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

Test Materials

Code/proDERM	Product/Code/Sponsor	Commercial Name
A	Untreated (Negative Control)	--
B	SPF Standards P3 and P8 (Positive Controls)	--
E	SUNCARE PRODUCT REF 752.35 (CCAA-FTP-2021-056) (expected SPF 50)	FOTOPROTECTOR ISDIN PEDIATRICS FUSION FLUID MINERAL BABY SPF 50

Sponsor

ISDIN S.A., Barcelona, SPAIN

Study Site

proDERM Institut für Angewandte Dermatologische Forschung GmbH, Schenefeld/Hamburg, Germany

Study Schedule

Start of the Study: July 06 , 2021
End of the Study: July 29, 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 'Woods' lamp with at least 6 W of power, 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 MED (ITA°)	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	For all steps in the procedure (color measurement, product application, UV exposure, MEDu assessment) the subjects were lying in prone position. The subjects came to the Study Site. They were informed about the study and gave their written consent. 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 test design (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	10
Mean Age	49.0
Standard Deviation of Age	17.2
Minimum Age	19
Maximum Age	67
ITA Range ≥ 56°	3
ITA Range 41° to 55°	6
ITA Range 28° to 40°	2
Mean ITA°	48.55
Minimum ITA°	37.00
Maximum ITA°	57.00

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
SUNCARE PRODUCT REF 752.35	11	59.3 (10.8)	50	High	15.8	72.1

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

The mean SPF value for test product 752.35 (CCAA-FTP-2021-056) was 59.3.

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

Conclusion

For test product FOTOPROTECTOR ISDIN PEDIATRICS FUSION FLUID MINERAL BABY SPF 50 a SPF of 50 (type of sun protection: high) can be labelled.

Appendix: Results

Subject #	ITA°	MED_u [J/m²]eff	MED_p [J/m²]eff	SPF_i
2	57	168	12207	**72.7**
3	53	192	10570	**55.0**
4	56	168	8026	**47.8**
5	56	168	12207	**72.7**
6	55	167	12155	**72.7**
7	54	167	9191	**55.0**
9	37	277	15257	**55.0**
10	41	246	11769	**47.8**
11	44	246	13535	**55.0**
12	42	246	15565	**63.2**
13	39	343	18861	**55.0**