

15.0 Conclusion:

The Sun Protection Factor (SPF) of the test material [No.: S 1207-A; Client No.: SUNCARE PRODUCT REF: 986.01(201201.013)] when tested on ten panelists as described herein under static conditions yielded the mean SPF value of 54.8.

The mean SPF of the P2 standard on the same panel was 16.9.

**EVALUATION OF SUN PROTECTION BY STATIC SPF DETERMINATION
(ISO 24444 SUN PROTECTION FACTOR TEST METHOD)**

Table

Sponsor : ISDIN
Client No. : SUNCARE PRODUCT REF: 986.01(201201.013)
Expected SPF: 50

Exp Date	#	Tech Init	Subject					I (Amps)	MEDu (sec)	MEDp (sec)		SPF Values	
			ID #	Age	Sex	Race	Type			P2	Product	P2	Product
12/28	1	MI	03 9734	57	M	C	I	5.0	6	90	336	15.0	56.0
12/30	2	JM	03 9733	38	M	C	II	5.5	6	90	336	15.0	56.0
1/4	3	SS	03 9062	58	M	H	III	6.0	8	120	448	15.0	56.0
1/7	4	SS	03 9536	66	F	H	II	6.0	6	113	336	18.8	56.0
1/11	5	SS	03 6144	69	F	C	II	6.5	6	113	300	18.8	50.0
1/27	6	MI	03 9374	56	F	C	II	4.0	6	113	336	18.8	56.0
1/27	7	NB	03 8982	45	F	C	II	6.0	6	113	336	18.8	56.0
1/28	8	RB	03 9679	29	M	C	II	6.0	6	113	300	18.8	50.0
2/3	9	RB	03 9287	60	F	AA	III	6.5	10	150	560	15.0	56.0
2/4	10	MI	03 9441	53	M	H	III	4.5	8	120	448	15.0	56.0
Mean SPF (x)											16.9	54.8	
Standard Deviation (s)											2.00	2.53	
Standard Error (SE)											0.63	0.80	
C											1.43	1.81	
CI %											8.47	3.30	
95% CI											15.5	53.0	
											to	to	
											18.3	56.6	
Number of Subjects (n)											10	10	
Conclusion: (CI % ≤ 17%)											Complies	Complies	

< Erythema in all subsites

* Data not included in calculations

I: Intensity of Light Source
UV Source: Xenon Arc Solar Simulator
MEDu: Minimal Erythema Dose of Unprotected Skin
MEDp: Minimal Erythema Dose of Protected Skin
P2: P2 Standard SPF 15

Study Period: This study was conducted from December 23, 2021 through February 5, 2021.