

## Sun Protection Factor Determination

### Examination of the Product

#### “Lippenbalsam SPF 20“

71-17-1-20, 08.02.2017

### According to ISO 24444:2010

**Sponsor.....: Preval Dermatica GmbH**

Lehmkoppel 2  
25499 Tangstedt  
Germany

**Performing Laboratory .: Derma Consult Concept GmbH, Germany**

**Study Directors.....: Dr. med. H. Prieur, Dermatologist - Allergist  
B. Nissen, Manager Derma Consult Concept**

**Test Period.....: February / March 2017**

**Standard Formulation ...: Sunscreen product P 3 (mean SPF 15,7; acceptance limits 13,7 - 17,7)  
as recommended by ISO 24444:2010**

**Literature.....: ISO 24444:2010 In vivo determination of the sun protection factor  
(SPF)**

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

## Volunteers

13 healthy human volunteers (21 – 62 years of age, Phototype I, II or III) 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. Only subjects in good health without any dermatological conditions and with no history of abnormal responses to UV exposure and not taking any topical or systemic medication known to alter responsiveness to UV radiation or inflammatory processes were included in the study. Pregnant or lactating women, subjects accustomed to using tanning beds or having had sun exposure in the past four weeks before the study were not allowed to participate.

## **Pretest Examination**

A physical examination of the back of each volunteer between the scapula line and the waist was undertaken. Subjects were excluded from participation at the presence of sunburn, suntan, scars, marks, active dermal lesions, uneven skin tones, nevi, blemishes or excessive body hair in the designated test area.

## **Classification of skin types**

- Skin type I : Always burns easily; never tans
- Skin type II : Always burns easily; tans minimally
- Skin type III : Burns moderately; tans gradually

## **UV Source**

The UV source was a 300W Xenon arc lamp solar simulator (Model 601 V2.5 Multiport, Solar Light Co. Inc., Philadelphia, PA, USA) equipped with a homogenizer with square 8\*8mm output ports. The output spectrum of the UV solar simulator is periodically controlled by an external expert in (last inspection: August 2016) and complies with the criteria (uniformity, UVA irradiance requirement, %RCEE limits) set forth by ISO 24444:2010. UV irradiance was measured and recorded before each UV exposure by radiometric measurement (PMA 2100 with detector PMA 2108 calibrated against the spectroradiometric measurement). To comply with the maximum total irradiance limit of 1600W/m<sup>2</sup>, erythema weighted output was limited on the output port with maximum intensity to 1275μW/cm<sup>2</sup>.

## **Method**

The MED (minimal erythema dose) is defined as the smallest UV dose that produces unambiguously perceptible redness of the skin (erythema) with clearly defined borders appearing over most of the field of UV exposure, when assessed 16 - 24h after UV exposure. The individual SPF for a subject is calculated as the ratio of the MED of protected skin (MED<sub>p</sub>) to the MED for unprotected skin (MED<sub>u</sub>).

### ***Pretest Determination of Minimal Erythema Dose (MED)***

In order to assess each volunteer's inherent reactivity to UV radiation, a pretest determination of the MED for unprotected skin was conducted during the week before the main test with an exposure progression of 25%. The irradiated sites were assessed 16 - 24h after irradiation to read the provisional MED<sub>u</sub>, used to decide on the exposure required in the main test.

### ***Main Test***

The MED for protected skin (MED<sub>p</sub>) for the product and the standard and the final MED<sub>u</sub> (used for SPF calculation), were determined on unique test sites (randomized positioning) on the back of each subject. The test sites were positioned in the general test area between scapula line and waist, each 35cm<sup>2</sup> in size and delineated with a skin marker.

### ***Application of product and standard***

For each 35cm<sup>2</sup> test area 70mg of the product, or standard respectively, were applied to give an application of 2,00 ± 0,05 mg/cm<sup>2</sup>. After application in droplets, each substance was evenly spread for a period of 35 ± 15 seconds over its test area using a gloved finger. A method using weighing per loss was used.

### ***Waiting period***

After application a waiting period of 15min to 30min was allowed for skin absorption of the test material before exposure to UV radiation.

### ***UV Exposure***

After the waiting period, the test areas were irradiated by series of UV exposures; each sub-site being exposed to a different dose. The UV dose series was a 25% geometric progression, centred for the untreated area on the individual's provisional MED<sub>u</sub> and for the treated areas on the respective SPF times the individual's provisional MED<sub>u</sub>. 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***

The test areas were assessed visually 16 - 24h after irradiation by a trained professional in a blinded manner under uniform illumination of 500 lux (at test area location) in the same position as irradiation took place.

## **Results**

Individual results listed for each participant for the test product (n=12 valid subjects) and the standard (n=13 valid subjects) are given in the tables in the appendix. The final results were calculated from the read MEDs as follows:

| <b>Product</b>                                | <b>SPF (mean)</b> | <b>SD</b> | <b>Labelled SPF</b><br>EU Rec. 2006 | <b>95% CI</b> | <b>PCD</b><br>EU Rec. 2006 |
|---|-------------------|-----------|-------------------------------------|---------------|----------------------------|
| Lippenbalsam SPF 20<br>71-17-1-20, 08.02.2017 | 26,2              | 6,5       | 25                                  | 22,1 - 30,3   | Medium protection          |
| P3  | 15,6              | 3,5       | -                                   | 13,5 - 17,7   | -                          |

The result for the test product and the standard comply with the statistical criteria set forth by ISO 24444:2010. The mean SPF value for the standard product was within the acceptance limits (13,7 - 17,7).

On the basis of the mean SPF value of 26,2 determined according to ISO 24444:2010 In vivo determination of the sun protection factor (SPF), the recommended labelled SPF for the test product according to the EU Commission Recommendation from 2006 is **SPF 25**.

Signature:

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| B. Nissen<br>Manager Derma Consult Concept |
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Signature:

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| Dr. med. H. Prieur<br>Dermatologist - Allergist |
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**Appendix:** test protocol

## SPF TEST RESULT TABLE

Laboratory: **Derma Consult Concept GmbH, Germany**

Product Code: Lippenbalsam SPF 20 - 71-17-1-20

Date: 20.02.17

UV source: Solar Light Multiport (Model 601 V2.5)

| TEST                                      |               |            | SUBJECTS               |        |     |                               |          |                            |                            |      | RESULTS |                             |       |            |    | CONCLUSION:     |                 |
|---|---------------|------------|------------------------|--------|-----|-------------------------------|----------|----------------------------|----------------------------|------|---------|-----------------------------|-------|------------|----|-----------------|-----------------|
| Subj. N°                                  | Exposure date | Technician | Subject code           | Gender | Age | Photo type                    | Exp. SPF | MEDu (mJ/cm <sup>2</sup> ) | MEDp (mJ/cm <sup>2</sup> ) | SPFi | SPF(n') | s(n')                       | c(n') | CI(n') [%] | n  | CI(n') ≤ 17%    | COMMENTS        |
| 1   | 20.02.17      | Schüller   | JS                     | F      | 43  | II                            | 17       | 27.6                       | 733.8                      | 26.6 | -       | -                           | -     | -          | 1  | -               |                 |
| 2   | 20.02.17      | Schüller   | MM                     | M      | 32  | II                            | 17       | 22.5                       | 478.3                      | 21.3 | 24.0    | 3.7                         | -     | -          | 2  | -               |                 |
| 3   | 21.02.17      | Krampitz   | AD                     | M      | 31  | I                             | 24       | 15.3                       | 460.4                      | 30.0 | 26.0    | 4.4                         | -     | -          | 3  | -               |                 |
| 4   | 21.02.17      | Krampitz   | SW                     | M      | 62  | II                            | 24       | 22.5                       | 432.2                      | 19.2 | 24.3    | 4.9                         | -     | -          | 4  | -               |                 |
| 5   | 21.02.17      | Krampitz   | ML                     | F      | 21  | II                            | 24       | 25.6                       | 767.3                      | 30.0 | 25.4    | 5.0                         | -     | -          | 5  | -               |                 |
| 6   | 01.03.17      | Schüller   | BW                     | F      | 55  | III                           | 25       | 31.7                       | 792.9                      | 25.0 | 25.4    | 4.5                         | -     | -          | 6  | -               |                 |
| 7   | 09.03.17      | Schüller   | GM                     | F      | 34  | II                            | 25       | 25.6                       | 799.3                      | 31.3 | 26.2    | 4.6                         | -     | -          | 7  | -               |                 |
| 8   | 09.03.17      | Schüller   | SB                     | F      | 22  | II                            | 25       | 22.5                       |                            |      | -       | -                           | -     | -          | -  | -               | errant response |
| 9   | 09.03.17      | Schüller   | SP                     | F      | 29  | I                             | 25       | 16.4                       | 327.4                      | 20.0 | 25.4    | 4.8                         | -     | -          | 8  | -               |                 |
| 10  | 09.03.17      | Schüller   | BL                     | F      | 40  | II                            | 25       | 23.5                       | 919.2                      | 39.1 | 26.9    | 6.4                         | -     | -          | 9  | -               |                 |
| 11  | 10.03.17      | Krampitz   | JF                     | M      | 62  | III                           | 25       | 34.8                       | 869.6                      | 25.0 | 26.8    | 6.1                         | 4.35  | 16.2%      | 10 | Complies        |                 |
| 12  | 10.03.17      | Krampitz   | MH                     | F      | 52  | II                            | 25       | 27.6                       | 442.0                      | 16.0 | 25.8    | 6.6                         | 4.44  | 17.2%      | 11 | Does not comply |                 |
| 13  | 10.03.17      | Krampitz   | JM                     | M      | 45  | III                           | 25       | 29.7                       | 927.2                      | 31.3 | 26.2    | 6.5                         | 4.13  | 15.8%      | 12 | Complies        |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
|   |               |            |                        |        |     |                               |          |                            |                            |      |         |                             |       |            |    |                 |                 |
| <b>Final Result:</b>                      |               |            | <b>SPF= 26.2</b>       |        |     | <b>s= 6.5</b>                 |          |                            | <b>c= 4.1</b>              |      |         | <b>95% CI: 22.1 to 30.3</b> |       |            |    |                 |                 |
| <b>EU Commission Recommendation 2006:</b> |               |            | <b>Labeled SPF: 25</b> |        |     | <b>PCD: Medium protection</b> |          |                            |                            |      |         |                             |       |            |    |                 |                 |

