3904 Del Amo Blvd Torrance, CA 90503
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SPF Test Methods Comparative Summary

Parameter	International- (CTFA-SA/ COLIPA/ JCIA)	United States	Australia
Date	2/03	5/99	3/97
UV definition	UVB 280-320 UVA 320-400	UVB 290-320 UVA 320-400	UVB 290-320 UVA 320-400
Selection of volunteers	Medical-informed consent, Technical-visual, colorimetry	Questionnaire, informed consent	Questionnaire, personal interview
Exclusion criteria	Pregnant, lactating, medication, dermatological problems, abnormal response, UVA suntan	Medical history, abnormal skin response, medication	Photosensitizing medication, skin disease, abnormal response to UV, allergies
Skin type	Phototypes I, II, III	Phototypes I, II, III	Phototypes, I, II, III
Test area	Back	Back	Back
Age limitation	>18 Years	---	---
Frequency	6 times/12-month period	---	---
Number of subjects	10-20-statistical criterion	20 data = 25 subjects	=10
Statistical criterion	95% CI <17% mean SPF	----	SEM =7% SPF
Reference standard	P1 2.7% OMC SPF = 4 P2 7% ODP, 3% OB, SPF = 12, P 3 3% OMC, 0.5% AVB, 2.78% PBI SPF = 15	8% HMS SPF = 4	8% HMS SPF = 4 P 3 3% OMC, 0.5% AVB, 2.78% PBIS SPF =15

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SPF Test Methods Comparative Summary (page 2)

Parameter	International- (CTFA-SA/ COLIPA/ JCIA)	United States	Australia
Acceptance limits for standards	---	+/- S.D., 95 % CI includes value of 4.0	With 25% of nominal value, applicable to each subject
Quantity applied	2.00 +/- 0.04 mg/cm^2	2 mg/cm^2	2.0 mg/cm^2 +/-5%
Mode of delivery	Weight (by loss),fingercot,, No loss, droplets, gentle rubbing	Fingercot (oil, lotion: syringe; gel, butter: warmed)	Weight, fingerstall, validated method; uniform thickness
Test site	30cm^2 – 60cm^2	≥50 cm^2 randomized	≥30 cm^2
Drying Time	15 min-30min	≥15 min	≥15 min, 20-25^o C air conditioned
Solar simulator	Continuous spectrum, erytheml efficacy similar to that of Standard Sun	Continuous emission spectrum 290-400 nm, similar to sunlight at sea level, 10^o zenith angle, <1% energy<290 n <5% energy>400 nm	<1% energy<290nm; no peaks in UVB, cont. spectr. in UVA; Xe preferred (150-6000 W) +WG 320/1mm (2% at 300 nm) + dichroic mirror or IR filter
UV Monitoring	Radiometer (280-400 nm)	Spectroradiometry within	-----
Flux uniformity	15% (min-max)/subsite	10%/subsite	-----
Number of exposure sites	at least 5	5 for MEDu, 7 for MEDp	≥5
Progression of doses	1.25 or 1.25 – Max 1.12	1.25 SPF <8: 0.64-1.56 exp. SPF 8-15: 0.69-1.44, SPF>15 0.76-1.32.	≤26% (geometric) for SPF >25 ≤12% for SPF ≥ 25
Exposure site: Minimum size	Minimum 0.5 cm^2 Recommended ≥ 1cm^2	≥1 cm^2	≥1 cm^2
Skin response	Erythema	Erythema	Erythema
Observation time Postexposure	16-24 hours	22-24 hours	16-24 hours

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SPF Test Methods Comparative Summary (page 3)

Parameter	International- (CTFA-SA/ COLIPA/ JCIA)	United States	Australia
Min. erythema	First perceptible unambiguous redness, with clearly defined borders	Smallest dose of energy that produces redness reaching site at 22-24 hours postexposure	Minimum quantity of radiant energy to produce the first detectable reddering of fair human skin
MED determination	Simultaneous, paired,	Blind MEDus previous and visual, or colorimetric Same day	Visual Only, same observer and similar
manner for	evaluation		MEDμ and MEDp
MED	Energy (mJ or J/m^2 cm^2 or Time (seconds)	Eeff= Sum Vi(λ)*I(λ) J/m^2 effective	Energy or time.
Individual SPFi definition	MEDpi/MEDui	MEDps(J/ m^2)/ MEDus(J/ m^2)	MEDdp/MEDu
Validation of individual	Not the lowest dose In the result	Rejection: no erythema/ps or us ; series subject Noncompliant	SPFi-SPF of std 4≤25%
SPF definition variability	Arthmetical mean of SPFi And 95% CI with n volunteers	Arthmetical mean x of SPFi S.D.,A = t.s/v n with n volunteers	Arthmetical mean of SPFi, one decimal point, labeled to to lowest integer (SEM ≤% mean SPF)