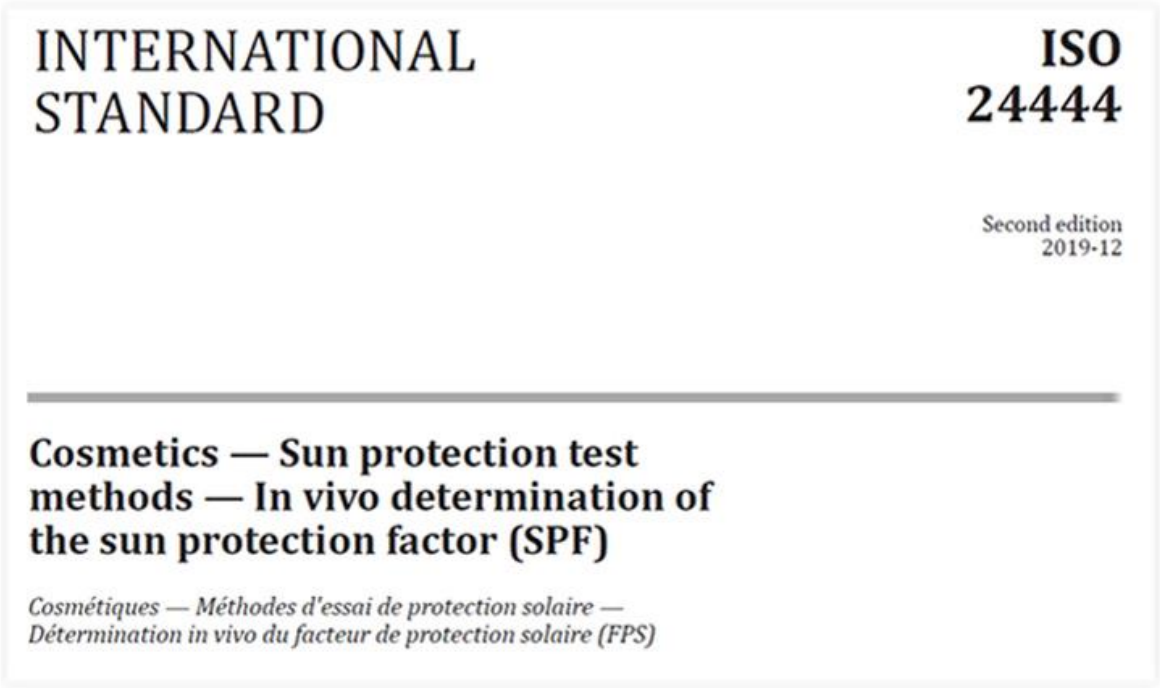
Dear everyone,
SUNJIN is now providing “free preliminary clinical test” for sun protection with new ISO24444 edited last December.


INTERNATIONAL STANDARD

ISO 24444

Second edition
2019-12

Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF)

Cosmétiques — Méthodes d'essai de protection solaire — Détermination in vivo du facteur de protection solaire (FPS)

In edited version, they revised the definition of Minimal Erythema Does (MED), selection of participants, application procedures, reference standard sunscreens, evaluation method and test reports. Please see more details on the changes made in the edited version through following pages.

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Editions

1. The definition of the minimal erythema dose (MED)

Before	After
2.4 **minimal erythemal dose** **MED** lowest dose of ultraviolet radiation (UVR) 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	**3.4** **minimal erythemal dose** **MED** lowest *erythemal effective radiant exposure* (H_{er}) (3.1.4) that produces the first perceptible unambiguous erythema with defined borders appearing over more than 50 % of UV exposure subsite, 16 h to 24 h after UV exposure Note 1 to entry: Annex F contains visual references and guidance for the acceptable MED appearance.
MED (minimal erythema dose) : First noticeable erythema found with minimal UV radiation.	**MED (minimal erythema dose)** : 50 % of erythema found with minimal UV radiation.

2. The selection of participants

Before	After
4.1.2 Skin phototype of the test subjects Test subjects included in the SPF test shall be only phototypes I, II or III according to Fitzpatrick[7] or shall have an ITA° value > 28° by colorimetric methods (see Annexes A and E) and be untanned on the test area. An SPF test should not contain subjects who are all of the same phototype. A competent scientist or technician should examine each subject to ensure that there is no condition which might put the subject at risk and that the outcome of the test cannot be compromised by adverse skin conditions such as sun damage, pigmentation marks and previous history of abnormal response to the sun (see Annex A).	**5.1.2 Skin colour of the test subjects** Test subjects included in the SPF test shall have an ITA° value of at least 28° by colourimetric methods (see Annexes A and E) and be untanned on the test area. The average of the subjects making up a test panel shall have an ITA° between 41° and 55°. When possible, there should be subjects with ITA°s in each of the three ITA° bands, 28° to 40°, 41° to 55°, and >56°. Where this is not possible, there shall be at least three individuals in each of two of the three ITA° bands described in the previous sentence. A trained and competent scientist or technician should examine each subject to ensure that there is no condition which might put the subject at risk and that the outcome of the test cannot be compromised by adverse skin conditions such as sun damage, pigmentation marks and previous history of abnormal response to the sun (see Annex A). The test sites intended for UV exposure shall be free from blemishes and hair, and have an even colour tone with no variation in ITA° greater than 5° from each other or the MED_u test area.
Standard for the selection of participants : Participants need to have ITA° value above 28° and they can be tested for skin type I, II, III. 55 < ITA value Type 1 41 < ITA value Type 2 — **SPF is Measureable** 28 < ITA value Type 3 10 < ITA value Type 4 — **PA is Measureable**	**Standard for the selection of participants** : Average of ITA° value for total participants need to be between 41°~ 55° with average skin type of II. 55 < ITA value Type 1 41 < ITA value Type 2 — **SPF is Measureable** 28 < ITA value Type 3 10 < ITA value Type 4 — **PA is Measureable**

3. The additional standard samples for SPF measurement

<table>
<tr><th colspan="2">Before</th><th colspan="2">After</th></tr>
<tr><td colspan="2">

8.2.2 Expected SPF < SPF 20

Any one of the following reference sunscreen formulations shall be used: P2, P3 or P7.

If a high SPF reference formulation is used, there is no necessity to also include the low SPF reference formulation in the test even though there may be low SPF test products.

8.2.3 Expected SPF ⩾ SPF 20

One of the following reference sunscreen formulations shall be used: P2 or P3.

If a high SPF reference formulation is used, there is no necessity to also include the low SPF reference formulation in the test even though there may be low SPF test products.

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8.2.2 Establishment of SPF for product claim: When testing is conducted for the purpose of supporting a label claim of a product intended for market the following reference standards shall be used for testing with the test product:

— SPF Claim ≤24: P2 or P3 reference standard (all subjects);

— SPF ≥25 but less than SPF 50: P5 or P6 reference standard (on at least 5 subjects) and P2 or P3 on remaining subjects;

— SPF ≥50: P8 reference standard (on at least 5 subjects) and P2 or P3 on the remaining subjects.

Additional subjects may be added as necessary to achieve means for the reference standards that are within the acceptance range.

</td></tr>
<tr><th>Estimated Value</th><th>Reference sunscreen formulation</th><th>Estimated Value</th><th>Reference sunscreen formulation</th></tr>
<tr><td>SPF < 20</td><td>P2, P3, P7</td><td>SPF ≤ 24</td><td>P2, P3</td></tr>
<tr><td rowspan="2">SPF ≥ 20</td><td rowspan="2">P2, P3</td><td>25 < SPF ≤ 5 0</td><td>P2, P3, P5, P6</td></tr>
<tr><td>50 ≤ SPF</td><td>P2, P3, P8</td></tr>
<tr><td colspan="4">Previously, only P2, P3, and P7 standard samples were available to measure below or above SPF 20, but now P5, P6, and P8 standard samples are added in order to measure more precisely for the samples above SPF 25.</td></tr>
</table>

4. The application procedures

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Method A: Fluid products. To aid uniform coverage, droplets (at least 15 per 30 cm^2, 30 per 60 cm^2) of the product should be deposited within the test site using a syringe/pipette at one time, then spread over the whole test site, first with circular movements to gather the droplets and second in horizontal and vertical directions using light pressure as shown in Figure 3. It is recommended that during the whole process, the application finger stays in contact with the skin.

Spray products provided in a pressurized container should first be degassed by puncturing a very small pinhole in the container to relieve all of the pressure. Degassing shall be done with appropriate safety precautions by securing the can within a ventilated safety hood with appropriate personnel safety equipment. The degassed can shall be allowed to rest for 24 h at room temperature when the product shall be decanted into a separate closed container with minimal headspace to minimize evaporation.

Method B: Non-flowing viscous liquids and semi-solids. Test product should be measured into a weigh boat and applied by finger in multiple areas of the test site, first with circular movements to gather the material and second in horizontal and vertical directions using light pressure as in Figure 3. It is recommended that during the whole process, the application finger stays in contact with the skin.

Method C: Powders. Aliquots of powder should be transferred to the skin in a grid-like manner, using a spatula, sponge, or finger.

The accumulated powder shall be tapped and then spread over the whole test site using a finger with or without a finger cot. Alternatively, the tip of a pre-loaded cosmetic applicator puff may be used instead of a finger. In this case, it is important to verify that (2,00 ± 0,05) mg/cm^2 of test powder product remains on the skin after spreading, by weighing the powder remaining on the tip of the applicator puff.

Purified water or another suitable solvent that has no UV protection properties may be applied on the skin before the powder application to help the sample adhere to the application site. Water or solvent should not transform the powder into a paste and thus influence its SPF value.

Method D: Foaming formulations. For samples which are presented as foams and where the contents cannot be extracted or dispensed other than as a foam, the test product should be measured into a weighing boat and then the sample allowed to degas or deaerate until they can be easily applied to the skin. Application will be subsequently accomplished following Method B.

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9.4.8.1 Product application technique

The application technique to be used is dependent on the product type.

Form	Recommended application method
Lotion	Method A
Cream	Method A
Oil	Method A
Liquid	Method A
Gel	Method A
Stick	Method B
Balm	Method B
Aerosol spray	Degas then Method A
Pump spray	Method A
Roll on	Method A or B
Powder	Method C
Foaming Formulations	Method D

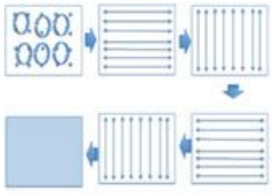

Figure 3 — Application techniques for Methods A and B

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<tr><td colspan="2">Previously, application methods were only available for liquid and powder types, but now they provided application method for various types of samples including Lotion, Cream, Liquid, Stick, Spray and Powder with appropriate flow chart.</td></tr>
</table>

5. The evaluation methods

After

F.1.3 Erythemal responses shall be observed in a "blind" manner (with exception of the provisional MED_{ip}). The observers of erythemal responses on any subjects shall not be the same persons as the ones who perform product application and exposure. The observers shall not be aware of the test design (randomization of the test sites) on that subject.

The grading scale for UV exposed test subsites shall be:

— **0**: no erythema present

— **0.5**: ambiguous erythema, and/or no clear border, and/or not filling more than 50 % of the exposure subsite

— **1**: Perceptible unambiguous erythema with defined borders filling more than 50 % of the exposure subsite (MED if it is the lowest exposure dose with grade 1)

— **2**: Moderate to intense erythema

Evaluation shall be done on each subsite individually using the definition of MED_i. The evaluation has to be done on the presence or absence of the erythema and not on the intensity. An illogical progression but with erythema (≥Grade 0.5) present does not have to be discarded. Examples are given for guidance.

Table 1 — Data rejection criteria

Observation	MED_{ip}	MED_{ip}	Reference standard
No grade of at least 1 for any exposed sub sites[a]	Data for subject is rejected Does not count against total allowable rejected number of subjects	Data for test product is rejected. Does not count against total allowable rejected number of subjects	Data for subject is rejected Failure counts against allowable rejected number of subjects
All test subsites show erythema of at least grade 1[b]	Data for subject is rejected Does not count against number of total allowable rejections	Data for test product is rejected Counts against number of total allowable rejections	Data for subject is rejected Counts against number of total allowable rejections
erythemal response(s) is (are) absent for exposures higher than the determined MED dose (randomly absent)[c]	Data for subject is rejected Does not count against number of total allowable rejections	Data for subject is rejected Counts against number of total allowable rejections	Data for subject is rejected Counts against number of total allowable rejections
Non-compliance of the subject[d] OR Technical failure[e]	Data for subject is rejected Does not count against number of total allowable rejections	Data for subject is rejected Does not count against number of total allowable rejections	Data for subject is rejected Does not count against number of total allowable rejections

Observations definitions:

[a] **No Grade of at least 1 for any exposed sub:** All exposed subsites have grades of 0, or 0.5, and no qualifying MED (Grade 1) is observed.

[b] **All test sites show erythema of at least Grade 1:** No sites have grades of 0 or 0.5, and a MED response cannot be established.

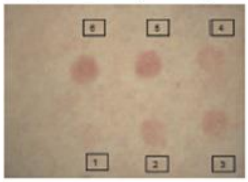
[c] **Erythemal response(s) is (are) absent for exposures higher than the determined MED dose (randomly absent):** A Grade of 0 is observed at an exposure dose higher than the determined MED, (randomly absent or illogical sequence).

[d] **Non-compliance of the subject:** Subject does not follow instructions during or after the treatment or UV exposures (that could affect the outcome of the test [wipes sunscreen treated areas during application or exposures, medicates with anti-inflammatory drugs, exposes treatment areas to UV light (sunlight or other UV source), irritates treated area, etc.).

[e] **Technical failure:** Failure of equipment or procedures during the treatment phases of the procedure (for example: incorrect lamp intensity or fluctuations, incorrect exposure times, incorrect site application of sunscreen, and similar reasons) that would jeopardize the integrity of the treatments and conclusions.

Example

Figure F.1 — Skin Response Example 1



Key

Subsite 1: ambiguous erythema, no clear border Grade 0.5
Subsite 2: unambiguous erythema, >50 % of area, clear border: Grade 1 = **MED**
Subsite 3: unambiguous erythema, >50 % of area, clear border: Grade 1
Subsite 4: unambiguous erythema, >50 % of area, clear border: Grade 1
Subsite 5: unambiguous erythema, >50 % of area, clear border: Grade 2
Subsite 6: unambiguous erythema, >50 % of area, clear border: Grade 2

NOTE The MED_i is taken on subsite 2.

They classified with specific grades depend on the level of erythema formed and they provided appropriate evaluation methods for each different grade with examples of each.
In addition standardized for rejection as well.

6. Additional data for a test report

Before

EVALUATION OF SPF(ISO24444,601-300W Multiport UV Solar Simulator)

Client: SUNJIN
Formula: SAMPLE#1
Test No: SJIV-200803-1

Expected SPF: 30 Expected standard SPF : 13.7~17.7

No.	Date	Panel	Sex	Age	ITA°	Skin type	UW/cm² Amps	MEDu (sec)	UW/cm² Amps	MEDp Std (sec)	UW/cm² Amps	MEDp Product (sec)	SPF Std	SPF Product	Tech Initials
1	2020. 08. 03	LVJ	F	23	48.7	II	6304	60	857	1148.37	740.7	1379.6	15.50	30.00	SA

MED : Minimal Erythemal Dose

After

EVALUATION OF SPF(ISO24444,601-300W Multiport UV Solar Simulator)

Client: SUNJIN
Formula: SAMPLE#1
Test No: SJIV-200803-1

Expected SPF: 30 Expected standard SPF : 13.7~17.7

							MEDu			MEDp Std			MEDp Product			Final Result			
No.	Date	Panel	Sex	Age	ITA°	Skin type	geometric progression	UW/cm² Amps	MEDu (sec)	geometric progression	UW/cm² Amps	MEDp Std (sec)	geometric progression	UW/cm² Amps	MEDp Product (sec)	SPF Std	SPF Rejection	SPF Product	Tech Initials
1	2020.08.01 ~ 2020.08.03	LVJ	F	23	48.7	II	1.18X	6304	60	1.18X	857	1148.37	1.07X	740.7	1379.6	15.50	Y/N	30.00	SA

MED : Minimal Erythemal Dose

Test report will be including intensity increment value and following reason for a rejection.

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Free clinical test service by SUNJIN

SUNJIN provides free clinical test service for anyone who uses SUNJIN materials in their formulation so please feel free to use the service.

Free education on SPF/PA clinical test

Free preliminary UV In-vivo/ In-vitro clinical test

Service Features

1. Free

SUNJIN customers can apply the service for free

2. Fast

Generally it takes 2~3 weeks to receive results

3. High reliability

More than 700 cases per a year
Annually calibrate results with external agencies