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Dermatest® GmbH | Postfach 2165 | 48008 Münster

HERWE GmbH

Kleines Feldlein 16 - 20
D-74889 Sinsheim-Dühren

Münster, 08.04.2013

Zertifikat

über das Kosmetikprodukt

Herwesan UV

Dermatologische Prüfungen am Menschen 2013

Die von mir unter fachärztlicher Kontrolle durchgeführten dermatologischen Prüfungen Ihres o.g. Produktes bestand das Produkt mit

„sehr gut“

Bei dem genannten Präparat traten im Epikutantest nach internationalen Richtlinien k e i n e toxisch- irritativen Unverträglichkeitsreaktionen auf. Das Präparat kann deshalb mit dermatologisch getestet deklariert werden.

Dr. med. Werner Voss
Facharzt für Dermatologie
Venerologie, Allergologie,
Phlebologie und Umweltmedizin

Dermatest GmbH
Engelstrasse 37
48143 Münster Germany
dermatest®
Fon: +49-(0)251-4 88 22 49
Fax: +49-(0)251-4 90 27 27
www.dermatest.de

Dermatest® GmbH | Engelstr. 37 | 48143 Münster | Germany

Tel.: +49 251 4882249 | Fax: +49 251 4902727
www.dermatest.de | info@dermatest.de
Geschäftsführer: Dr. med. Werner Voss
Amtsgericht Münster HRB 1348 | Münsterländische Bank Thie & Co.
BLZ 400 300 00 | Konto-Nr. 3 492 784 800 | USt-ID: DE126040147

Derma
Consult
GmbH
Gesellschaft zur Prüfung von
Dermatika

DC Brunnenstraße 61 53347 Alfter Germany

Phone: 0 22 22 / 91 08 - 10
FAX: 0 22 22 / 91 08 - 40
E-mail: info@dermaconsult.com
Web: www.dermaconsult.com
Date: 07.07.2007

Sun Protection Factor Determination

Examination of the Product

"Herwesan UV - neu"

PC 060701-20a

According to the International Sun Protection Factor (SPF) Test Method

Sponsor.....: HERWE - chem.-techn. Erzeugnisse GmbH
Kleines Feldlein 16-20
74889 Sinsheim-Dühren
Germany

Performing Laboratory .: Derma Consult GmbH, Germany

Study Directors.....: Dr. med. H. Prieur, Dermatologist - Allergist
Dr. Hans-Peter Nissen, Chemist – Ph.D.

Test Period .....: July 07

Standard Formulation ...: Sunscreen product P 3, mean SPF 15 as recommended by the International Sun Protection Factor (SPF) Test Method

Literature .....: International Sun Protection Factor (SPF) Test Method, COLIPA, May 2006

Colipa Recommendation No. 11 – SPF Classification / upper limit, COLIPA, June 2002

EU Commission Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto (2006/647/EC)

Volunteers

11 healthy human volunteers (29 – 52 years of age, Phototype I, II or III) with no history of photosensitivity were selected from the Derma Consult volunteer panel. Each volunteer was informed about the purpose, procedure and possible hazards of the test and written informed consent was obtained prior to test commencement.

Pretest Examination

A physical examination of the back of each volunteer between the waistline and shoulder blades was undertaken to determine the presence of sunburn, suntan, scars, active dermal lesions and uneven skin tones. If, in the opinion of the investigator, any of the above artefacts was significantly outwith what could be expected in a normal individual, the volunteer was excused from the study.

Classification of skin types

- Skin type I : skin which burns and never tans
- Skin type II : skin which burns readily and tans slightly
- Skin type III : skin which burns and tans moderately

UV Source

The UV source was a 300 W Xenon arc lamp solar simulator (Model 601-300 Multiport, Solar Light Co. Inc., Philadelphia, PA, USA). The entire UV spectrum complies with the International Sun Protection Factor (SPF) Test Method. The uniformity of the solar simulator was measured prior to each test and the spectral output controlled at least yearly in an independent inspection.

Method

Pretest Determination of Minimal Erythemal Dose (MED)

In order to assess each volunteer's inherent reactivity to UV radiation, a series of 6 UV exposures was given to the treatment area 24h prior to the test. Each spot has a diameter of 1 cm. The time intervals selected were a geometric series, where each exposure time was 25% greater than the previous exposure time. The irradiated sites were assessed 16 - 24h after irradiation and the MED for unprotected skin was determined. The MED was used as indicator from which to decide on the exposure times required in the main test. A further determination of the MED for unprotected skin was carried out in the main test. This result was used in the SPF calculation. The visual MED on unprotected skin is defined as the quantity of radiant energy required to produce the first perceptible unambiguous redness reaction with clearly defined borders, when assessed 16 - 24h after UV exposure. The irradiation doses in this test were measured in time.

Main Test

The SPF value for the product with and without water immersion and the standard were determined on a unique position on the back of each subject. The procedure used to delineate the unique positions was as follows:

- Delineation of the general test area
- Delineation of test areas of 35cm² each

Application of product and standard

For each 35cm² test area 70mg of the product, or standard respectively, were applied to give an application of 2mg/cm² ± 2,5%. After application, each substance was evenly spread over its test area using a gloved finger. A method using weighing per loss was used.

Waiting period

After application a waiting period of at least 15min was allowed for skin absorption of the test material before exposure to UV radiation or water immersion.

Determination if a product is water resistant

The following procedure was used for the water resistance test (K. und A. Schrader: Akt. Dermatol. **20**, 130 - 134, 1994):

- Application of the product
- Waiting period (15min)
- water immersion: special system
- duration: 2min 21s
- quantity: 7l tap water
- temperature: 23C°
- air drying of the test sites without towelling
- UV exposure
- **Water resistance criterion:** SPF>50% of the SPF without immersion in same subjects

UV Exposure

After the waiting period, each test area was subdivided into 6 sites. The test sites were irradiated by a series of UV exposures - each test site being exposed to different energy of irradiation. The actual exposure times were determined by reference to the individual's pretest MED for unprotected skin and to the expected SPF of the test material. In specific, the MED for unprotected was multiplied by the expected SPF of the respective test material, giving an exposure time in minutes. The UV dose was a 12% geometric progression. After completion of irradiation the position of the tested areas was marked by Gentian Violet. Each subject was asked to shield the area of the back from extraneous UV and to return to the lab the following day.

Assessment of response

Treated skin areas were assessed 16 - 24h after irradiation by trained personnel.

Results

Individual and mean SPF-values for the test product (n=10 valid subjects) and the standard (n=11 valid subjects) are given in the appendices. The average SPF values, the standard deviations, the recommended labelled SPF, the recommended product category designation (PCD) and the 95% confidence interval were calculated to be as follows:

Product	**SPF (mean)**	**SD**	**Labelled SPF** COLIPA / EU	**95% CI**	**PCD** COLIPA / EU
Herwesan UV - neu PC 060701-20a	37,7	7,4	30 / 30	32,4 - 43,0	very high / High protection
P3	16,1	2,4	-	14,5 - 17,7	-

The result for the test product complies with the statistical criteria set forth by the International Sun Protection Factor (SPF) Test Method. The mean SPF value for the standard product was within the guidance range of expected value.

On the basis of the mean SPF value of 37,7 determined according to the International Sun Protection Factor (SPF) Test Method, the recommended maximum labelled SPF for the test product according to 'Colipa Recommendation No. 11' is a **SPF 30**, according to the EU Commission a **SPF 30**.

The values after water immersion (n=11 valid subjects) were calculated to be as follows:

Product	SPF (mean)	SD	95% CI	Waterresistant
Herwesan UV - neu PC 060701-20a	21,4	4,1	18,6 - 24,2	Yes

The result for the test product after water immersion complies with the statistical criteria set forth by the International Sun Protection Factor (SPF) Test Method.

Signature:

Dr. Hans-Peter Nissen
Chemist – Ph.D.

Signature:

Dr. med. H. Prieur
Dermatologist - Allergist

Appendix: test protocol

Derma Consult Concept GmbH

DCC Von-Weichs-Str. 9A 53121 Bonn Germany

Phone: +49 - (0)228 / 308901 - 0
Fax: +49 - (0)228 / 308901 - 9
E-mail: info@dermaconsult.com
Web: www.dermaconsult.com
Date: 07.07.2007

Expertise

Determination of the UVA-Balance
according to DIN 67502 of

"Herwesan UV - neu"

(PC 060701-20a)

Sponsor
Herwe - chem. Techn. Erzeugnisse GmbH
Kleines Feldlein 16-20
74889 Sinsheim-Dühren
Germany

Performing Laboratory
Derma Consult Concept GmbH
Von-Weichs-Str. 9A
53121 Bonn
Germany

Study Details

Type of study ..... : In-vitro UVA protection factor (PPD) and UVA-Balance determination according to DIN 67502 (2005-02)
Study Period ..... : July 2007
Technician ..... : H. Schueller
Spectrophotometer . : Optometrics SPF 290s (S/N 290200, Optometrics LLC, Ayer USA)
Substrate ..... : Roughened PMMA (Plexiglas® XT, colorless 24770 UVD, Röhm GmbH, Darmstadt) prepared by Schönberg GmbH & Co. KG, Hamburg (T8904, 14.12.2006)
Parameters ..... : Declared In-vivo SPF ..... : 30
No. of plates / scans per plate . : 4 / 3
Sample preparation ..... : 0,5 mg/cm²
Reference ..... : PMMA coated with glycerol

Summary Results

The UVA protection characteristics of the product Herwesan UV - neu, supplied by Herwe - chem. Techn. Erzeugnisse GmbH, according to DIN 67502 were determined as:

In-vitro PPD factor: 12,7 (SD: 0,23)

UVA-Balance: 40,3 (SD: 0,80)

Signature:

Dipl. Biol. Matthias Krampitz
Biologist