DERMA TRONNIER

Experimental Dermatology

Testing sunscreen effectiveness

N. Gerlach, M. Herling, B. Garbe, U. Heinrich, H. Tronnier
*DERMATRONNIER, Institute for Experimental Dermatology at Witten/Herdecke University, 58455 Witten, Germany

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 Cosmetics – Sun protection test methods –In vivo determination of the sun protection factor (SPF) test method.

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 or ITA° 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 CIE erythema action spectrum.

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

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.

$$SPF = \frac{MED\ (protected\ skin\ area)}{MED\ (unprotected\ skin\ area)}$$

UVA-Protection Factor (UVAPF) Determination in vitro

Introduction

In general, UVA is responsible for skin aging (photo-aging, as manifested by loss of dermal collagen) and for inducing as well as eliciting phototoxicity, photosensitivity and photoallergy. In addition, UVA radiation generates 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:

$$UVAPF = \frac{\int_{320}^{400} E(\lambda)\, s_{PPD}(\lambda)\, d\lambda}{\int_{320}^{400} E(\lambda)\, s_{PPD}(\lambda)\, T(\lambda)/100\, d\lambda}$$

E(l) = spectral irradiance, which is used for the in vivo determination of the PFA
$s_{PPD}(l)$ = action spectrum for PPD
T(l) = spectral transmittance [%] of the sample

The required consideration of the photostability 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 $_{(labeled)}$ protection factor has to be 1:3 at a minimum, this corresponds to a PFA / SPF ration of ≥ 0.33.

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

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

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

Figure 3: Labsphere UV-2000S Transmittance Analyzer.

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
   - -Intensely pruritic papules

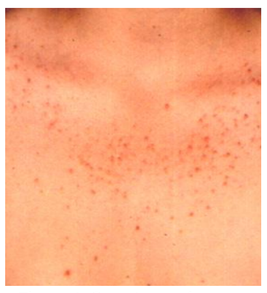

Figure 4: Symptoms of Mallorca-acne.

Pathogenesis

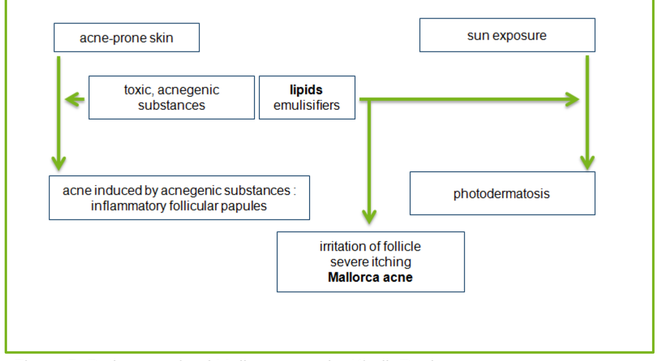

Figure 5: Pathogenesis of Mallorca acne by Kindl, Raab.

Test procedure

The irradiation of the volunteers is done by means of the filtered solar simulator Sol 5 by the company Hönle with 100 % UVA-light on five consecutive days. The irradiation intensity, below erythema threshold, is fixed to 20 Joule/cm².
The positive reference is the test emulsion 216 G 401/1. The negative reference is a customary photoprotection gel.

The test substances are applied to the test areas on the neckline 10 minutes prior to irradiation. The same goes for the reference substances (positive as well as negative reference). 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.

Test procedure

- 1. day: application of test product followed by irradiation
- 2.- 4. day: evaluation of test areas, renewed application and irradiation
- 5. day: evaluation of test areas
- Readings: **immediately** after irradiation and after **24h**

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.

Evaluation

	negativ-control	positiv-control	test product	
1. Day	0	0	0	0
2. Day	0	3.0	0	0
3. Day	0	4.5	1.0	0
4. Day	0	8.0	2.0	1.0
5. Day	0	16.0	5.0	4.0

Scoring: 0-3
Products: positive control: test emulsion 216 G401/1
negative control: commercially available light protection gel

RESEARCH

DermaTronnier GmbH & Co. KG
Institute for Experimental Dermatology
at Witten/Herdecke University

Alfred-Herrhausen-Str. 44
58455 Witten • Germany
www.dermatronnier.de

T +49 2302 28 26 300
F +49 2302 28 26 326
info@dermatronnier.de