

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. 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 interval (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.

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: SPF Standards P3 and P8 (Positive Controls),

Code E: SUNCARE PRODUCT REF. 986.01 (expected SPF 50).

On every irradiation day a negative control (A, untreated area) was irradiated with the sun simulator to detect the minimal erythemal dose of the unprotected skin (MED_u). 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 erythemal dose (MED) was performed 16 to 24 hours after the end of irradiation time.

The mean SPF value for test product **SUNCARE PRODUCT REF. 986.01** was 55.5. Therefore, the mean SPF was as expected for this product. All results complied with the requirements of the ISO EN 2444: 2019.

For test product **SUNCARE PRODUCT REF. 986.01** a SPF of **50** (type of sun protection: **high**) can be labelled.

Determination of Sun Protection Factor in vivo according to ISO 24444

Code of the Product:
Study No.:
Sponsor:

E
21.0073-61
ISDIN S.A.

Sponsor Code of the Product:
Nominal Sun Protection Factor:

SUNCARE PRODUCT REF. 986.01
50

Dose Increments: 1.15 START DATE: January 19, 2021 END DATE: February 6, 2021

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	5958	56	19.01.2021	CaB	JKI	8	00:32	193	29:15	10615	55.0	N	P8	36:10	17356	89.9				
2	33817	50	19.01.2021	CaB	JKI	8	00:41	217	37:53	18184	83.6	N	P8	46:50	19550	89.9				
3	33190	43	20.01.2021	JKI	CaB	8	00:47	246	42:53	11769	47.8	N	P8	53:01	16734	68.0				
4	16324	54	20.01.2021	JKI	CaB	8	00:37	254	33:29	9191	36.1	N	P8	41:24	19875	78.2				
5	24578	60	21.01.2021	JKI	CaB	8	00:32	193	29:15	9230	47.8	N	P8	36:10	13124	68.0				
6	30744	50	21.01.2021	JKI	CaB	8	00:41	217	37:53	10397	47.8	N	P8	46:50	17000	78.2				
7	33363	55	22.01.2021	JKI	CaB	8	00:37	221	33:29	12155	55.0	N	P8	41:24	15028	68.0				
8	18269	45	22.01.2021	JKI	CaB	8	00:47	283	42:53	15565	55.0	N					P3	12:14	3864	13.6
9	32130	40	01.02.2021	CaB	JKI	8	00:53	367	48:20	23203	63.2	N					P3	13:48	4355	11.8
10	2872	55	01.02.2021	KJ	CaB	8	00:37	254	33:29	9191	36.1	N					P3	09:34	3017	11.8
11	30307	47	02.02.2021	CaB	KJ	8	00:41	288	37:53	15813	55.0	N					P3	10:49	3925	13.6
12	20668	54	02.02.2021	CaB	KJ	8	00:37	192	33:29	16075	83.6	N					P3	09:34	3470	18.0
13	23220		05.02.2021	CaB	KJ	8		excluded; t	42:53	13535		N					P3		excluded; t	
14	20602	57	05.02.2021	CaB	KJ	8	00:32	193	29:15	10615	55.0	N					P3	08:21	2635	13.6
15																				
16																				
17																				
18																				
19																				
20																				
21																				
22																				
23																				
24																				
25																				

Labelled SPF:	50
Type of Sun Protection:	High
Number of all Cases	14
Number of valid Cases	13
Number of relevant Rejections	0

SPF Product	
MV	55.5
STD DEV	14.6
95% CI [%]	15.9
95% CI	8.8
17% of Mean	9.4
CI Accepted:	YES
Complies With Norm:	YES

SPF Ref. Std 1	
MV	77.2
STD DEV	9.8
Ranges of Std. OK?	YES
No. of Subjects for Std. OK?	YES

SPF Ref. Std 2	
MV	13.7
STD DEV	2.3
Ranges of Std. OK?	YES
No. of Subjects for Std. OK?	YES