Summary Report –
Sun Protection Factor Determination (ISO EN 24444: 2019)

Products under Test

Code/proDERM	Product/Code/Sponsor	Commercial Name
A	Untreated (Negative Control)	--
B	SPF Standards P3 and P8 (Positive Controls)	--
E	SUNCARE PRODUCT REF. 762.01 (210215.008I) (expected SPF 50)	Fotoprotector ISDIN Fusion Water

Sponsor ISDIN S.A., Barcelona, SPAIN

Study Site proDERM Institute for Applied Dermatological Research, Schenefeld/Hamburg, Germany

Study Schedule Start of the Study: March 17 , 2021
End of the Study: April 13, 2021

Aim of the Study The most important parameter of efficacy for sunscreen products is the sun protection factor (SPF). The SPF gives a measure of how much longer a subject can stay in the sun until a sunburn occurs when the subject is protected with the sunscreen related to an unprotected stay in the sun.

The purpose of this study was to determine in vivo the sun protection factor (SPF) of sunscreen products according to the ISO EN 24444: 2019.

Subjects Subjects were recruited according to the inclusion and exclusion criteria specified in ISO 24444:2019.

Application Area Back (in prone position)

Application Volume An amount of 2.0 mg/cm² (± 0.05 mg/cm²) test product was applied to the test areas. A method of weighing by loss was done.

Application Mode All products were shaken before weighing, to ensure uniform dispersion.

The application was performed by a technician using a non-saturated finger cot.

After application was completed, and before commencement of the UV exposure doses, the application was checked with an ultraviolet-A lamp, that was capable to visualize the uniformity of the application.

Test Schedule

Day	1	2
Definition of test areas	X	
Determination of ITA° value and difference in average ITA° values between test areas for check of eligibility	X	
Colorimetric prediction of MEDu by use of ITA° values	X	
Application of test materials to the skin	X	
UV-irradiation of test materials and untreated skin	X	
Visual rating of irradiated skin		X

Summary of Test Procedure

The subjects came to the Study Site. They were informed about the study and gave their written consent.

For all steps in the procedure (color measurement, product application, UV exposure, MEDu assessment) the subjects were lying in prone position.

To check eligibility of the subject the determination of the ITA° value and difference in average ITA° values between test areas was performed after a 10 minutes rest period. The individual mean ITA° values of eligible subjects were used for determination of irradiation times.

An untreated area (negative control) was irradiated with the sun simulator, to detect the minimal erythemal dose of the unprotected skin (MEDu).

The test products were applied to the test areas. After application of a test product, a waiting time between 15 to 30 minutes was kept before starting irradiation of the test area with the sun simulator. Irradiation time was depending on the expected SPF of the test materials, the ITA° of the subject as detected by colorimetric measurement, the corresponding MED, and the actual power of the sun simulator. The total irradiance was lower than 160 mW/cm².

Visual evaluation of the minimal erythemal dose (MED) was performed 16 to 24 hours after the irradiation.

Evaluation Criteria

For each treatment the irradiation spot with the minimal erythemal dose (MED) was determined. Erythemal responses were observed in a “blind” manner by a trained and experienced technician and were differentiated from pigmentation responses. The observers of erythemal responses on any subjects were not the same persons as the ones who performed product application and exposure. The observers were not aware of the randomization of the test areas on that subject.

MED evaluation was performed according to ISO 24444:2019.

Analysis of Data

The analysis of data was performed according to ISO 24444:2019.

Test data were deemed invalid and were rejected under the circumstances given in the in the ISO 24444: 2019.

Results and Discussion

Panel Characteristics (valid cases)

Number of Male	1
Number of Female	11
Mean Age	56.4
Standard Deviation of Age	12.8
Minimum Age	29
Maximum Age	70
ITA Range ≥ 56°	4
ITA Range 41° to 55°	8
ITA Range 28° to 40°	0
Mean ITA°	52.83
Minimum ITA°	43.00
Maximum ITA°	67.00

Summary of SPF Test Results

Test Product	Valid Subjects (n)	Mean SPF (95 %CI [%])	Labelled SPF[1]	Type of Sun Protection	SPF STD P3	SPF STD P8
762.01 (210215.008I)	12	78.6 (12.4)	50+	**very high**	16.1	74.1

[1] according to the Commission Recommendation of the European Union of September 22, 2006

The mean SPF value for test product 762.01 (210215.008I) was 78.6.

All results complied with the requirements of the ISO EN 24444:2019.

Conclusion

For test product FOTOPROTECTOR ISDIN FUSION WATER, an SPF of 50+ (type of sun protection: very high) can be labelled.

Appendix: Results

Subject #	ITA°	MED_u [J/m²]eff	MED_p [J/m²]eff	SPF_i
1	60	146	14038	**96.1**
2	53	221	16075	**72.7**
4	48	288	24136	**83.9**
6	45	283	20659	**73.0**
9	48	189	15870	**83.9**
10	55	192	16133	**83.9**
11	67	147	8114	**55.1**
12	46	217	13800	**63.4**
13	43	246	17964	**73.0**
14	53	192	12199	**63.4**
15	59	168	18633	**111.0**
16	57	222	18633	**83.9**