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SPF Test Result Table | ISO 24444 SPF Test Method- 2010

Client: **Celinde**

Test Condition: Static Testing

Product: **PANTALLA SOLAR & AMBIENTAL 60+ PA+++**

Appendix A Report p1
UV Source: **XE**

Report Reference Number: **20375**

	Test Subjects											Product: Results								
	Subj Code	Skin Type	ITA	Sex	Age	Exposure Date	Applied By	Read By	MED /hr	MEDus** secs	MEDus** mJ	MEDps secs	SPFi	SPFn'	s(n')	c(n')	CIn' [%] (100cn'/SPFn')	Conclusion: c(n') < Cn'	P2 Ref MEDp	P2 Ref SPF
1	92493	III	36	f	25	31/8 /20	S. M	H. F	128	21	23.2	1260	60.0						326	15.5
2	92357	III	33	F	31	1/9 /20	H. L	H. F	129	22	24.5	1344	61.1						336	15.3
3	92299	II	54	F	18	3/9 /20	S. M	H. F	129	17	19.0	1279	75.2						255	15.0
4	91435	I	61	F	54	24/9 /20	A. W	H. F	122	17	17.9	1238	72.8						272	16.0
5	92589	III	36	F	47	1/10 /20	A. W	H. F	125	21	22.7	1470	70.0						315	15.0
6	92514	III	33	F	37	12/10 /20	A. W	H. F	120	21	21.8	1350	64.3						300	14.3
7	92134	II	42	F	66	13/10 /20	A. W	H. F	123	20	21.3	1555	77.8						336	16.8
8	92598	II	49	F	63	14/10 /20	A. W	H. F	120	17	17.6	1238	72.8						262	15.4
9	92596	I	63	F	19	14/10 /20	S. M	H. F	120	14	14.5	1129	80.6						251	17.9
10	91560	II	54	F	34	15/10 /20	A. W	H. F	121	18	18.8	1205	66.9	70.2	7.0	4.99	7.11	COMPLIES	288	16.0
11																				
12																				
13																				
14																				
15																				
16																				
17																				
18																				
19																				
20																				

Study Dates From: 31 Aug 2020 To: 16 Oct 2020

s= **7.0** c= **4.99** CI% = **7.11** n= **10**

FINAL

Product Mean SPF = **70.2**

95% CI : **65.2** to **75.0**

Ref Std Mean: **15.7**
Range: 14.3 – 17.9

Signoff Clinical Manager: Holly Huang [illegible] Dip. Appl.Sc

Signoff Study Director: Jennifer Wan BSc (Hons) MASM

REPORT OF EVALUATION OF SUN PROTECTION PRODUCT ACCORDING TO THE ISO PROTOCOL

1. Objective:

This panel was convened to evaluate the effectiveness of a test material as a sunscreen product by determining the Sun Protection Factor (SPF) on human skin as described in the document: International Standard ISO 24444 - Cosmetics - Sun Protection Test methods -*in-vivo* determination of the sun protection factor (SPF) Factor (SPF), using a continuous emission xenon arc solar simulator as the UV source.

2. Sample Description:

A sample labelled Pantalla Solar & Ambiental 60+ PA+++ was received from Eurofins Cosmetic&Personal Care Spain and assigned a Dermatest Reference No. 20375

3. Test Material Handling

The record of the sample was entered into a log identifying the lot number, sample description, batch number, sponsor, date received and tests requested. Samples are retained for a period of two years beyond final report generation.

4. Standard for Inclusion of a Panelist in a Study

4.1 Individuals over the age of consent and below 71 years.
4.2 Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the investigator.
4.3 Individuals who have completed a preliminary medical history evaluation.
4.4 Individuals who have read, understood and signed an informed consent document relating to the specific study to which they are subscribing.
4.5 Individuals with no known abnormal response to sunlight.

5. Standard for Exclusion of a Panelist from a Study

5.1. Pregnant or lactating females.
5.2. Individuals taking medication which in the opinion of the investigator would mask or interfere with the results. These include anti-inflammatory and antihistamine medications or medications with photo-sensitising potential.
5.3. Individuals with chronic skin allergies or other dematological conditions
5.4. Individuals with suntan or sunburn as a result of recent sun exposure.
5.5. Individuals with a history of abnormal reaction or response to the sun.
5.6 Subjects accustomed to using sun beds.
5.7 Subjects who had participated in an SPF study within the last two months.
5.8 subjects having marks, blemishes or nevi or presenting existing sun damage in the test area.
5.9 Subjects having excessive hair in the area of the test.
5.10 Subjects who have had sun exposure on the target area of the back in the four weeks prior to the study.

6. Informed Consent and Medical History Forms

An informed consent was obtained from each volunteer prior to initiating the study describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability. Panelists signed and dated the informed consent document to indicate their authorisation to proceed and acknowledge their understanding of the contents. Each subject was assigned a permanent identification number and completed an extensive medical history form. These forms along with the signed consent forms, are available for inspection only on the premises of Dermatest Pty Ltd and during normal office hours.

7. Panel Composition:

Healthy volunteers were recruited for this study. The panel consisted of fair skin individuals with Fitzpatrick skin types I, II or III. Additionally, the ITA° was documented for each and is documented on page 7 of this report.

8. Clinical Ethics.

Testing is conducted in accordance with Ethical Principles contained in the Declaration of Helsinki. An Independent Ethics Committee chosen in accordance with ICH Guidelines for Good Clinical Practice has also reviewed the SPF Testing.

9. Solar Simulation

The light source employed was a small beam 150 watt Xenon Arc Solar Simulator (Solar Light Co., Philadelphia, Pennsylvania, Model 16S or Model 601) having a continuous emission spectrum in the UV range from 290 to 400 nm and compliant with the spectral performance requirements of the Annex B of the ISO protocol. Xenon arc is selected on the basis of its black body radiation temperature of 6000°K which produces continuous UV spectra (all wavelengths) substantially equivalent to that of natural sunlight. This device is equipped with a dichroic mirror (which reflects all radiation below 400nm) and works in conjunction with a 1 mm thick Schott WG320 filter (which absorbs >99% of radiation below 290nm) to produce simulation of the solar UVA/UVB spectrum. A 1 mm thick UG 11 filter (black lens) was added to remove reflected (infra-red, greater than 700 nm) heat and remaining visible radiation. UV radiation was monitored continuously during exposure using a Sunburn UV Meter/Dose Controller System (Solar Light Co) . Measurements were taken at a position within 8 mm from the surface of the skin. The field of irradiation was >0.5 cm in diameter, with at least 1 cm between each adjacent site. Realignment of the Light Sources and calibration of the sunburn meters are conducted by independent certification facilities and adjustment to light source power supply only by the Director.

10. Water Resistance Not Determined

A water challenge was not completed during this study.

Water Resistance Category Description for AS/NZS 2604 (2012)-When tested

Tested SPF after Immersion	Maximum Water Resistance Claimable
At least 4 but less than 8	No Claim
At least 8 but less than 15	40 min
At least 15 but less than 30	2 hrs
At least 30 or above	4 hrs

11. Determination of the Sun Protection Factor

One test site area of 40 sq.cm served to determine each subject's Minimal Erythema Dose (MEDu). This was executed by exposing the back to a series of 5 timed incremental UV exposures at 112% intervals. The individual subject's MEDu is the shortest time of exposure that produces perceptible unambiguous redness at 16 to 24 hours post irradiation. The test area is described as the infrascapular area of the back to the right and left of the midline. The application area was 40 sq.cm. The material was evenly applied to a rectangular area for a final covering of 2.0 mg/sqcm +/- 2.5%. The product was deposited in a series of evenly distributed spots and then spread evenly with a fingercot. Product application, UV exposures and measurements of responses were conducted in stable environmental conditions with the room temperature maintained between 18 degree Celsius and 26 degree Celsius. The product applications were examined for evenness and coverage utilising a Woods U.V. lamp.

Twenty minutes after application, a series of 5 UV light exposures in 112% increments calculated from previously determined MED's bracketing the expected SPF were administered from the solar simulator to 5 subsites, each with an area of not less than 1 cm sq and spaced at 1 cm separation within the treated area. On the actual day of testing another series of exposures was administered to an adjacent untreated site of unprotected skin to redetermine the MED. An adjacent test site was then selected to perform a static determination on the test substance.

A reference sunscreen, as described in Annex c of the Standard, was also applied to each of the test subjects, utilising an application exposure procedure which was the same as that utilised for the test product.

Following UV exposure to all test sites, the product was gently removed using moist soft tissue together with ethanol if needed.

12. Evaluation of Response

The volunteers were instructed to return to the testing facility sixteen to twenty four hours post exposure, for evaluation of delayed erythemic response. The smallest exposure or the least amount of energy required to produce unambiguous redness (MED_p) in the treated site was recorded. The SPF was then calculated by the equation: MED_p (Protected Skin) / MED_u (Unprotected Skin) = SPF_i (calculated to one decimal place).

13. Calculations and Statistics

The SPFi values from an initial panel of the first 10 test subjects were sequentially evaluated in order to determine a provisional mean Sun Protection Factor (SPFn1). The statistical criteria described in the test method were then applied to determine a confidence interval and statistical variance.
Where necessary, additional subjects were tested according to the protocol. The first 10 results were found to be within the specified range and testing was completed and the report collated.

14. Rejection Criteria

Panelist's results were rejected and the panelist replaced if:

14.1. The responses on the treated test site were randomly absent or out of sequence. This was an indication that the products were not spread uniformly.

14.2. An MED could not be obtained due to elicited response at all exposure sites.

14.3. The exposure series failed to elicit an MED response on either the untreated or the applied skin areas.

The test was then considered a technical failure and the subject's data was discounted.

15. Individual Panelist Results

These are set out in the attached report.

16. Observations

No adverse reactions were reported for this study.

17. Archiving: All original samples, raw data sheets, technicians notebooks, correspondence files and copies of final reports and remaining specimens are maintained on premises of Dermatest Pty Ltd in limited access storage files. A duplicate disk copy of final reports is archived separately off site.

18. Colour Discrimination Test

All technical employees of Dermatest Pty Ltd who are involved in scoring of exposed skin spots are required to take and pass a visual colour discrimination examination using the Farnsworth-Munsell 100 Hue Test.

19. Solar Simulator Compliance

All Solar Simulators used in this study complied with the requirements of Annex B of ISO 24444. Spectral Range % RCEE limits are recorded below.

Spectral Range nm	Measured % RCEE Limits		Solar Sim		
	Lower	Upper	No:	3	7
			s/n:	3644	13028
<290		<0.1		0.01	0.05
290 to 300	1.0	8.0		8.0	7.7
290 to 310	49.0	65.0		59.3	58.0
290 to 320	85.0	90.0		86.8	86.0
290 to 330	91.5	95.5		94.7	94.3
290 to 340	94.0	97.0		96.7	96.5
290 to 400	99.9	100.0		100.0	100.0

** Accumulated energy in Joules calculated to ARPANSA Cross-Calbration Ref 10824-1 and relative to the MED dose of 210 J/sq m - eff for Type I Skin as measured on a DCS 2 /2105 Sensor system.

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Certificate for AS/NZS 2604 Compliance

Product: **PANTALLA SOLAR & AMBIENTAL 60+ PA+++**

Report Reference Number: **20375**	Test Condition: Static Testing

The above product was evaluated for Sun Protection Factor (SPF) according to the procedures specified in Australian/New Zealand Standard 2604: 2012

According to AS/NZS 2604:2012, the product was found to have an SPF Value as shown below. Provided that the Broad Spectrum requirements for minimum UVAPF and Critical Wavelength are met, the product could be labelled as SPF 50+. The Category Description for labelling purposes according to the 2012 Standard is Very High Protection Sunscreen

Category Description: Very High Protection Sunscreen

Label SPF: 50+

MaxWater Resistance Claimable: n/a

Australian SPF Categories

SPF Found		Category Description
Tested SPF	Label SPF	
4-14	4	Low
	6	Low
	8	Low
	10	Low
15-29	15	Medium or Moderate
	20	
	25	
30-59	30	High
	40	High
	50	High
60 or higher	50+	Very High

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A full record of the procedure and related documentation is retained on file in our laboratory.

Product: **PANTALLA SOLAR & AMBIENTAL 60+ PA+++**

Report Reference Number: **20375**

Test Condition: Static Testing

E.U. SPF Category: Very High Protection

Labelled category	Labelled sun protection factor	Measured sun protection factor (measured in accordance with the principles recommended in point 10 (a))
'Low protection'	'6'	6-9,9
	'10'	10-14,9
'Medium protection'	'15'	15-19,9
	'20'	20-24,9
	'25'	25-29,9
'High protection'	'30'	30-49,9
	'50'	50-59,9
'Very high protection'	'50 +'	60 ≤

The SPF was determined to be 70. Provided that the requirements for minimum UVAPF and Critical Wavelength are met, the product could be labelled up to SPF 50+ and classified as Very High Protection according to the classifications set out in the European Union Commission Recommendation 22nd Sept 2006 on the efficacy of sunscreen products and claims made relating thereto.

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Report of Comparative Real Sunlight Performance

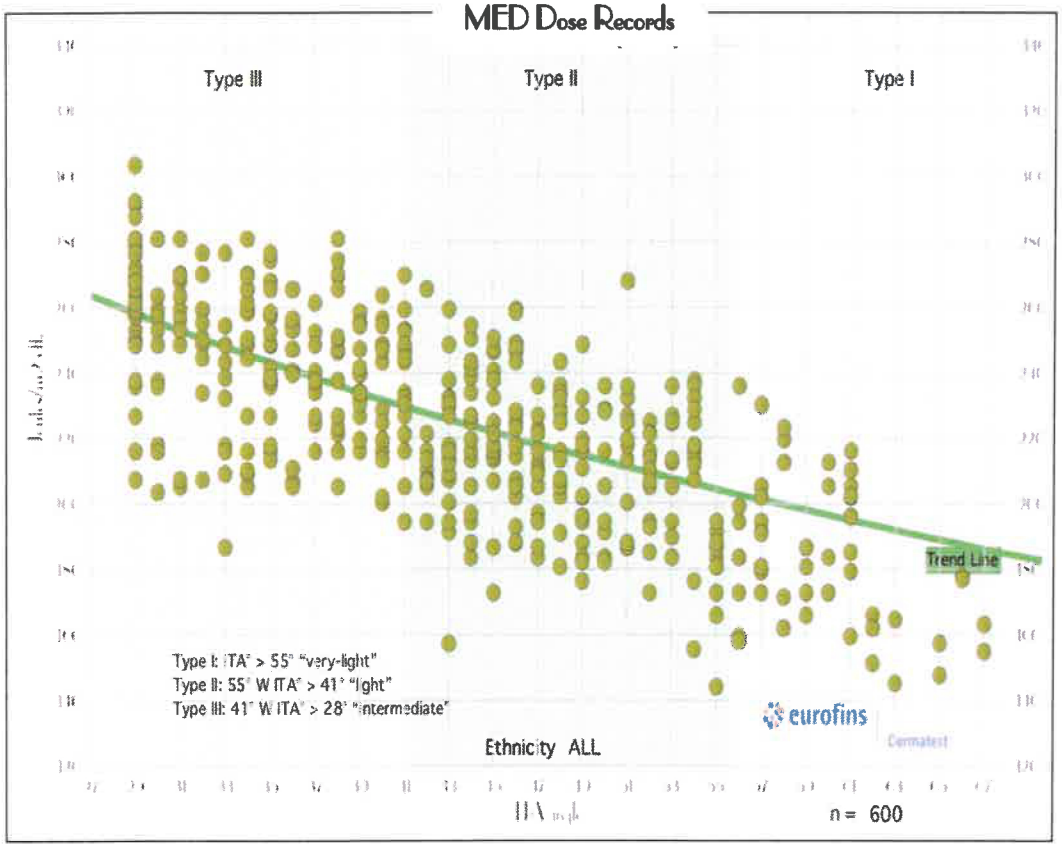
Client: **Celinde**

Product: **PANTALLA SOLAR & AMBIENTAL 60+ PA+++**

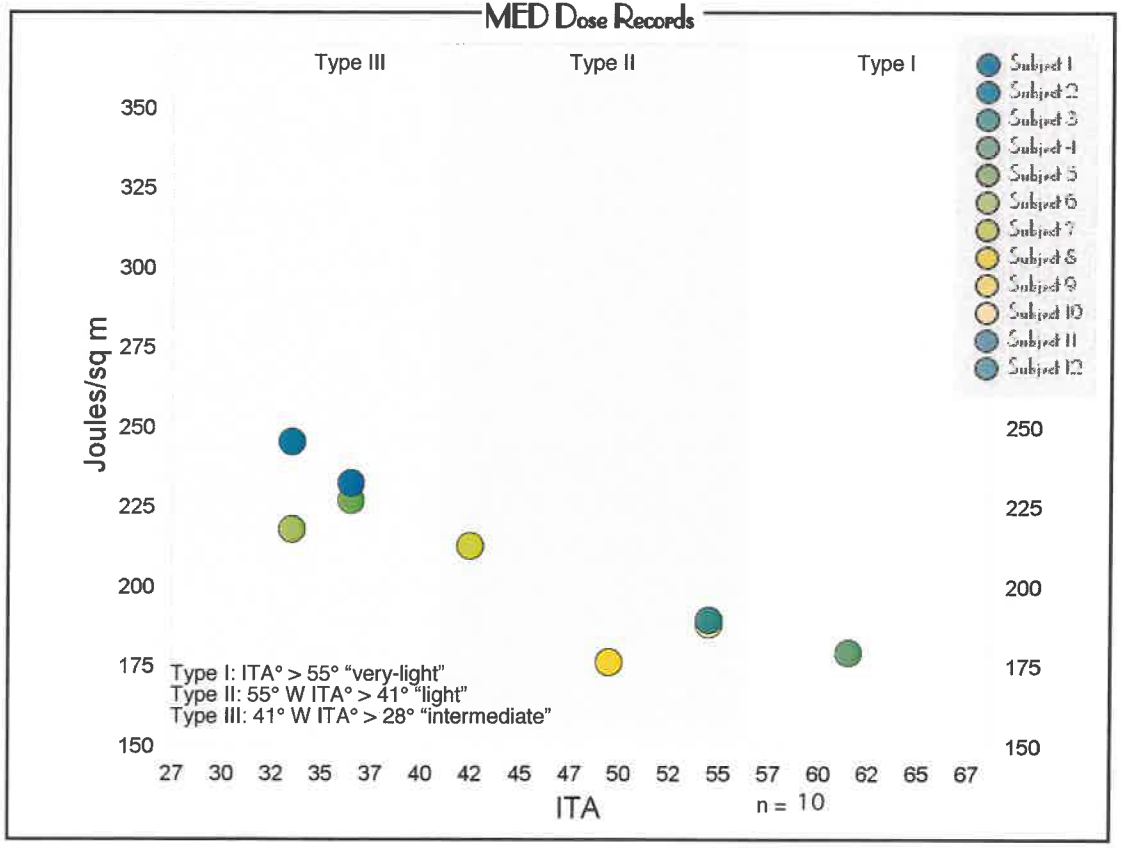
Report Reference Number: **20375**

The graphs below indicate the total dose of Erythemally Effective radiation applied to Dermatest test subjects for exposure of unprotected skin for calculation of Minimal Erythemal Dose (MED) . The values correlate with the Joules/sq m used by ARPANSA** and other metrology authorities for the calculation of the UV index. This shows that the UV dose applied by Dermatest solar simulators corresponds more closely to what will be experienced in real sunlight.

All Studies



This Study



***Australian Radiation and Nuclear Protection Agency*