warnings**
	Chemical name/INN/XAN	**Name of common ingredients glossary**	**CAS number**	**EC number**	**Product type, body parts**	**Maximum concentration in ready for use preparation**	**Other**	
A	B	C	D	E	F	G	H	I
23	2,2'-Methylene-bis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethyl-butyl)phenol) / Bisoctrizole	Methylene Bis-Benzotriazolyl Tetramethylbutylphenol	103597-45-1	403-800-1	–	10 %	–	–
24	Sodium salt of 2,2'-bis(1,4-phenylene)-1H-benzimidazole-4,6-disulfonic acid) / Bisdisulizole disodium (USAN)	Disodium Phenyl Dibenzimidazole Tetrasulfonate	180898-37-7	429-750-0	–	10 % (as acid)	–	–
25	2,2'-(6-(4-Methoxyphenyl)-1,3,5-triazine-2,4-diyl)bis(5-((2-ethylhexyl)oxy)phenol) / Bemotrizinol	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	187393-00-6	–	–	10 %	–	–
26	Dimethicodiethylbenzalmalonate	Polysilicone-15	207574-74-1	426-000-4	–	10 %	–	–
27	Titanium dioxide[b]	Titanium Dioxide	13463-67-7/ 1317-70-0/ 1317-80-2	236-675-5/ 205-280-1/ 215-282-2	–	25 %[d]	–	–

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Table A.1 *(continued)*

1	2				3			4
Reference number	**Substance identification**				**Conditions**			**Wording of conditions of use and warnings**
	Chemical name/INN/XAN	**Name of common ingredients glossary**	**CAS number**	**EC number**	**Product type, body parts**	**Maximum concentration in ready for use preparation**	**Other**	
A	B	C	D	E	F	G	H	I
27a	Titanium dioxide[b]	Titanium dioxide (nano)	13463-67-7/ 1317-70-0/ 1317-80-2	236-675-5/ 205-280-1/ 215-282-2	–	25 %[d]	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation Only nanomaterials having the following characteristics are allowed: a) purity ≥ 99 %; b) rutile form, or rutile with up to 5 % anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes; c) median particle size based on number size distribution ≥ 30 nm; d) aspect ratio from 1 to 4,5, and volume specific surface area ≤ 460 m2/cm3; e) coated with Silica, Hydrated Silica, Alumina, Aluminium Hydroxide, Aluminium Stearate, Stearic Acid, Trimethoxycaprylylsilane, Glycerin, Dimethicone, Hydrogen Dimethicone, Simethicone; f) photocatalytic activity ≤ 10 % compared to corresponding non-coated or non-doped reference; and g) nanoparticles are photostable in the final formulation.	All ingredients present in the form of nanomaterials shall be clearly indicated in the ingredients list with the word "NANO" in brackets.

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Table A.1 *(continued)*

1	2				3			4
Reference number	**Substance identification**				**Conditions**			**Wording of conditions of use and warnings**
	Chemical name/INN/XAN	**Name of Common Ingredients Glossary**	**CAS number**	**EC number**	**Product type, body parts**	**Maximum concentration in ready for use preparation**	**Other**	
A	B	C	D	E	F	G	H	I
28	Benzoic acid, 2-[-4-(diethylamino)-2-hydroxybenzoyl]-. Hexylester	Diethylamino Hydroxy benzoyl Hexyl Benzoate	302776-68-7	443-860-6	–	10 %	–	–
29	1,3,5-Triazine, 2,4,6-tris [1,1'-biphenyl]-4-yl-, including as nanomaterial	Tris-biphenyl triazine Tris-biphenyl triazine (nano)	31274-51-8	–	–	10 %	Not to be used in sprays. Only nanomaterials having the following characteristics are allowed: a) median primary particle size > 80 nm; b) Purity ≥ 98 %; and c) Uncoated	All ingredients present in the form of nanomaterials shall be clearly indicated in the ingredients list with the word "NANO" in brackets.
30	Zinc oxide	Zinc oxide	1314-13-2	215-222-5	–	25 %[c]	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.	–

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Table A.1 *(concluded)*

1	2				3			4
Reference number	**Substance identification**				**Conditions**			**Wording of conditions of use and warnings**
	Chemical name/INN/XAN	**Name of common ingredients glossary**	**CAS number**	**EC number**	**Product type, body parts**	**Maximum concentration in ready for use preparation**	**Other**	
A	B	C	D	E	F	G	H	I
30a	Zinc oxide	Zinc oxide (nano)	1314-13-2	215-222-5	–	25 %[c]	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: a) purity ≥ 96 %, with wurtzite crystalline structure and physical appearance as clusters that are rod-like, star-like or isometric shapes (or both), with impurities consisting only of carbon dioxide and water, whilst any other impurities are less than 1 % in total; b) median diameter of the particle number size distribution D50 (50 % of the number below this diameter) > 30 nm and D1 (1 % below this size) > 20 nm; c) water solubility < 50 mg/L; and d) uncoated, or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetriethoxycaprylylsilane cross- polymer, or octyl triethoxy silane.	

[a] Not required if concentration is 0.5% or less and when it is used only for product protection purposes.

[b] For use as colourant, see annex IV, No 143, of the *CTFA Cosmetic Guideline.*

[c] In case of combined use of zinc oxide and zinc oxide (nano), the sum shall not exceed the limit given in column G.

[d] In case of combined use of titanium dioxide and titanium dioxide (nano), the sum shall not exceed the limit given in column G.

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Annex B
(informative)

UVA symbol for the labelling of sunscreen products

B.1 Figure B.1 shows the UVA symbol.



Figure B.1 — UVA symbol

B.2 UVA symbol for the labelling of sunscreen products that comply with ISO 24442, SANS 24443 or any other equivalent method.

B.3 This symbol shall not have any specific dimensions.

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Annex C
(normative)

Calculations and statistics

C.1 General equations

C.1.1 Individual sun protection factor (SPFi)

The SPFi of each test product on each test subject is calculated from the individual MED on unprotected skin (MEDu) and the individial MED on test product-protected skin (MEDp) using the following equation:

$$SPFi = \frac{MED_p}{MED_u} \quad (1)$$

C.1.2 Product sun protection factor

The SPF of the test product is the arithmetical mean of the SPFi values obtained from the total number of test subjects used (n), expressed to one decimal point. It is calculated using the following equation:

$$SPF = \frac{(\sum SPFi)}{n} \quad (2)$$

C.1.3 Standard deviation

The standard deviation (s) of SPFi is determined using the following equation:

$$s = \sqrt{\frac{\left(\sum(SPFi)^2 - \left((\sum SPFi)^2 / n\right)\right)}{(n-1)}} \quad (3)$$

C.1.4 Ninety-five per cent confidence interval (95 % CI)

The 95 % CI for the mean SPF is expressed as follows:

$$95\ \%\ CI = SPF - c \text{ to } SPF + c \quad (4)$$

where

$$c = t \times SEM$$

$$\text{i.e.} \quad c = \frac{t \times s}{\sqrt{n}} \quad (5)$$

where

SEM is the standard error of the mean;

t is the t value from the "two-sided" student-t distribution table at a probability level p = 0,05 and with degrees of freedom (ν (n-1)) (see table C.1); and

n is the total number of test subjects used.

$$CI[\ \%] = \frac{100 \times c}{SPF} \quad (6)$$

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Table C.1 — Student-*t* distribution

1	2
Total number of test subjects *n*	***t* value**
10	2,262
11	2,228
12	2,201
13	2,179
14	2,160
15	2,145
16	2,131
17	2,120
18	2,110
19	2,101
20	2,093
NOTE For spreadsheet calculations, the *t* value can be modelled by $t = 2{,}03 + 12{,}7/n^{1{,}75}$ (for $n \geq 4$).	

C.2 Experimental calculation procedure

C.2.1 Sequential procedure

C.2.1.1 An SPF test begins by testing the sunscreen product on an initial number of test subjects (n), which shall be at least 10. The individual sun protection factor (SPFi) for the product on each test subject is calculated by using the equation in C.1.1.

C.2.1.2 From the SPFi values a provisional mean sun protection factor for the initial test subjects (for example, 10 subjects (SPF_n)) is calculated using the equation in C.1.2 together with a provisional 95 % CI (95 % CI_n), using equations (4), (5), (6) given in C.1.4 and the *t* values in table C.1, as follows:

$$SPF_n = \frac{\Sigma SPF_i}{n}$$

95 % CIn = SPFn − cn to SPFn + cn

$$cn = \frac{t_n \times s_n}{\sqrt{n}}$$

where

c_n is the percentage of the mean SPF_n, representing the required CI;

t_n is the *t* value from the "two-sided" student-*t* distribution table at a probability level $p = 0{,}05$ and with degrees of freedom (ν (n-1)) (see table C.1);

s_n is the standard deviation from the first number of test subjects calculated by using the equation in C.1.3.

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$$CI_n[\%] = \frac{100 \times c_n}{SPF_n}$$

C.2.1.3 If the calculated provisional CI_n[%] is greater than 17 % of the provisional mean SPF_n value, then testing of the sunscreen product shall continue on additional subjects until the provisional CI_n[%] is equal to or less than 17 % of the mean provisional SPF.

C.2.1.4 If this criterion is not fulfilled after 20 valid test subjects, then the test shall be repeated.

C.2.2 Predicted number of test subjects (n^*)

If the CI_n[%] on the provisional SPF_n is greater than 0,17 SPF_n, then the predicted total number of test subjects (n^*) necessary to meet the statistical criterion can be estimated using the following equation:

$$n^* = \left(\frac{t_n \times s_n}{c_n} \right)^2$$

where

t_n is the t value from table C.1;

s_n is the best estimate from the population standard deviation (for example, the n results); and

c_n is 17 % of the mean SPF_n, representing the required CI.

Example: When n^* is calculated after the first 10 data:

$$n^* = \left(\frac{2{,}262 \ s_n}{0{,}17 \ SPF_n} \right)^2$$

i.e. $$n^* = \left(\frac{13{,}30 \ s_n}{SPF_n} \right)^2$$

C.3 Examples

C.3.1 Example 1

C.3.1.1 Table C.2 is an example of a table gathering data, calculations and results. When data are entered in spreadsheet software, all calculations can be performed automatically.

C.3.1.2 Table C.2 shows the results for product EX1 with expected SPF 10. After 10 subjects had been exposed, the results were as follows:

a) SPF_n = 11,4;

b) s_n = 2,4;

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c) c_n = 1,73;

d) 95 % CI_n = 9,7 to 13,1; and

e) CI_n[%] = 15,1 %.

C.3.1.3 Since the CI_n[%] was less than 17 % of the mean SPF, no further testing was necessary and the final SPF of the product EX1 was:

SPF = 11,4 with CI[%] = 15,1 (2,6).

C.3.2 Example 2

C.3.2.1 Table C.3 shows the results for product EX2 with expected SPF 20. After 10 subjects had been exposed, the results were as follows:

a) SPF_n= 21,3;

b) s_n = 6,0;

c) c_n = 4,3;

d) 95 % CI_n = 17 to 25,6; and

e) CI_n[%] = 20,3 %.

C.3.2.2 The relative variation of the results was higher than in example 1 (see C.3.1) and the statistical criterion was not met (CI_n[%] was greater than 17 % of the mean SPF). The test had to be continued and the likely total number (n) of subjects necessary was calculated as follows:

$$n = \left(\frac{t_n \times s_n}{c_n}\right)^2$$

$$= \left(\frac{2,262 \times 6,0}{3,61}\right)^2$$

$$= 14$$

C.3.2.3 Five subjects were later added and the newly calculated provisional results were as follows:

a) SPF_{15} = 21,2;

b) s_{15} = 6,2;

c) c_{15} = 3,4 (with n = 15 and t_{15} = 2,145);

d) 95 % CI_{15} = 17,8 to 24,6; and

e) CI_{15}[%] = 16,2 %.

C.3.2.4 The criterion was met (see 7.3.4) after the fifteenth subject (CI_n[%] less than 17 % of the mean SPF) and the final SPF of product EX2 was:

SPF = 21,2 with CI[%] = 16,2 % (2,6).

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Table C.2 — Example of calculation with 10 subjects (expected SPF: 10)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Harmonized SPF test result table									**Laboratory**						
Product code: EX1			Expected SPF: 10				Date:…		Data sheet No.: 2 of 3					UV source: Xe MP	
Test			**Subjects**						**Results**					**Conclusion:** CI_n[%] = <17 %	**Comment**
Subject No.	Exposure date	Technician name	Subject code	Skin ITA°	Photo type	MEDu (mJ/cm^{-2})	MEDp (mJ/cm^{-2})	SPFi	SPF_n	s_n	c_n	CI_n[%] $\left(\frac{100\ Cn}{SPFn}\right)$	n		
1				56,4	I	19	290	15,3	–	–	–	–			
2				48,6	II	29	370	12,8	–	–	–	–			
3				58,1	I	23	230	10,0	–	–	–	–			
4				43,5	II	37	420	11,4	–	–	–	–			
5				44,0	II	29	230	7,9	–	–	–	–			
6				42,7	II	23	290	12,6	–	–	–	–			
7				34,9	III	46	370	8,0	–	–	–	–			
8				57,0	I	19	260	13,7	–	–	–	–			
9				54,8	II	29	370	12,8	–	–	–	–			
10				45,3	II	23	230	10,0	11,4	2,4	1,73	15,1 %	8	Complies	
11															
12															
13															
14															

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Table C.2 (*concluded*)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Harmonized SPF test result table									**Laboratory**						
Product code: EX1			Expected SPF: 10				Date:…		Data sheet No.: 2 of 3					UV source: Xe MP	
Test			**Subjects**						**Results**					**Conclusion:** CI_n[%] = <17 %	**Comment**
Subject No.	Exposure date	Technician name	Subject code	Skin ITA°	Photo type	MEDu (mJ/cm^{-2})	MEDp (mJ/cm^{-2})	SPFi	SPF_n	s_n	c_n	$CI_n[\%]\left(\frac{100\,C_n}{SPF_n}\right)$	n		
15															
16															
17															
18															
19															
20															
Final result:		Mean SPF = 11	11,4				s = 2,4		c = 1,7		CI[%] = 15,1 %			95 % CI: 9,7 – 13,1 (n=10)	

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Table C.3 — Example of calculation with 15 subjects (expected SPF: 20)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Harmonized SPF test result table									**Laboratory**						
Product code: EX2			Expected SPF: 20			Date:…			Data sheet No.: 3 of 3					UV source: Xe MP	
Test			**Subjects**						**Results**					**Conclusion:** CI_n[%] = <17 %	**Comment**
Subject No.	Exposure date	Technician name	Subject code	Skin ITA°	Photo type	MEDu (mJ/cm^{-2})	MEDp (mJ/cm^{-2})	SPFi	SPF_n	s_n	c_n	CI_n[%] $\left(\frac{100\,Cn}{SPFn}\right)$	n		
1				56,2	I	35	700	20,0	–	–	–	–			
2				42,5	II	44	1 084	24,9	–	–	–	–			
3				50,6	II	35	875	25,0	–	–	–	–			
4				32,8	III	68	875	12,9	–	–	–	–			
5				45,1	II	44	1 094	24,9	–	–	–	–			
6				47,9	II	35	875	25,0	–	–	–	–			
7				**29,4**	**III**	**85**	**1 367**	**16,1**	**–**	**–**	**–**	**–**			
8				54,3	II	44	560	12,7	–	–	–	–			
9				43,3	II	35	1 094	31,3	–	–	–	–			
10				59,9	I	44	872	19,9	21,3	6,0	4,31	20,3 %	14	Does not comply	
11				35,0	III	68	875	12,9	20,5	6,3	4,20	20,5 %	17	Does not comply	
12				48,8	II	44	1 367	31,1	21,4	6,7	4,26	19,9 %	18	Does not comply	
13				36,5	I	35	875	25,0	21,7	6,5	3,92	18,1 %	16	Does not comply	
14				47,1	II	44	700	15,9	21,2	6,4	3,71	17,5 %	16	Does not comply	
15				38,1	III	55	1 094	19,9	21,2	6,2	3,43	16,2 %	15	Complies	

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Table C.3 (*concluded*)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Harmonized SPF test result table									**Laboratory**						
Product code: EX2			Expected SPF: 20				Date:…		Data sheet No.: 3 of 3					UV source: Xe MP	
Test			**Subjects**						**Results**					**Conclusion:** CI_n[%] = <17 %	**Comment**
Subject No.	Exposure date	Technician name	Subject code	Skin ITA°	Photo type	MEDu (mJ/cm^{-2})	MEDp (mJ/cm^{-2})	SPFi	SPF_n	s_n	c_n	$CI_n[\%]\left(\frac{100\,Cn}{SPFn}\right)$	n		
16															
17															
18															
19															
20															
Final result:			Mean SPF = 21,1				s = 19,9		c = 21,2		CI[%] = 16,2 %			95 % CI: 17,8 – 24,6 (n = 15)	

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Annex D
(normative)

SPF reference sunscreen formulations

D.1 Mean SPF and acceptance limits for reference sunscreen formulations

NOTE The acceptance limits for P2 and P7 are from the Food and Drug Administration (FDA) Sunscreen Drug Products for over the counter (OTC) human use, and the acceptance limit for P3 is from the international SPF test method. Table D.1 gives the mean SPF and acceptance limits.

Table D.1 — Mean SPF and acceptance limits

1	2	3	
Reference sunscreen formulation	**Mean SPF**	**Indicative range**	
		Lower limit	**Upper limit**
P2	16,1	13,7	18,5
P3	15,7	13,7	17,7
P7	4,4	4,0	4,8

D.2 P2 High SPF reference sunscreen formulation (100 g)

D.2.1 Ingredients for phase 1

Lanolin	4,5 g
Theobroma cacao (cocoa) seed butter	2,0 g
Glyceryl stearate SE	3,0 g
Stearic acid	2,0 g
Ethylhexyldimethyl PABA (padimate O)	7,0 g
Benzophenone-3 (Oxybenzone)	3,0 g

D.2.2 Ingredients for phase 2

Water	71,6 g
Sorbitol (liquid 70 %)	5,0 g
Triethanolamine	1,0 g
Methylparaben	0,3 g
Propylparaben	0,1 g

D.2.3 Ingredient for phase 3

Benzyl alcohol	0,5 g

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D.2.4 Preparation

C.2.4.1 Heat the ingredients of phase 1 (see D.2.1) at a temperature between 77 °C and 82 °C while mixing with a propeller agitator until uniform.

D.2.4.2 Mix phase 2 ingredients (see D.2.2) with a propeller agitator at a temperature between 77 °C and 82 °C.

D.2.4.3 Add the phase 1 preparation (see D.2.4.1) to the phase 2 preparation (see D.2.4.2) and mix until smooth and uniform.

D.2.4.4 Slowly cool the mixture to a temperature between 49 °C and 54 °C.

D.2.4.5 Add phase 3 ingredients (see D.2.3) and mix until smooth and uniform.

D.2.4.6 Cool the mixture to a temperature between 35 °C and 41 °C.

D.2.4.7 Compensate for waterloss (for example, make up to 100 g) and homogenize. Avoid air entrapment.

D.2.4.8 Cool the mixture further to a temperature between 27 °C and 32 °C.

D.2.5 Physiochemical data

Appearance:	White, yellowish fluid emulsion
pH:	8,0 ± 0,5
Viscosity (20 °C):	250 mPa·s to 400 mPa·s (Rheomat RM 180-Mobile 3, 200 r/min; time of assessment: 10 min)
	8400 cps to 13 000 cps (RVT Helipath B 10 r/min)
Density (20 °C):	0,970 g/cm^3 ± 0,05 g/cm^3

D.2.6 Storage

The P2 reference sunscreen formulation shall be stored at 20 °C for 12 months, in a container that is protected from light.

D.3 P3 High SPF reference sunscreen formulation (100 g)

D.3.1 Ingredients for phase 1

Cetearyl alcohol	2,205 g
PEG-40 Castor oil	0,63 g
Sodium cetostearyl sulfate	0,315 g
Decyl oleate	15,0 g
Ethylhexyl methoxycinnamate	3,0 g
Butyl methoxydibenzoylmethane	0,5 g
Propylparaben	0,1 g

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D.3.2 Ingredients for phase 2

Water	53,57 g
Phenylbensimidazole sulfonic acid	2,78 g
Sodium hydroxide (45 % solution)	0,9 g
Methylparaben	0,3 g
Disodium EDTA	0,1 g

D.3.3 Ingredients for phase 3

Water	20,0 g
Carbomer (grade 980)	0,3 g
Sodium hydroxide (45 % solution)	0,3 g

D.3.4 Preparation

D.3.4.1 Heat the ingredients of phase 1 (see D.3.1) at a temperature between 75 °C and 80 °C.

C.3.4.2 Heat the ingredients of phase 2 (see D.3.2) at 80 °C. If necessary, increase the heat until the solution is clear and cool to a temperature between 75 °C and 80 °C.

D.3.4.3 While stirring phase 2, add the phase 1 mixture (see D.3.4.1).

D.3.4.4 Disperse the carbomer (see D.3.3) in water by stirring with a rotor dispenser and add the sodium hydroxide.

D.3.4.5 While stirring the mixture in D.3.4.3, add ingredients for phase 3 (see D.3.3) and homogenize for 3 min.

D.3.4.6 Adjust the pH with sodium hydroxide or lactic acid and stir until completely cool.

D.3.4.7 Compensate for waterloss (for example, make up to 100 g) and homogenize.

D.3.5 Physicochemical data

Appearance:	White to slightly yellowish emulsion
pH:	7,5 ± 0,5
Viscosity (20 °C):	500 mPa·s to 750 mPa·s (Rheomat RM 180-Mobile 3, 200 r/min; time of assessment: 10 min)
	1 800 mPa·s to 3 000 mPa·s (Haake VT 181 Rheometer, Rotary body MV II ST, Process U = 4, time of assessment: 20 s)
	1 300 cps to 3 500 cps (RVT Spindle 4, 20 r/min)
Density (20 °C):	0,970 g/cm^3 ± 0,05 g/cm^3

D.3.6 Storage

The P3 reference sunscreen formulation shall be stored at 20 °C for 12 months, in a container that is protected from light.

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D.4 P7 Low SPF reference sunscreen formulation (100 g)

D.4.1 Ingredients for phase 1

Lanolin	5,0 g
Homosalate	8,0 g
Petrolatum	2,50 g
Stearic acid	4,0 g
Propylparaben	0,05 g

D.4.2 Ingredients for phase 2

Methylparaben	0,1 g
Disodium EDTA	0,05 g
Propylene glycol	5,0 g
Triethanolamine	1,0 g
Water (purified)	74,3 g

D.4.3 Preparation

D.4.3.1 Heat phase 1 ingredients (see D.4.1) at a temperature between 77 °C and 82 °C, with constant stirring, until soluble.

D.4.3.2 Heat phase 2 ingredients (see D.4.2) at a temperature between 77 °C and 82 °C, with constant stirring, until soluble.

D.4.3.3 Add the phase 1 mixture (see D.4.3.1) slowly to the phase 2 mixture (see D.4.3.2) while stirring.

D.4.3.4 Continue stirring until the emulsion formed is cooled to a temperature between 15 °C and 30 °C.

D.4.3.5 Add sufficient water to obtain 100 g of the reference sunscreen formulation.

D.4.4 Physicochemical data

pH:	8,0 ± 0,5
Viscosity (20 °C):	250 mPa·s to 400 mPa·s (Rheomat RM 180-Mobile 3, 200 r/min; time of assessment: 10 min)
Density (20 °C):	0,970 g/cm^3 ± 0,05 g/cm^3

D.4.5 Storage

The P7 reference sunscreen formulation shall be stored at 20 °C for 12 months, in a container that is protected from light.

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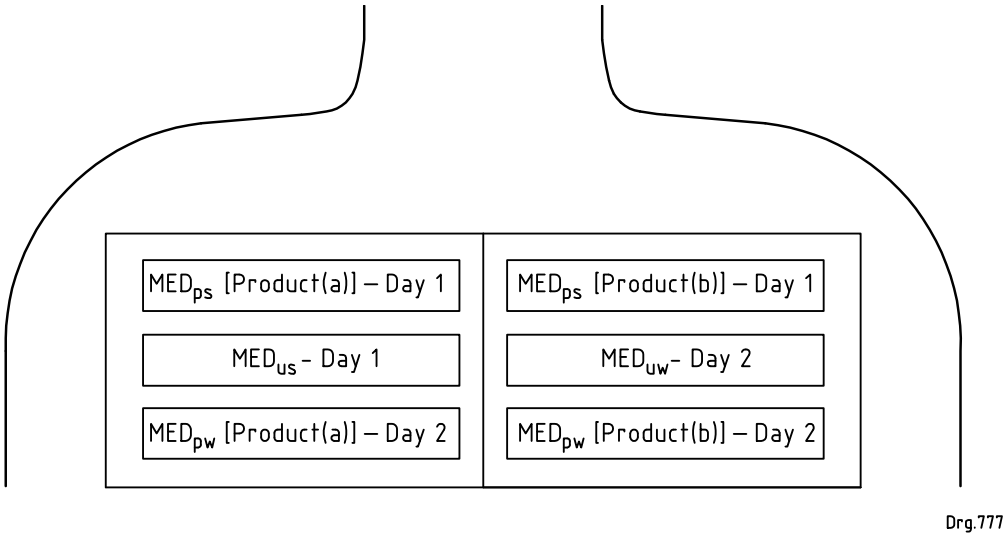
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Annex E
(normative)

Test procedure and chronology for the determination of water resistance

E.1 Randomization of test sites

The test procedure allows for two or more products to be tested at the same time. Figure E.1 gives an illustrative example of how multiple products may be positioned on a single subject. Test site positioning shall always be randomized on each individual subject and across the whole panel of volunteers.



Key

MEDus is the unprotected, dry MED (non-immersed in water).

MEDuw is the unprotected, wet MED (post-immersion in water).

MEDps is the protected, dry MED (non-immersed in water).

MEDpw is the protected, wet MED (post-immersion in water).

Figure E.1 — Test sites

E.2 Test chronology and procedure

E.2.1 General

The procedure given in E.2.2 to E.2.4 (inclusive) shall be followed for each volunteer, and shall be repeated on between 10 and up to 20 volunteers, until statistical criteria are satisfied.

E.2.2 Day 1

E.2.2.1 Determine the unprotected, dry MED (MEDus) on previously unexposed skin.

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E.2.2.2 Apply product to designated dry SPF sites (MEDps [Product(a)]; MEDps [Product(b)] etc.).

E.2.2.3 Allow 15 min to 30 min for the product to dry.

E.2.2.4 Expose the test product-treated dry sites [MEDps Product(a), MEDps Product(b), etc.] to progressive UV doses in accordance with 8.3.5.

E.2.3 Day 2

E.2.3.1 Assess the erythemal reactions from previous day's UV exposures on unprotected, dry MEDus sites and determine the dry MEDus for unprotected, non-water-immersed skin.

E.2.3.2 Assess the erythemal reactions from previous day's UV exposures on test product-protected dry MEDps sites and determine the dry MEDps for test product-protected, non-water-immersed skin.

E.2.3.3 Calculate the individual dry SPF (SPFis).

E.2.3.4 Apply product to test sites designated for water immersion (MEDpw [Product(a)], MEDpw [Product(b)] etc.).

E.2.3.5 Allow to dry for 15 min to 30 min.

E.2.3.6 Immerse volunteer in water for 20 min with continuous water circulation.

E.2.3.7 Remove volunteer from immersion equipment and allow test sites to air dry with no towelling for 15 min.

E.2.3.8 Return volunteer to immersion equipment and immerse in water for a further 20 min with continuous water circulation.

E.2.3.9 Remove volunteer from immersion equipment and allow test sites to air dry with no towelling for 15 min or until the test site is completely dry. Ensure that all test sites are free from water droplets. If water droplets are present, extend air drying time.

E.2.3.10 Expose test product-treated water-immersed sites [MEDpw Product(a), MEDpw Product(b) etc.] to progressive UV doses in accordance with 8.3.5.

E.2.3.11 Expose the unprotected MED (MEDuw) to progressive UV doses in accordance with 8.3.5.

NOTE This unprotected MED is post-immersion in water so as to be compatible with the protected wet MEDpw.

E.2.4 Day 3

E.2.4.1 Assess the erythemal reactions from previous day's UV exposures on unprotected, wet MEDuw sites and determine MEDuw for unprotected skin, after water immersion.

E.2.4.2 Assess the erythemal reactions from previous day's UV exposures on test product-protected, wet MEDpw sites and determine MEDpw for test product-protected, water-immersed skin.

E.2.4.3 Calculate individual wet SPF (SPFiw (see 9.2.6.2)).

NOTE 1 If necessary, the test may be shortened to cover only two days by combining days 1 and 2. In this case, the dry MED and wet MED determinations are then conducted on the same day with an assessment of all erythemal responses on the start of day 2. If this shortened procedure is adopted, then the investigator should be aware that water immersion, subsequent to exposing the skin to UV light in order to determine the dry SPF, might affect the dry SPF measured.

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NOTE 2 Conducting a dry SPF on skin which has been previously hydrated or is at an altered temperature as a result of a previous water immersion can lead to variability in the SPF measured. Since this does not happen in a standard SPF test, the dry SPF should not be determined after immersion in water.

NOTE 3 It is also possible to conduct the wet SPF determination several days after the dry SPF. However, if this amended procedure is adopted, it is essential that an appropriate repeat, unprotected MED is performed on every day that test product-protected exposure occurs.

NOTE 4 Dry and wet SPFs should always be determined on the same volunteer in the same laboratory using the same instrumentation and test conditions.

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