

#### 4.5 Results of SPF determination

The SPF test method is an accepted standardized laboratory test.

To pass the SPF determination according to the mentioned guidelines, at least 10 valid results have to be documented with a 95 % confidence interval lower than or equal to 17 % for the test product and the corresponding results of the Standard P3 and P8. The mean value for the Standard P3 has to be within the range of 13.7 and 17.7, the mean value of the Standard P8 within the range of 43.9 and 82.3.

Individual SPF results, means, confidence intervals (95 % CI [%]) and pass/fail criteria for SPF results are shown in Appendix A. Main results are listed in Table 1.

The tested product was designated with an expected SPF value of 50.

**Table 1: Summary of SPF Test Results**

<b>Test Product</b>	<b>Valid Subjects (n)</b>	<b>Mean SPF (95 % CI [%])</b>	<b>Labelled SPF<sup>1</sup></b>	<b>Type of Sun Protection<sup>1</sup></b>	<b>SPF Standard P3 (95 % CI [%])</b>	<b>SPF Standard P8 (95 % CI [%])</b>
Test product 762.01	13	62.2 (12.5)	50+	Very high	14.7 (9.5)	78.2 (14.8)

<sup>1</sup> according to the Commission Recommendation of the European Union of September 22, 2006

## 5 Discussion and Conclusion

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. The definition of the SPF to be labelled is taken from the Commission Recommendation of the European Union of September 22, 2006.

The following treatment codes were tested:

**Code A: Untreated (Negative Control),**

**Code B: High SPF Standards P3 and P8 (Positive Controls),**

**Code C: Test product 762.01 (expected SPF 50).**

On every irradiation day a negative control (A, untreated area) was irradiated with the sun simulator to detect the minimal erythral dose of the unprotected skin (MEDu). Then, the test products were applied to the test areas. After a waiting time between 15 to 30 minutes the test areas were irradiated. Visual evaluation of the minimal erythral dose (MED) was performed 16 to 24 hours after the end of irradiation time.

The mean SPF value for test product **762.01** was 62.2. Therefore, the mean SPF was slightly higher than expected for this product. All results complied with the requirements of the ISO EN 2444:2019.

For test product **762.01** a SPF of **50+** (Type of sun protection: **very high**) can be labelled.

Determination of Sun Protection Factor in vivo according to ISO 24444

Code of the Product:  
Study No.:  
Sponsor:

C  
20.0124-61  
ISDIN S.A.

Sponsor Code of the Product:  
Nominal Sun Protection Factor:

Test product 762.01  
50

Dose Increments: 1.15 START DATE: April 8, 2020 END DATE: April 23, 2020

Subject No.	Subject ID	Skin ITA°	Exposure Date	Applied/ Exposed By	Read By	SIM EE (highest) [W/m²] eff	MEDu		MEDp		SPFI	Relevant Rejection Y/N	Ref Standard 1			Ref Standard 2				
							mm:ss	[J/m²]eff	mm:ss	[J/m²]eff			P#	mm:ss	[J/m²]eff	SPFI	P#	mm:ss	[J/m²]eff	SPFI
1	33266	52	08.04.2020	JKI	AEI	8	00:37	192	33:29	16075	83.6	N	P8	38:25	16037	83.4				
2	32131	57	09.04.2020	JKI	AEI	8	00:32	168	29:15	12207	72.7	N	P8	33:33	16106	95.9				
3	505	59	14.04.2020	AEI	CD6	8	00:32	193	33:30	16080	83.3	N					P3	08:21	3030	15.7
4	5734	61	14.04.2020	AEI	CD6	8	00:28	224	29:20	14081	63.0	N	P8	29:23	14103	63.1				
5	18825		14.04.2020	AEI	CD6	8	00:41	217		excluded		Y	P8	43:28	18141	83.4				
6	17050	43	16.04.2020	CD6	AEI	8	00:47	325	49:07	17829	54.7	N					P3	12:14	4443	13.6
7	4852	55	16.04.2020	CD6	AEI	8	00:37	221	38:22	16011	72.4	N					P3	09:34	3990	18.0
8	32475	46	16.04.2020	CD6	AEI	8	00:41	217	43:24	13696	63.0	N					P3	10:49	2968	13.6
9	30781	46	20.04.2020	CD6	RB	8	00:41	288	43:24	11909	41.4	N					P3	10:49	3925	13.6
10	31030	52	20.04.2020	CD6	RB	8	00:37	192	38:22	10528	54.7	N	P8	38:25	18442	95.9				
11	11258	52	20.04.2020	CD6	RB	8	00:37	192	38:22	12107	63.0	N					P3	09:34	2624	13.6
12	12003	53	22.04.2020	KJ	CD6	8	00:37	254	38:22	12107	47.6	N	P8	38:25	12126	47.7				
13	16271	64	22.04.2020	KJ	CD6	8	00:28	147	29:20	8051	54.7	N					P3	07:19	2653	18.0
14	27607	43	22.04.2020	KJ	CD6	8	00:47	283	49:07	15503	54.7	N					P3	12:14	3360	11.8
15																				
16																				
17																				
18																				
19																				
20																				
21																				
22																				
23																				
24																				
25																				

Labelled SPF:	50+
Type of Sun Protection:	Very high
Number of all Cases	14
Number of valid Cases	13
Number of relevant Rejections	1

SPF Product			
MV	STD DEV	95%CI	17% of Mean
62.2	12.9	12.5	10.6
Complies With Norm: YES		CI Accepted: YES	

SPF Ref Standard 1				SPF Ref Standard 2			
MV	STD DEV	95%CI	17% of Mean	MV	STD DEV	95%CI	17% of Mean
78.2	19.2	14.8	13.3	14.7	2.3	9.5	2.5
Ranges of Standard OK? YES				Ranges of Standard OK? YES			
No. of Subjects for Standard OK? YES				No. of Subjects for Standard OK? YES			