Sun Protection Factor (SPF) Determination in vivo

Introduction

When purchasing a sunscreen product, the displayed Sun Protection Factor (SPF) is the most important information to quantify the effectiveness of a sunscreen. The SPF method utilizes erythema as the biological endpoint and thus refers to a product’s ability to protect against sunburn. Therefore, the SPF mainly evaluates the protection from UVB rays, whereas the protection against the remaining UVA spectrum is not represented in the SPF value.

Guidelines

In Europe, sunscreens are classified and regulated as cosmetics and their efficacy is evaluated under standardized condition in accordance with the International Standard ISO24444:2010. In Europe, sunscreens are classified and regulated as cosmetics based on the photosensitivity of the skin. The European guidelines of the Cosmetic Group of the European Commission explicitly state that they are concerned with the protection against the erythema response in human skin. They are not concerned with the effects on molecular structures and subsequent phenomena such as skin aging or photoallergy.

Conditions for SPF measurement

The following parameters are standardized for testing the efficacy of sunscreen products:

- Number of test subjects: 10-12
- Phototypes: I–III (I/II: value > 28°)
- Age limit: 70
- Time between tests: min 2 m
- Total irradiance of the UV: ≤ 1600 w/m²
- Standard: P2, P3, or P7
- Application amount: 2 mg/cm² ± 0.05
- Drying time: 15–30 min
- Reading: 16–24 h

Test procedure

1. Determining the minimal erythema dose (MED). The MED is defined as the lowest dose of UV radiation required to produce an only just perceptible erythema 16–24 hours after irradiation adjusted to the CE erythema action spectrum.

2. The sunscreen has to be applied precisely on the back of each test subject with an application amount of 2 mg/cm².

3. The test subjects are exposed to increasing doses of ultraviolet irradiation.

4. The skin reading of the MED in both protected and unprotected skin area is done at the same time and the ratio, which results in the SPF, is calculated.

UVA-Protection Factor (UVAPF) Determination in vitro

Introduction

In general, UVR is responsible for skin aging (photo-aging), as manifested by loss of dermal collagen and for inducing as well as eliciting photosensitization, photosensitivity and photobaility. Furthermore, UVA radiation regulates reactive oxygen species (ROS), which, in turn, can damage cell membranes, proteins and DNA. Therefore, it is a requirement to prove the consumer with a minimum level of UVA protection in relation to the SPF.

Guideline

The determination of the UVAPF is calculated following the ISO 24443:2012. Determination of Sunscreen UVA photoprotection in vitro as follows:

\[
\text{UVAPF} = \frac{E}{s} 
\]

where

- \(E\) = absorbed irradiance, which is used for the in-vivo determination of the PPA

The required consideration of the photosensitivity following ISO 24443:2012 does not apply if the stability of the UVA product could be demonstrated in a time-based irradiation test.

According to the norm the ratio of UVA / UVB, aiming for protection factor, has to be 1:3 at a minimum, this corresponds to a PFA / SPF ratio of 2-0.33.

In addition, the Company Boots has developed a label system that uses a four star rating system based on the critical wavelength.

Light dermatosis

Study design exemplified by Mallorca acne

Background

1. Synonym: Acne aestivalis

2. Most common light-induced skin disease in central europe

3. Characteristics:
- Affect middle-age women
- Tendency to oily skin
- Frequently affects the chest and neck area
- Intensively pruritic papules

Pathogenesis

The irradiation of the volunteers is done by means of the filtered solar simulator Sol 5 by the company Hönle. In Europe, sunscreens are classified and regulated as cosmetics based on the photosensitivity of the skin. The European guidelines of the Cosmetic Group of the European Commission explicitly state that they are concerned with the protection against the erythema response in human skin. They are not concerned with the effects on molecular structures and subsequent phenomena such as skin aging or photoallergy.

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The irradiation intensity, below erythema threshold, is fixed to 20 Joule/cm². The positive reference is the test emulsion 216 G 40/1. The negative reference is a customary photoprotection gel.

The test substances are applied to the test areas on the midline and exposed to simulated solar radiation for 10 minutes prior to irradiation. The same goes for the reference substances (positive as well as negative references). The reactions are registered directly after irradiation and again after 24 hours, i.e. before renewed irradiation. The above-described process is repeated on five consecutive days.

Evaluation

The positive control used in conjunction with UVA-irradiation has to induce a Mallorca-acne in volunteers with this disposition. The negative reference protects against Mallorca acne. In the test below both products cannot be considered as effective in the protection against Mallorca acne.

<table>
<thead>
<tr>
<th>Day</th>
<th>negative-control</th>
<th>positive-control</th>
<th>test-product</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Day</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2 Day</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3 Day</td>
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<td>0</td>
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<tr>
<td>4 Day</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5 Day</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Scoring: 0-3

0: No lesion
1: Lesion inhomogen, light protective gel
2: Lesion inhomogen, clear protective gel
3: Lesion inhomogen, severe protective gel

Figure 1: Microscope slides covered with a specific amount of sun screen.

Figure 2: CPS turned system – UV-source for irradiation.

Figure 3: Labsphere UV-2000S Transmittance Analyzer.

Figure 4: Symptoms of Mallorca acne.

Figure 5: Pathogenesis of Mallorca acne by Kindl, Raab.