How to investigate the protecting efficacy of sun protection products
What test methods can proDERM offer for the determination of the sun protection factor?

We can offer determination of the sun protection factor according to the following guidelines:

» ISO Norm 24444

» FDA Test Method

» Australian/New Zealand Standard Test Method AS/NZS 2604

Furthermore, a distinction between SPF screening and the full SPF test is possible. For the approval of your product, you will need a full test. Sometimes, it is useful to first conduct an in vivo screening instead of a full test, for example, if only a rough estimate of the protection factor is available. For an in vivo screening, 5 subjects are tested first. A full test is conducted on at least 10 subjects. A screening can be expanded to a full test.

What guideline should I use for testing my product?

The guideline used to determine the sun protection factor of your product depends on where you would like to market your product. Basically, it can be said that ISO 24444 is a standard that is now accepted by very many nations (including China). For approval in the U.S. market, however, you need to test according to the FDA test method.

Is it necessary to perform two different tests for international marketing in both the United States and Europe?

No, we can adjust the way the testing is conducted so that both standards are met and only one instead of two SPF determinations is necessary. Please let us know your desire to meet both standards before the start of testing.

Can the sun protection factor be determined in vitro?

An in vitro determination of the sun protection factor has been proposed and advocated again and again. So far, however, there is no accepted method because the predictive value for a later in vivo test is often insufficient. Therefore, we recommend the in vivo determination.
How do you ensure the safety of the subjects?

The safety of our subjects comes first for us. Our study technicians receive regular training, and each employee is aware of his or her responsibility. Our subjects are never alone during the exposure. Each technical problem can therefore be immediately detected and the exposure can be immediately interrupted, if necessary. By using 4-eyes principle controls and a Wood’s light, which makes sun protection products visible on the skin, we avoid incorrect applications and irradiation of the wrong fields.

In addition, we increase the safety of the subjects with the following measures:

» We have been able to optimize the fixation of solar simulators during irradiation by using special stands and thus significantly reduce incorrect exposure caused by movements of the subject.

» We apply the system of the initial test run: The measurement is first started on only two subjects so that we can correct the expected value of the sun protection factor, if necessary, for subsequent subjects based on the results. As a result, we can reduce the irradiation load to the necessary minimum.

» Exposure times are precisely observed through a time-controlled, technical locking system.

» Irradiation cabins for each subject convey a sense of calm and prevents hustle and bustle during the conduct.

How many product samples do you need for the SPF determination?

2 x 50 ml per test product
DETERMINATION OF THE SUN PROTECTION FACTOR (SPF)

How do you ensure that the values determined by your institute correspond to the actual protection values of the product?

On the one hand, quality assurance measures are dictated by the guidelines: The ISO 24444 standard, for instance, establishes quality requirements for corresponding tests. This includes the following measures:

» Air conditioning of the rooms (for uniformity of the framework conditions)

» Calibration and adjustment of the measuring devices and irradiation lamps by an accredited laboratory

proDERM also takes a number of other measures to ensure optimum quality:

» Training and calibration of the evaluators for reading the erythema

» Training in the application with pressure adjustment and Wood's light control to ensure good application homogeneity.

» Optimization of measurement accuracy (see Appendix 1)

» Participation in round robin tests: proDERM test results at Bipea (see Appendix 2)

Which information about my product does proDERM need?

» The SPF range that you expect

» The name of the product

» A declaration of the toxicological safety

» When the test products will be available and by when you need the test results

» Whether an SPF screening or a full test is to be conducted

» Whether, in addition to the SPF determination, additional measurements are desired, such as UVA protection and water resistance determination

» Information on formulation characteristics such as a high evaporation rate of ingredients

» Whether a direct comparison to another test sample also tested is desired
What sun protection factor can I achieve with my formulation?

Information on filters and filter concentrations and the associated sun protection factors to be expected are available on the Internet (we are happy to send more information on request).

According to which rules can I label my product in Europe?

According to the EC recommendations (Appendix F).
Can you determine the water resistance of a sun protection product?

The determination of water resistance is an in vivo test method, which we can perform according to the following guidelines:

» International Test Method (Colipa)

» FDA Test Method

» Australian/New Zealand Standard Test Method
  AS/NZS 2604

How reproducible is your water resistance testing method?

When evaluating water resistance, it is not sufficient to just rely on constant water movement to achieve reproducible results. We ensure, by using a water flow meter (impeller anemometer), that there is a defined flow of water in the region of the test areas on the back of the subject. We also regularly monitor constant conditions in the pool by measuring the standard product P2 for which we have long-term reference values on water resistance.
DETERMINATION OF UVA PROTECTION

Which test methods can you offer for the determination of UVA protection?

UVA protection can be determined both in vitro and in vivo. We can offer both test methods according to different guidelines:

In vivo UVA protection

- ISO 24442
- JCIA-Guideline
- Korean Method

In vitro UVA protection

- ISO 24443
- Boots
- Australian/New Zealand Standard AS/NZS 2604

Which test should I conduct: UVA in vitro or in vivo?

Usually, the UVA in vitro method is used (to do this, we need the SPF value of the product). If we assume, however, that this determination provides no meaningful results, as in the case of high pigment-containing formulations, then the in vivo determination should be performed.

The gold standard accepted by the EU for the determination of UVA is the in vivo PPD (Persistent Pigment Darkening) method according to the ISO 24442 standard. This is an investigation with the exposure of subjects to UVA irradiation.
TIMING

How long are the measurement times per study?

SPF-determination:
- Two weeks for screening
- Three weeks for the full test

UVA in-vivo:
- Two weeks for screening
- Three weeks for the full test

Shorter performance times can also be offered on request.

UVA in-vitro:
- One day

WR:
- Three weeks for screening
- Four weeks for the full test

How much lead time does proDERM need before conducting the study?

Usually we can start your study as soon as we have your test sample. Please contact us about possible timings.

When can we expect results?

Results are available no later than one week after the measurements have been completed. We can also deliver these to you earlier on request.
**PRICE**

Do you offer package prices for sunscreen tests?

Yes, for example, for SPF and UVA studies. Please feel free to contact us.

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**GCP**

Can you meet GCP criteria?

All methods are carried out in accordance with the GCP guidelines. A virtually 100% GCP standard with individual submission to an Ethics Committee is also available.

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**CLAIMS**

Can you demonstrate special claims on the subject of sun protection?

Yes, e.g.:

- Sweat-resistant
- Sand-resistant
- Long-term protection

- Immediate protection
- Protection during sports activities

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**CRITICAL WAVELENGTH**

What is the critical wavelength?

The critical wavelength is a quality characteristic and allows a statement about the scope of the UV protection. The EU Commission recommends a critical wavelength of at least 370 nm. This means that the area under the absorption curve measured, for example, with ISO 24443, reaches 90% of the area under the overall curve of 290 nm to 400 nm at 370 nm or more.

The above figure shows an absorption curve of any product whose critical wavelength is below 370 nm and thus does not meet the requirements of the EU Commission.
We place the highest demands on the quality of our ISO 24444 SPF measurements. We conduct regular audits, calibrations and training for the testing and sustained assurance of measurement quality. In the past year, we have once again fine-tuned our SPF determinations. The identification of the values we have determined for the P3 standard product is impressive.

For SPF determinations according to the ISO standard, P3 is a standard product that must always be determined by the testing laboratory for verification of the method. The nominal value of P3 determined in round robin trials is 15.7 (green broken line).

The annual mean of our results is illustrated by the blue diamonds. The blue field marks the area in which deviations from the P3 value are tolerated according to the ISO standard. Our values have always been within the tolerance range, but with a little ‘fine tuning’, we have been able to increase the quality even more. This is marked by the blue arrow. Thus, we were able to reduce the deviation from the nominal value to -0.1 SPF units.
## Attachment 2: Results of BIPEA round robin tests (2011 until 2016)

<table>
<thead>
<tr>
<th>Bipea Test No.</th>
<th>Year</th>
<th>Type of Product</th>
<th>SPF Range (Labeled SPF)</th>
<th>Lowest Test Result</th>
<th>Highest Test Result</th>
<th>Mean SPF</th>
<th>proDERM SPF</th>
<th>Match</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 - 16</td>
<td>2016</td>
<td>Sun Protection-Spray</td>
<td>30-49 (30)</td>
<td>29.9</td>
<td>39.9</td>
<td>35.0</td>
<td>35.7</td>
<td>ideal</td>
</tr>
<tr>
<td>60 - 15</td>
<td>2015</td>
<td>Sun Protection-Creme</td>
<td>30-49 (30)</td>
<td>38.8</td>
<td>53.3</td>
<td>46.7</td>
<td>42.6</td>
<td>OK</td>
</tr>
<tr>
<td>60 - 15</td>
<td>2015</td>
<td>Sun Protection-Foundation</td>
<td>25-29 (25)</td>
<td>24.0</td>
<td>35.7</td>
<td>29.5</td>
<td>29.9</td>
<td>ideal</td>
</tr>
<tr>
<td>60 - 14</td>
<td>2015</td>
<td>Sun Protection-Milk</td>
<td>&gt;60 (50+)</td>
<td>42.4</td>
<td>78.2</td>
<td>62.2</td>
<td>63.4</td>
<td>ideal</td>
</tr>
<tr>
<td>60 - 14</td>
<td>2015</td>
<td>Sun Protection-Creme</td>
<td>20-24 (20)</td>
<td>17.3</td>
<td>28.3</td>
<td>22.9</td>
<td>22.2</td>
<td>ideal</td>
</tr>
<tr>
<td>60 - 13</td>
<td>2014</td>
<td>Sun Protection-Powder</td>
<td>30-49 (30)</td>
<td>35.5</td>
<td>52.3</td>
<td>45.8</td>
<td>43.8</td>
<td>OK</td>
</tr>
<tr>
<td>60 - 13</td>
<td>2014</td>
<td>Sun Protection-Creme</td>
<td>25-29 (25)</td>
<td>21.3</td>
<td>33.2</td>
<td>26.6</td>
<td>21.3</td>
<td>OK</td>
</tr>
<tr>
<td>60 - 12</td>
<td>2014</td>
<td>Sun Protection-Oil</td>
<td>20-24 (20)</td>
<td>17.9</td>
<td>25.2</td>
<td>22.5</td>
<td>24.3</td>
<td>OK</td>
</tr>
<tr>
<td>60 - 12</td>
<td>2014</td>
<td>Sun Protection-Milk</td>
<td>30-49 (30)</td>
<td>31.4</td>
<td>67.0</td>
<td>49.4</td>
<td>45.7</td>
<td>OK</td>
</tr>
<tr>
<td>60 - 11</td>
<td>2013</td>
<td>Sun Protection-Foundation</td>
<td>25-29 (25)</td>
<td>24.6</td>
<td>34.3</td>
<td>29.9</td>
<td>33.8</td>
<td>OK</td>
</tr>
<tr>
<td>60 - 11</td>
<td>2013</td>
<td>Sun Protection-Creme</td>
<td>30-49 (30)</td>
<td>31.4</td>
<td>67.0</td>
<td>49.4</td>
<td>45.7</td>
<td>OK</td>
</tr>
<tr>
<td>60 - 010</td>
<td>2013</td>
<td>Sun Protection-Lip stick</td>
<td>30-49 (30)</td>
<td>28.1</td>
<td>38.3</td>
<td>31.7</td>
<td>27.7</td>
<td>OK</td>
</tr>
<tr>
<td>60 – 009</td>
<td>2012</td>
<td>Sun Protection-Creme</td>
<td>50-60 (50)</td>
<td>41.6</td>
<td>60.4</td>
<td>50.8</td>
<td>41.6</td>
<td>OK</td>
</tr>
<tr>
<td>60 - 009</td>
<td>2012</td>
<td>Sun Protection-Spray</td>
<td>30-49 (30)</td>
<td>33.4</td>
<td>53.5</td>
<td>43.4</td>
<td>44.8</td>
<td>ideal</td>
</tr>
<tr>
<td>60 - 008</td>
<td>2012</td>
<td>Sun Protection-Lip stick</td>
<td>&gt;60 (50+)</td>
<td>52.1</td>
<td>86.1</td>
<td>68.9</td>
<td>52.1</td>
<td>OK</td>
</tr>
<tr>
<td>60 - 008</td>
<td>2012</td>
<td>Sun Protection product</td>
<td>20-24 (20)</td>
<td>19.2</td>
<td>27.8</td>
<td>23.0</td>
<td>26.5</td>
<td>OK</td>
</tr>
<tr>
<td>60 - 007</td>
<td>2011</td>
<td>Sun Protection-Oil</td>
<td>20-24 (20)</td>
<td>18.2</td>
<td>25.9</td>
<td>22.5</td>
<td>21.6</td>
<td>ideal</td>
</tr>
<tr>
<td>60 - 007</td>
<td>2011</td>
<td>Sun Protection-Spray</td>
<td>25-29 (25)</td>
<td>22.2</td>
<td>36.7</td>
<td>29.2</td>
<td>29.9</td>
<td>ideal</td>
</tr>
<tr>
<td>60 - 006</td>
<td>2011</td>
<td>Sun Protection-Spray</td>
<td>30-49 (30)</td>
<td>21.4</td>
<td>39.1</td>
<td>30.5</td>
<td>39.1</td>
<td>OK</td>
</tr>
<tr>
<td>60 - 006</td>
<td>2011</td>
<td>Sun Protection-Lotion</td>
<td>&gt;60 (50+)</td>
<td>52.6</td>
<td>69.2</td>
<td>61.8</td>
<td>60.4</td>
<td>ideal</td>
</tr>
</tbody>
</table>
**Stephan Bielfeldt** is CTO and Director of Research at proDERM. Stephan already has more than 25 years of practical experience in the field of skin research, and he is considered a specialist in sun protection studies. Stephan is the architect of our sun protection department. He built up this department after he came to proDERM in 2001 and has continued to develop it since then. As a founding member of Colipa, he also contributed, with his specialist knowledge, to the development of the 1st Colipa guidelines. He is an active member of the DGK specialist group on the sun and the author of several relevant publications.


**Marianne Brandt** is the Claims Division Manager at proDERM and, as such, is the main person responsible for direct management of the overall ‘Sun’ area. She often pulls the strings behind the scenes and optimizes processes and concepts without losing a direct connection to the customer. Marianne has been at proDERM since 2002. She has a degree in physics and is a trained radiation and laser protection representative.

**Christiane Röck** oversees sun protection studies at proDERM as the responsible project manager. She is the first contact person for our clients, and with her experience of over 1700 managed studies, she always holds the steering wheel firmly and securely in hand, even when the seas get rough. Christiane has been with proDERM since 2001. Since her first day, she has focused on the field of sun protection. At first, she worked in the study conduct for two years. After that, she changed to project management of studies in the field of photobiology. Since 2010, she has also been responsible for studies in the field of tolerability.

**Good Measurement in SPF Testing**

**Abstract** Whilst light emitted to the earth is essential for life, overexposure to it can cause many adverse effects leading to premature actinic skin aging, photo-dermatoses, and even skin cancer. Due to the increase in the incidence of skin cancer and the public concerns of ozone layer depletion, more attention is being placed on protecting the skin from the sun’s ultraviolet rays with broad spectrum sunscreens, as well as developing other prevention strategies. As described herein, since sunscreen products provide an important protective function they should always be tested with due care, using accurate and validated methodology. If an imprecise method is used in sunscreen testing, this can lead to a misunderstanding of the protective function and result in considerable damage to both consumers and producers. It is therefore understandable that a labeled SPF that is based on a wrong measurement might have significant impact on the sales figures, brand image and might even lead to indemnity claims. Therefore, the quality and the accuracy of the measurement methods in particular, are critical. In addition due care must also be given to those methods used for evaluating the longevity of sunscreen protection when exposed to instances of water, sand and sporting activities.
Literature


- ISO 24443, Determination of sunscreen UVA photoprotection in vitro. Reference Number ISO 24443:2012(E)
