

THE COLIPA SPF TEST METHOD THE DEVIL IS IN THE DETAIL

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SCC Florida Chapter Sunscreen Symposium

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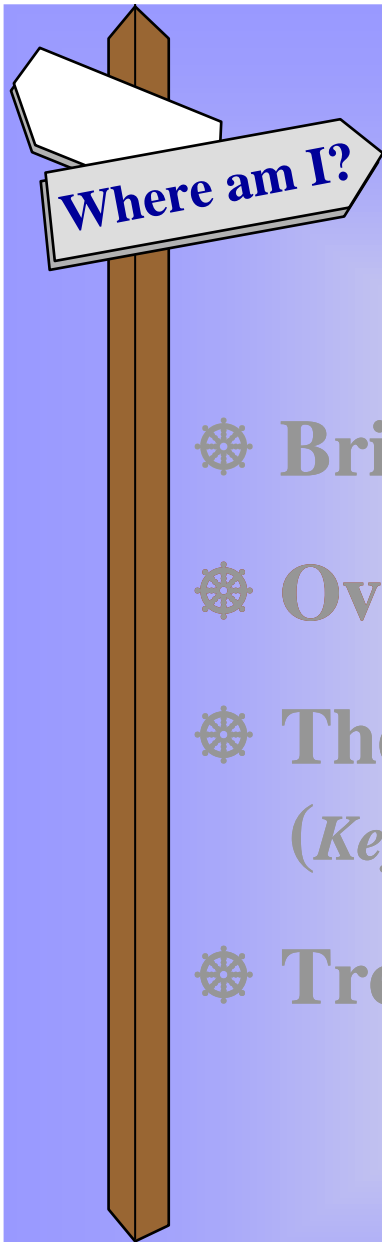
Contents

INTRODUCTION

- ⚙ **Brief history of the COLIPA SPF Test Method**
- ⚙ Overview of the method
- ⚙ The devil *is* in the detail:
(Key points of difference from the FDA method)
- ⚙ Trends in sun products in Europe

Brief History

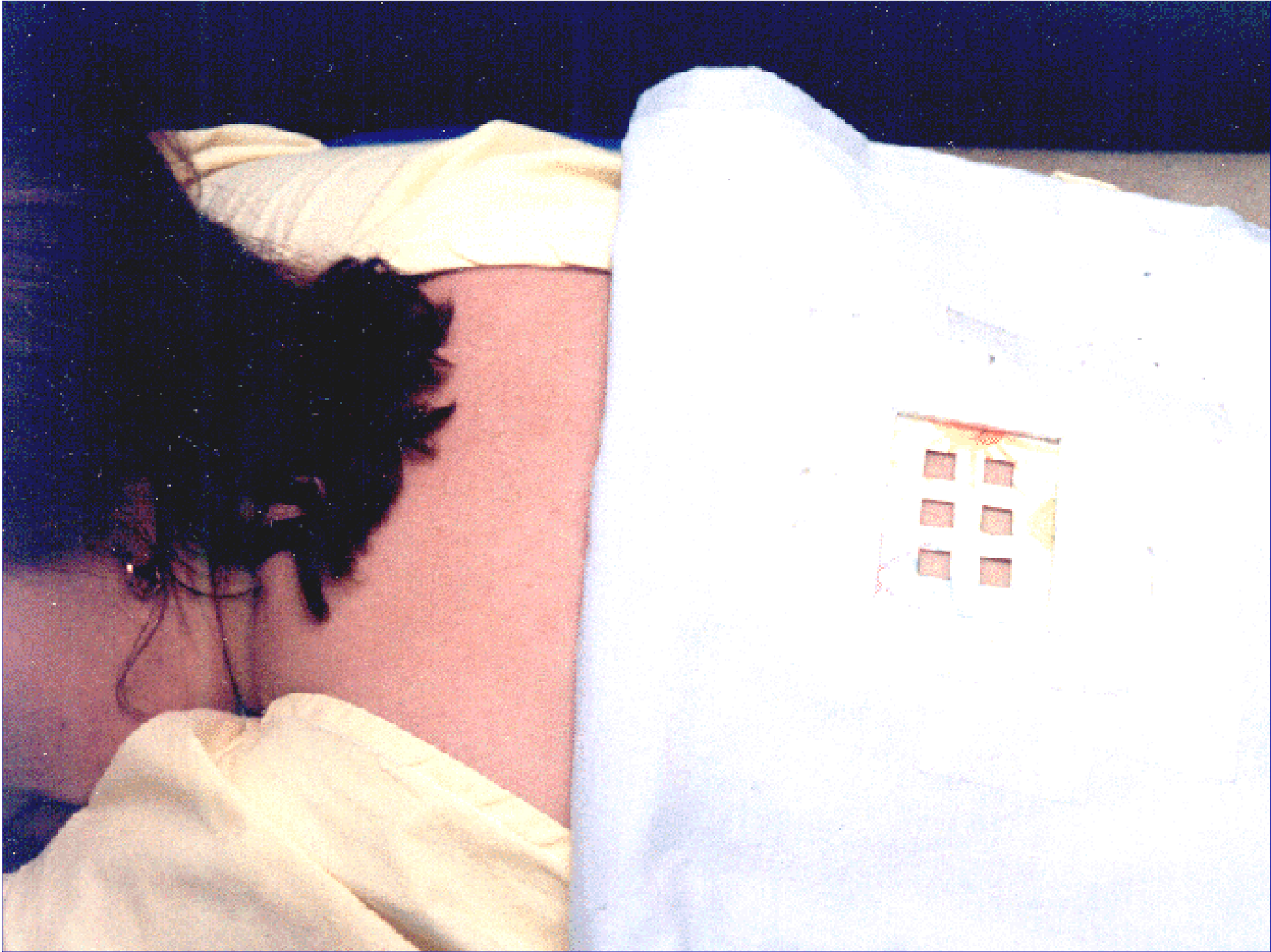
- **1980's - 3 methods (US-FDA, DIN & Australian)**
 - Major differences in methodology
 - Leading to large differences in SPF
- **1990 - COLIPA Task Force “SPM” established**
 - Assemble leading suncare experts from European industry
 - Review existing SPF methods and adopt all best practices
 - Propose a European method with a view to future International harmonisation
- **1994 - COLIPA SPF Test Method published**



- ⊗ **Brief history of the COLIPA SPF Test Method**
- ⊗ **Overview of the method**
- ⊗ **The devil in the detail:**
(Key points of difference from the FDA method)
- ⊗ **Trends in sun products in Europe**







1
minute

2
minutes

2.5
minutes

1.3
minutes

1.6
minutes

3.1
minutes







10.2
minutes

20
minutes

25
minutes

12.8
minutes

16
minutes

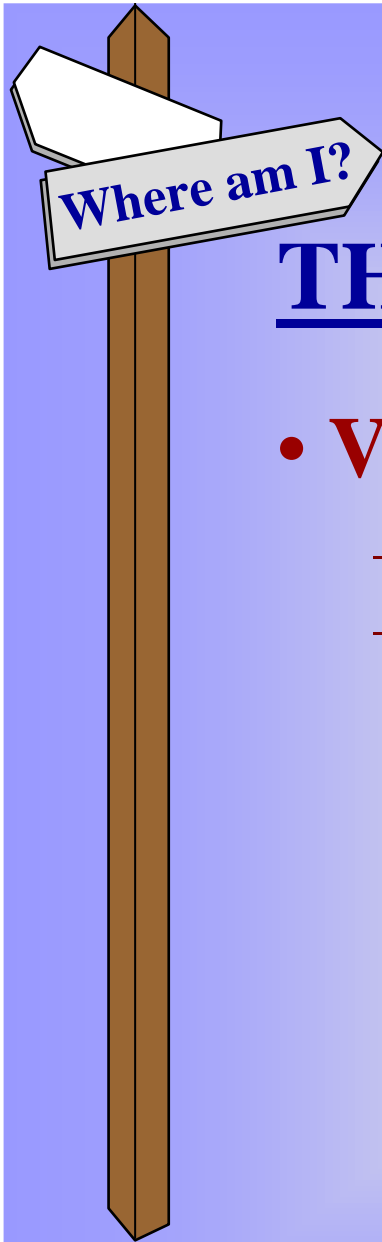
31.2
minutes



- ⊗ Brief history of the COLIPA SPF Test Method
- ⊗ Overview of the method
- ⊗ **The devil is in the detail:**
(Key points of difference from the FDA method)
- ⊗ Trends in sun products in Europe

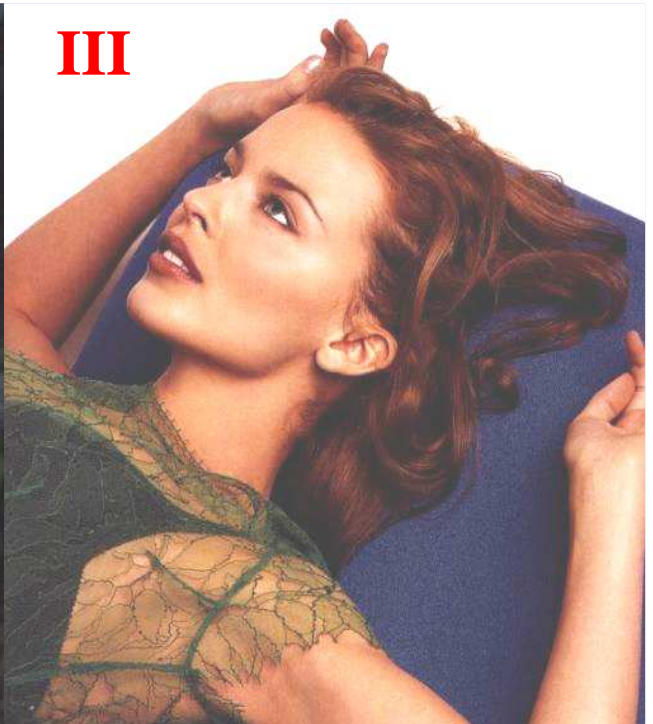


- ⌘ Brief history of the COLIPA SPF Test Method
- ⌘ Overview of the method
- ⌘ **The devil is in the detail:**
(Key points of difference from the FDA method)
 - **Volunteer Selection**
 - **Unprotected MED Measurement**
 - **Product Application & Protected MED Measurement**
 - **SPF Calculations**
 - **Equipment (Solar Simulator)**
- ⌘ Trends in sun products in Europe

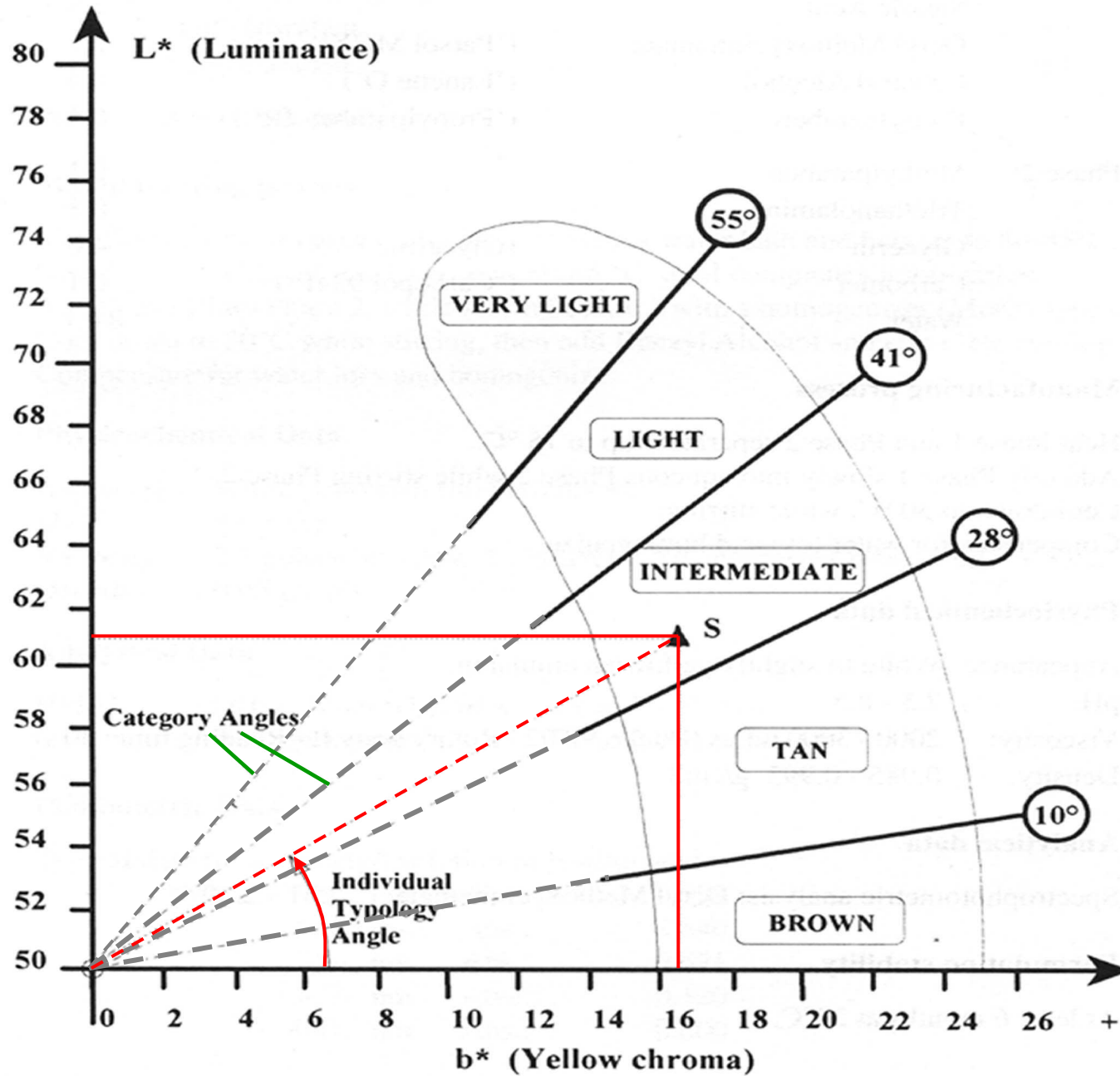


THE DEVIL *IS* IN THE DETAIL

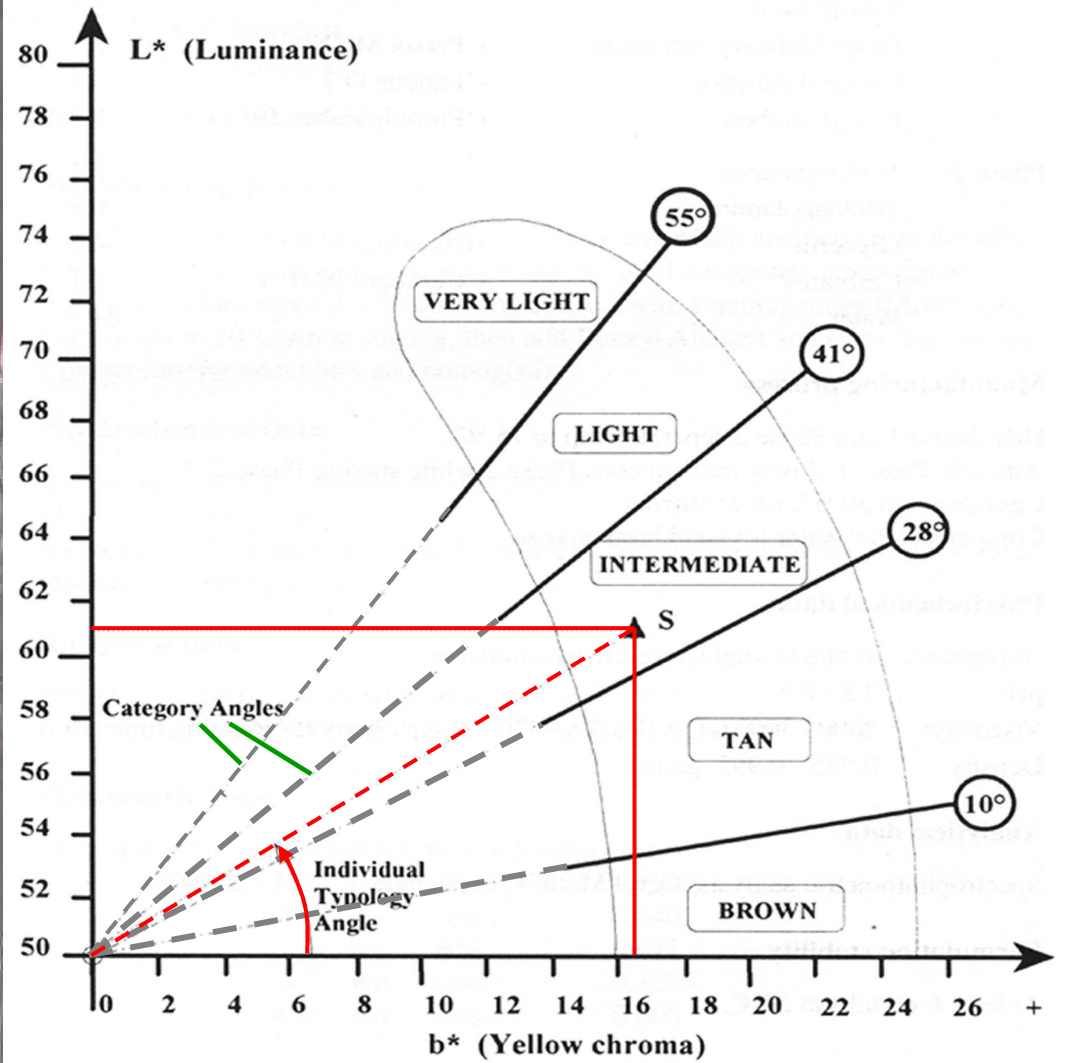
- **Volunteer Selection**
 - Skin Types
 - Number of volunteers



SKIN COLOUR TYPING



Skin Type II



ITA - 49°

Skin Type II



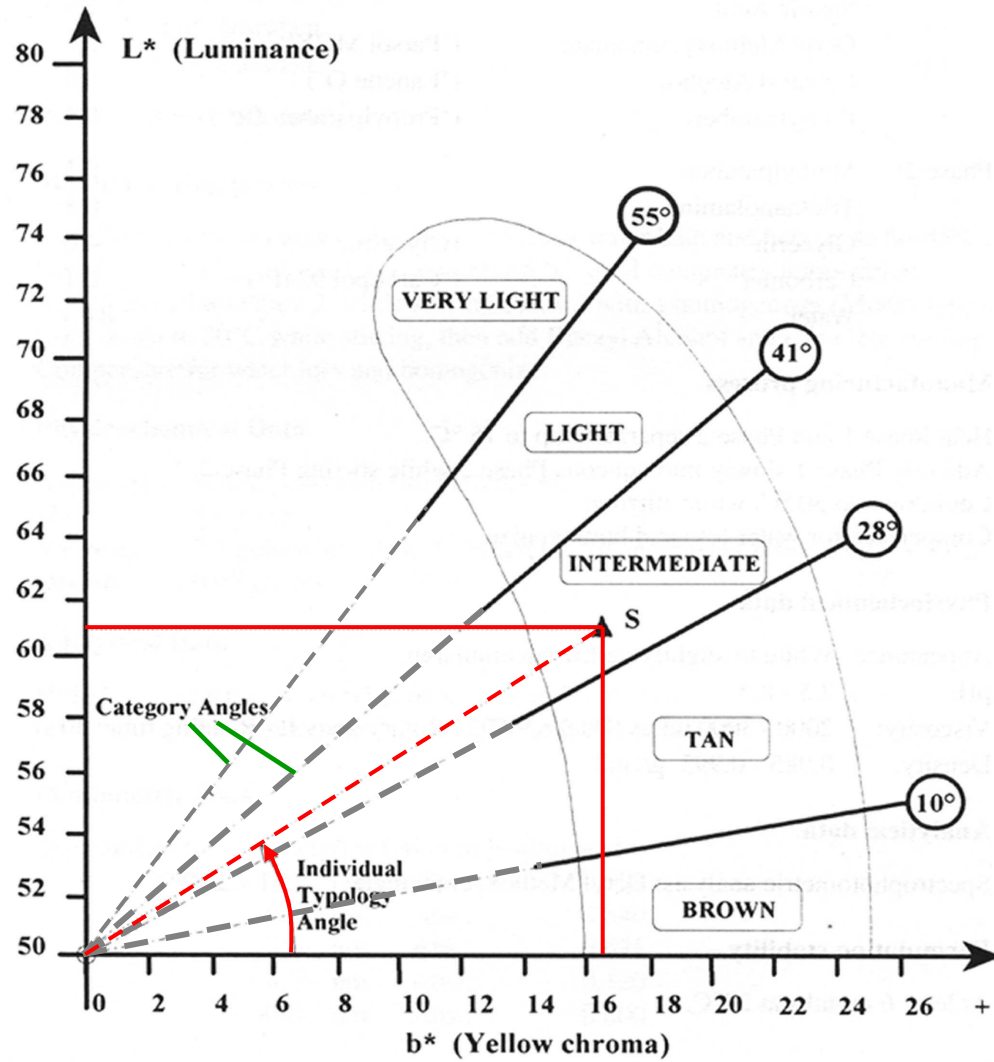
ITA - 49°

Skin Type II



ITA - 38°

Skin Type II



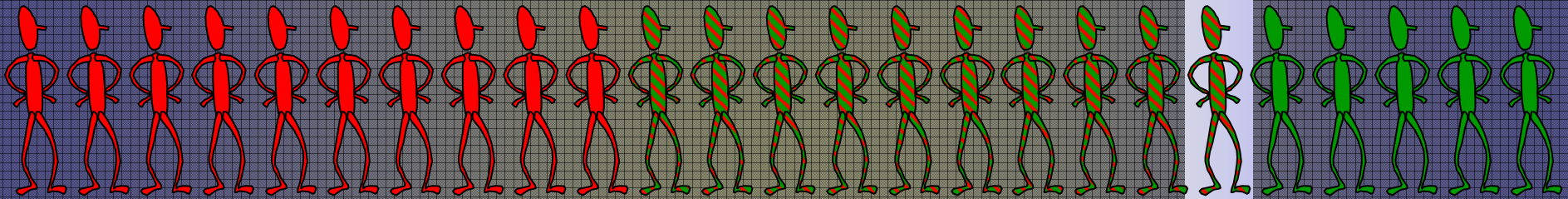
ITA - 38°

– Number of volunteers

COLIPA



1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

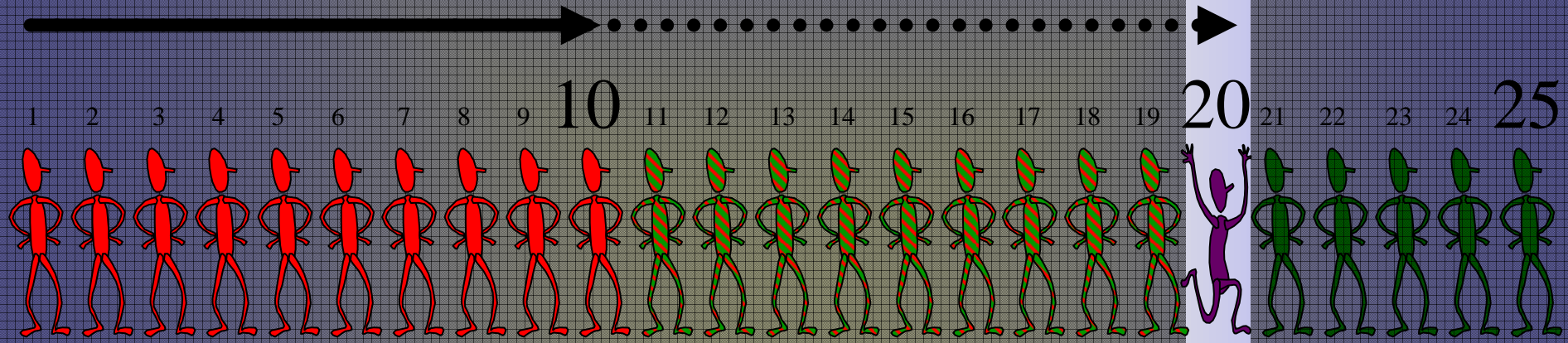


FDA



– Number of volunteers

COLIPA

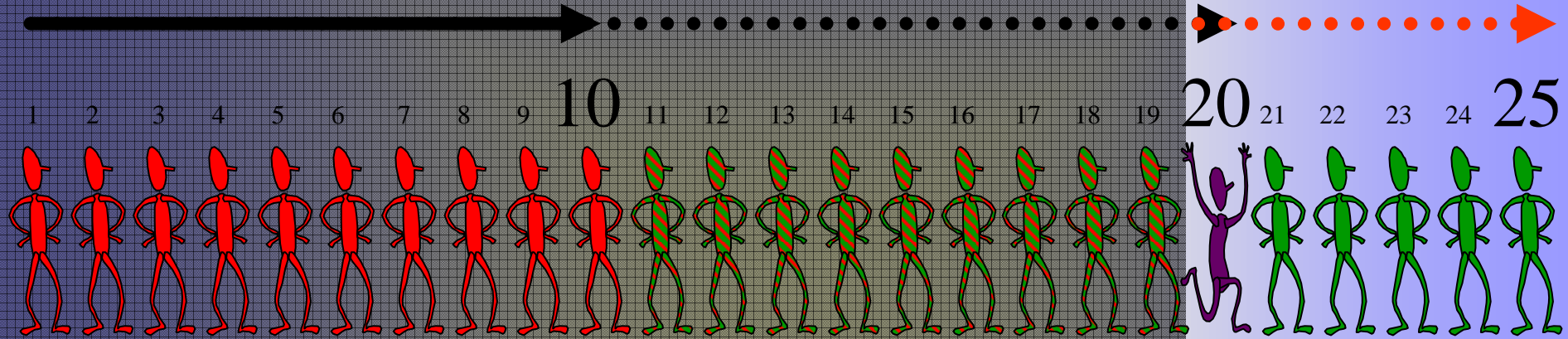


FDA

- Number of volunteers

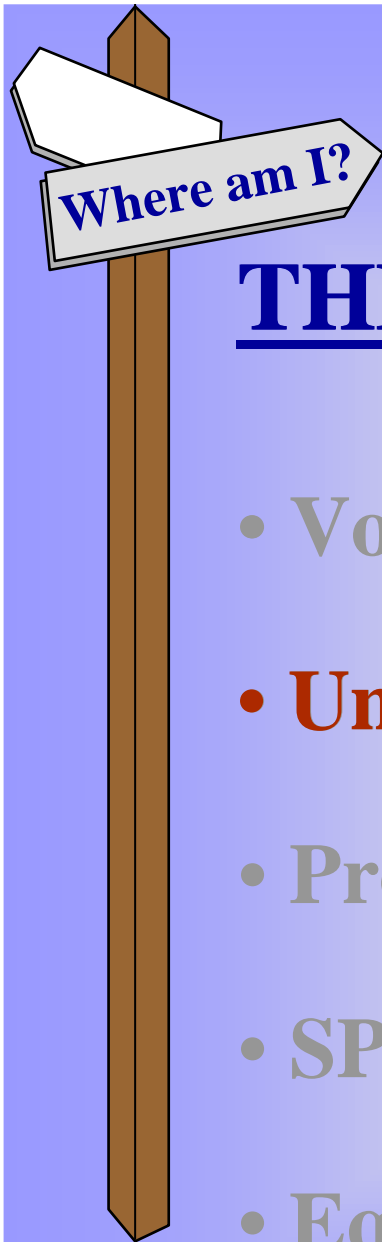
COLIPA

Review Technique



FDA



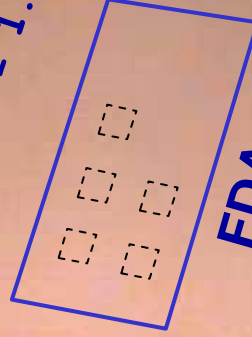


THE DEVIL *IS* IN THE DETAIL

- Volunteer Selection
- **Unprotected MED Measurement**
- Product Application & Protected MED
- SPF Calculations
- Equipment (Solar Simulator)

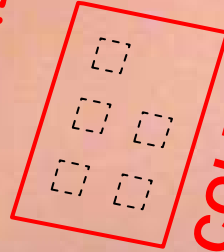
- MED - Unprotected

Increment = 1.25X



FDA
50 cm²

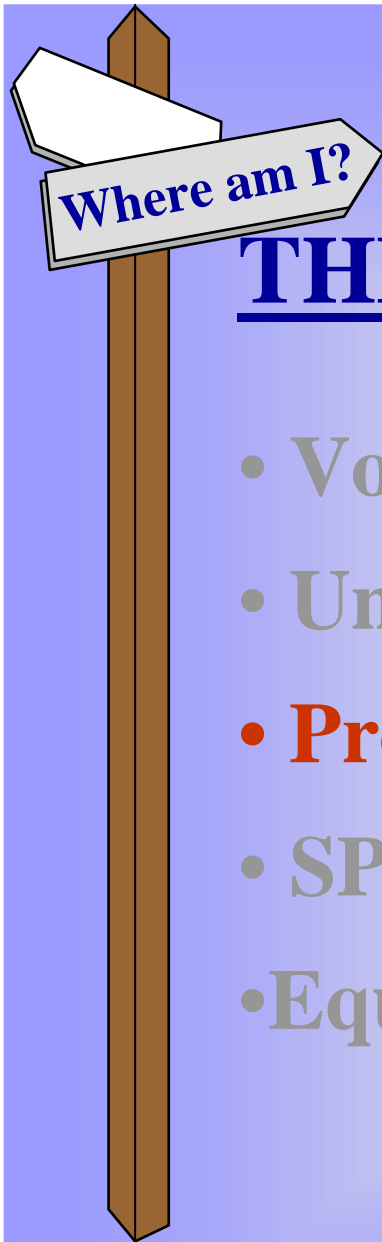
Increment = 1.25X



COLIPA
35 cm²

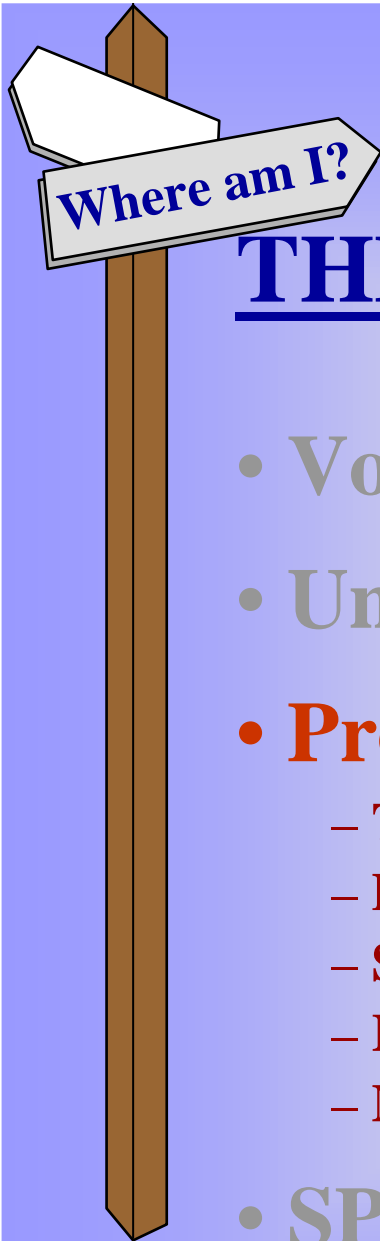
- **Unprotected MED (MED_u)**

	Number of exposure sites	Time after exposure for MED assessment	Illumination for MED evaluation	MED expressed as:
FDA	5	22 to 24 hours	450 - 500 LUX	J/m ² (erythema)
COLIPA	5	16 to 24 hours	Sufficient Light !	mJ/cm ² or seconds



THE DEVIL IS IN THE DETAIL

- Volunteer Selection
- Unprotected MED Measurement
- **Product Application & Protected MED**
- SPF Calculations
- Equipment (Solar Simulator)



THE DEVIL IS IN THE DETAIL

- Volunteer Selection
- Unprotected MED Measurement
- **Product Application & Protected MED**
 - Test Site
 - Product Application
 - Standard Product
 - Irradiation Doses
 - MED Assessment
- SPF Calculations
- Equipment (Solar Simulator)

– Test Site

MED - Product Protected

FDA
50 cm²

COLIPA
35 cm²



– Product Application



Application Rate:

FDA = 2 mg/cm²

COLIPA = 2.0 ± 0.04 mg/cm²

– Standard Product



– Irradiation Doses

FDA SPF <8

0.64x → 0.80x → 0.90x → 1.00x → 1.10x → 1.25x → 1.56x

FDA SPF 8-15

0.69x → 0.83x → 0.91x → 1.00x → 1.09x → 1.20x → 1.44x

FDA SPF >15

0.76x → 0.87x → 0.93x → 1.00x → 1.07x → 1.15x → 1.32x

COLIPA

0.64x → 0.80x → 1.00x → 1.25x → 1.56x

0.72x 0.90x 1.13x 1.41x

where x = expected SPF of product

– MED Assessment

DEFINITION of MED for Product Protected Skin

FDA:

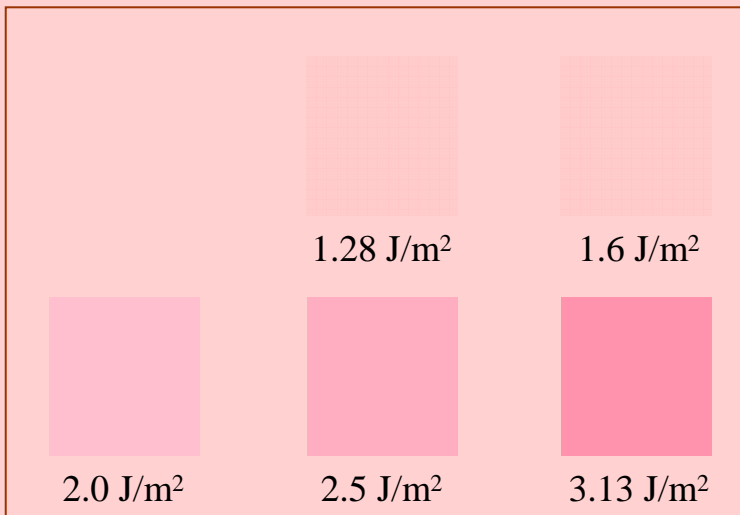
Quantity of erythema-effective energy required to produce the first perceptible unambiguous redness reaction with clearly defined borders.....

COLIPA:

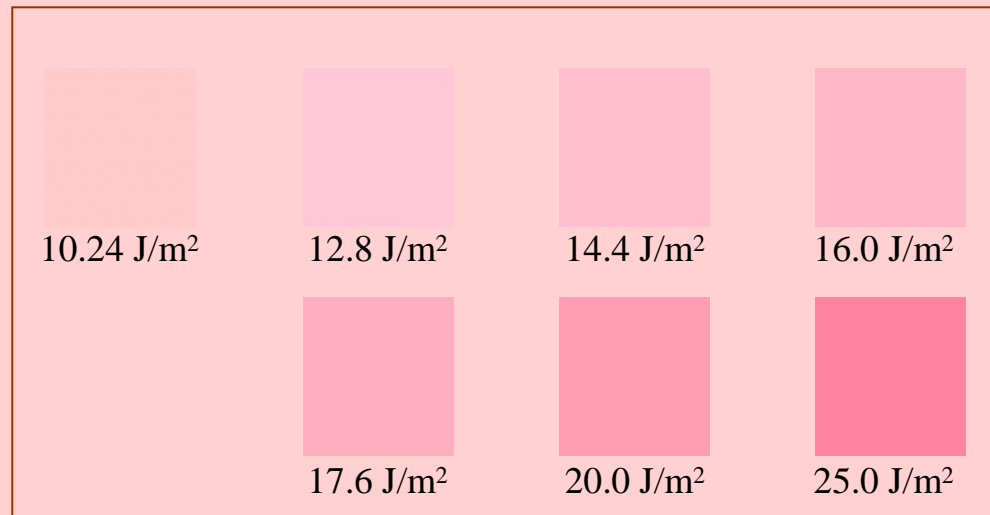
Quantity of radiant energy required to produce an unambiguous redness reaction, matching that selected for the corresponding $MED_{unprotected}$

– MED Assessment

MED unprotected



MED protected (FDA)



FDA

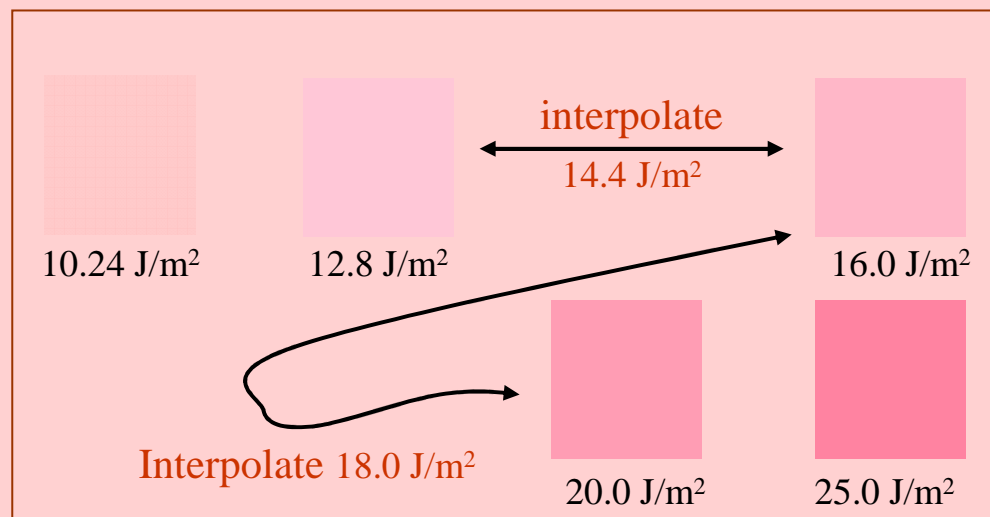
$$\begin{aligned} \text{SPF} &= 12.8 \div 2.0 \\ &= \text{SPF } 6.4 \end{aligned}$$

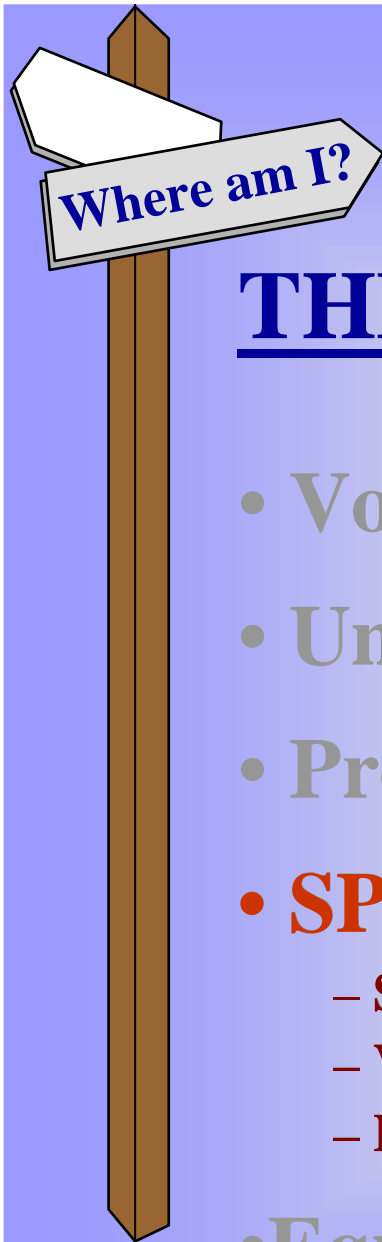
COLIPA

interpolate between 12.8 and 16

$$\begin{aligned} \text{SPF} &= 14.4 \div 2.0 \\ &= \text{SPF } 7.2 \end{aligned}$$

MED protected (COLIPA)





THE DEVIL IS IN THE DETAIL

- Volunteer Selection
- Unprotected MED Measurement
- Product Application & Protected MED
- **SPF Calculations**
 - **SPF Test Result**
 - **Variation Associated with test Result**
 - **Labelled SPF**
- Equipment (Solar Simulator)

• SPF CALCULATIONS

– **SPF Test Result**

FDA

= Arithmetic mean of all individual SPF values

COLIPA

= Arithmetic mean of all individual SPF values

– Variation Associated with test Result

SPF TEST RESULT TABLE								Laboratory:						
Product:.....Expected SPF:.....Date:.....Data Sheet N°:.....UV Source.....														
Vol. N°	TEST		SUBJECTS					RESULTS				VALIDATION 95% CI(n') within target?	COMMENTS	
	Date	Tech- nician	Vol. Code	Skin Type	MEDu (mJ/cm ²)	MEDp (mJ/cm ²)	SPFi	SPFn'	SD(n')	95% CI (n')	Target 95% CI			
1				I	10.2	230.0	22.5							interpolated
2				II	20.0	564.0	28.2							interpolated
3				III	31.3	400.0	12.8							
4				II	25.0	400.0	16.0							
5				II	16.0	400.0	25.0							
6				III	31.3	500.0	16.0							
7				I	12.8	164.0	12.8							
8				II	20.0	626.0	31.3							
9				III	25.0	360.0	14.4							interpolated
10				III	31.3	783.0	25.0	20.4	6.8	15.5 to 25.3	16.3 to 24.5	FAIL		
11														
12														
13														
14														
15														
16														
17														
18														
19														
20														
FINAL RESULT:			SPF =					95% CI =				n = 13		

– Variation Associated with test Result

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10				III	31.3	783.0	25.0	20.4	6.8	15.5 to 25.3	16.3 to 24.5	FAIL		
11				II	16.0	288.0	18.0	20.2	6.5	15.8 to 24.6	16.2 to 24.2	FAIL		interpolated
12														
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12				II	20.0	622.0	31.1	21.1	7.0	16.7 to 25.5	16.9 to 25.3	FAIL		
13														
14														
15														
16														
17														
18														
19														
20														
FINAL RESULT:			SPF =					95% CI =				n = 13		

– Variation Associated with test Result

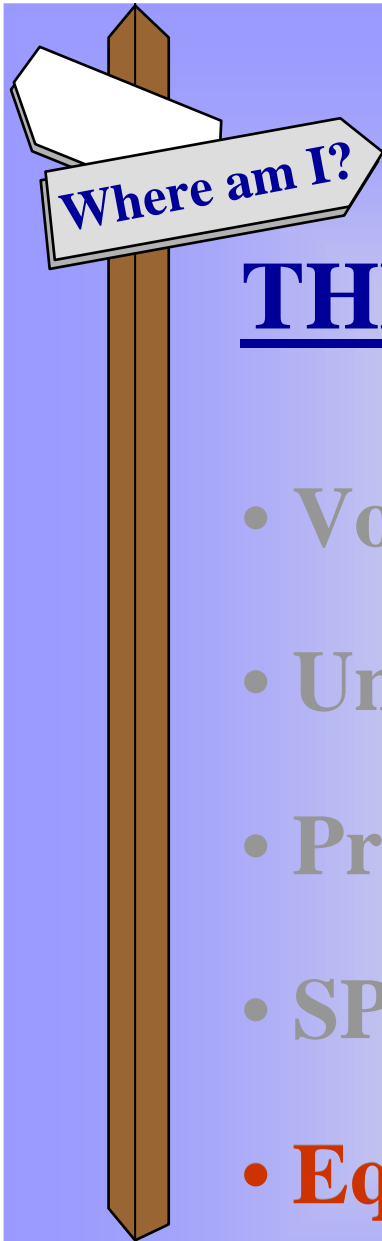
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12				II	20.0	622.0	31.1	21.1	7.0	16.7 to 25.5	16.9 to 25.3	FAIL		
13				III	31.3	450.7	14.4	20.6	6.9	16.4 to 24.8	16.5 to 24.7	FAIL		interpolated
14														
15														
16														
17														
18														
19														
20														
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14				II	20.0	400.0	20.0	20.6	6.7	16.8 to 24.4	16.5 to 24.7	PASS		
15														
16														
17														
18														
19														
20														
FINAL RESULT:			SPF =					20.6	95% CI =			16.8 to 24.4	n =	14

– Labelled SPF

	FDA	COLIPA
Tested SPF Value	Arithmetic mean of individual SPF values	Arithmetic mean of individual SPF values
Statistical Acceptance Criterion	None	95% Confidence Interval must lie within -20% & +20% of mean SPF.
Labelled SPF	Largest whole number below the lower 95% Confidence Interval	<u>Mean SPF</u> Numbers between the lower 95% Confidence Interval and the mean SPF also permitted
EXAMPLE		
Tested SPF Value	22.1	22.1
95% Confidence Interval	19.1 to 25.1	19.1 to 25.1
Acceptance Criterion	-----	PASS (95% CI within 17.7 to 26.5)
Labelled SPF: Maximum Minimum	SPF 19	SPF 22
	SPF 19	SPF 19



THE DEVIL IS IN THE DETAIL

- Volunteer Selection
- Unprotected MED Measurement
- Product Application & Protected MED
- SPF Calculations
- **Equipment (Solar Simulator)**
 - Beam Uniformity
 - Spectral Output



– Beam Uniformity



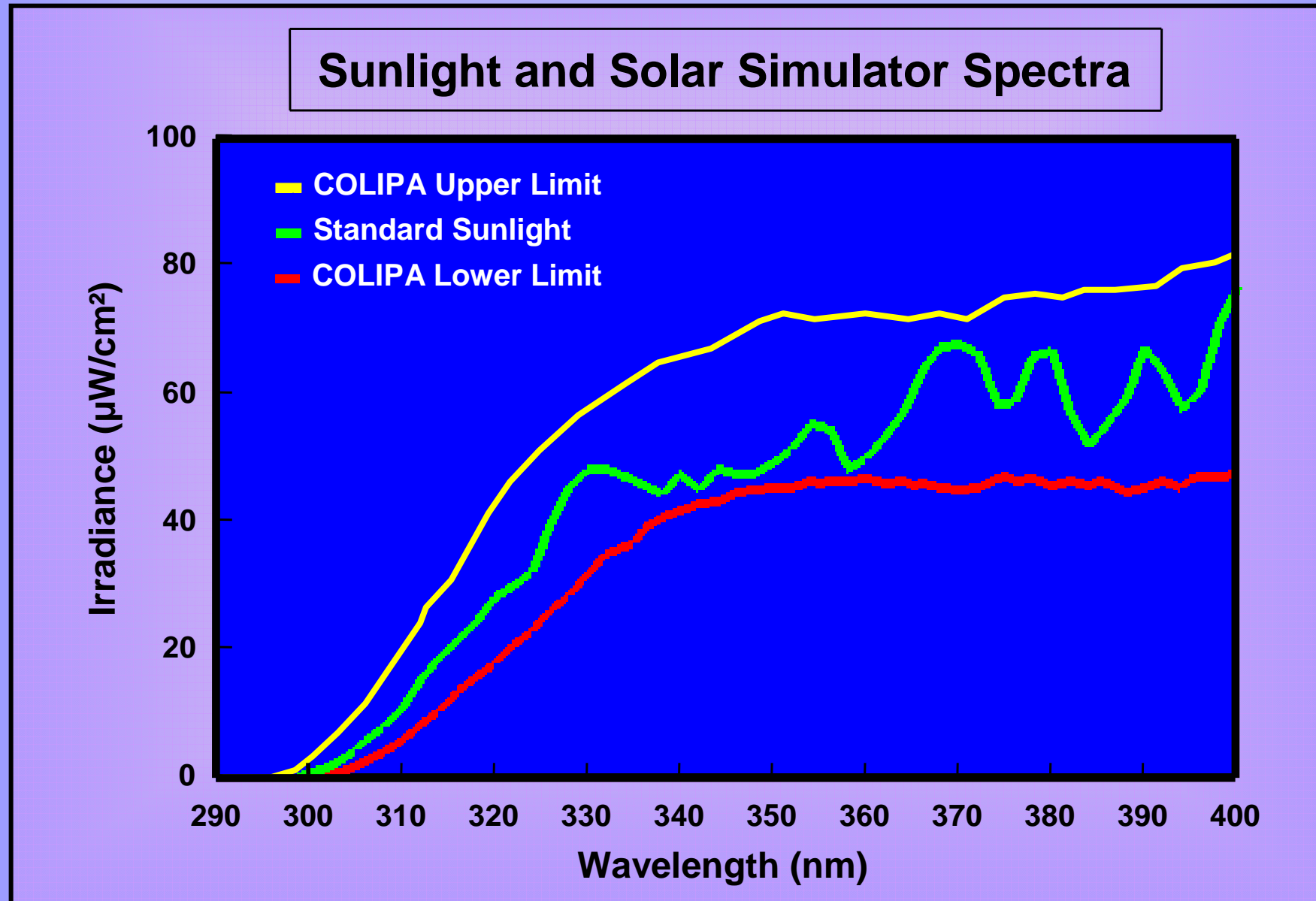
– Beam Uniformity



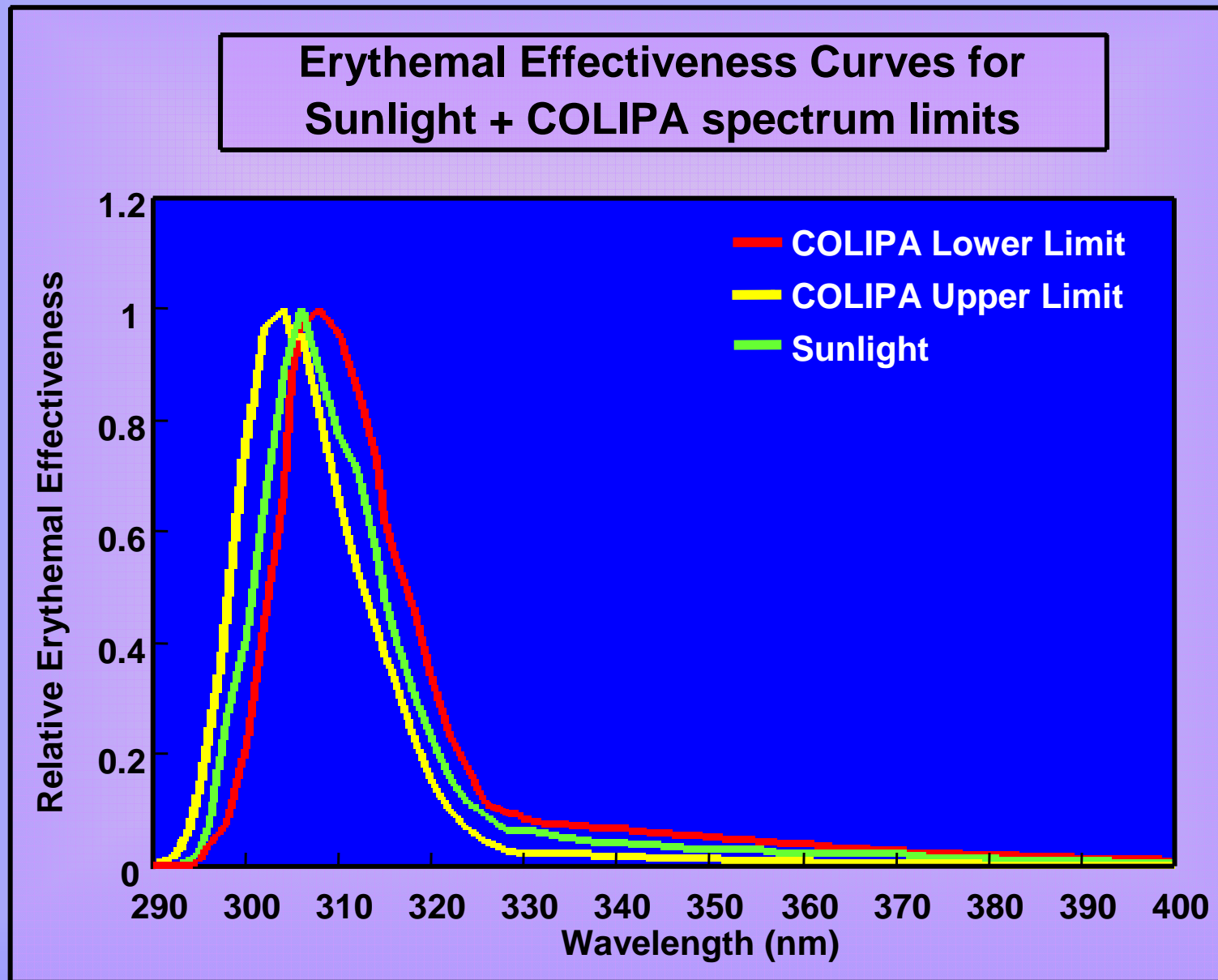
– Beam Uniformity



– Spectral Output

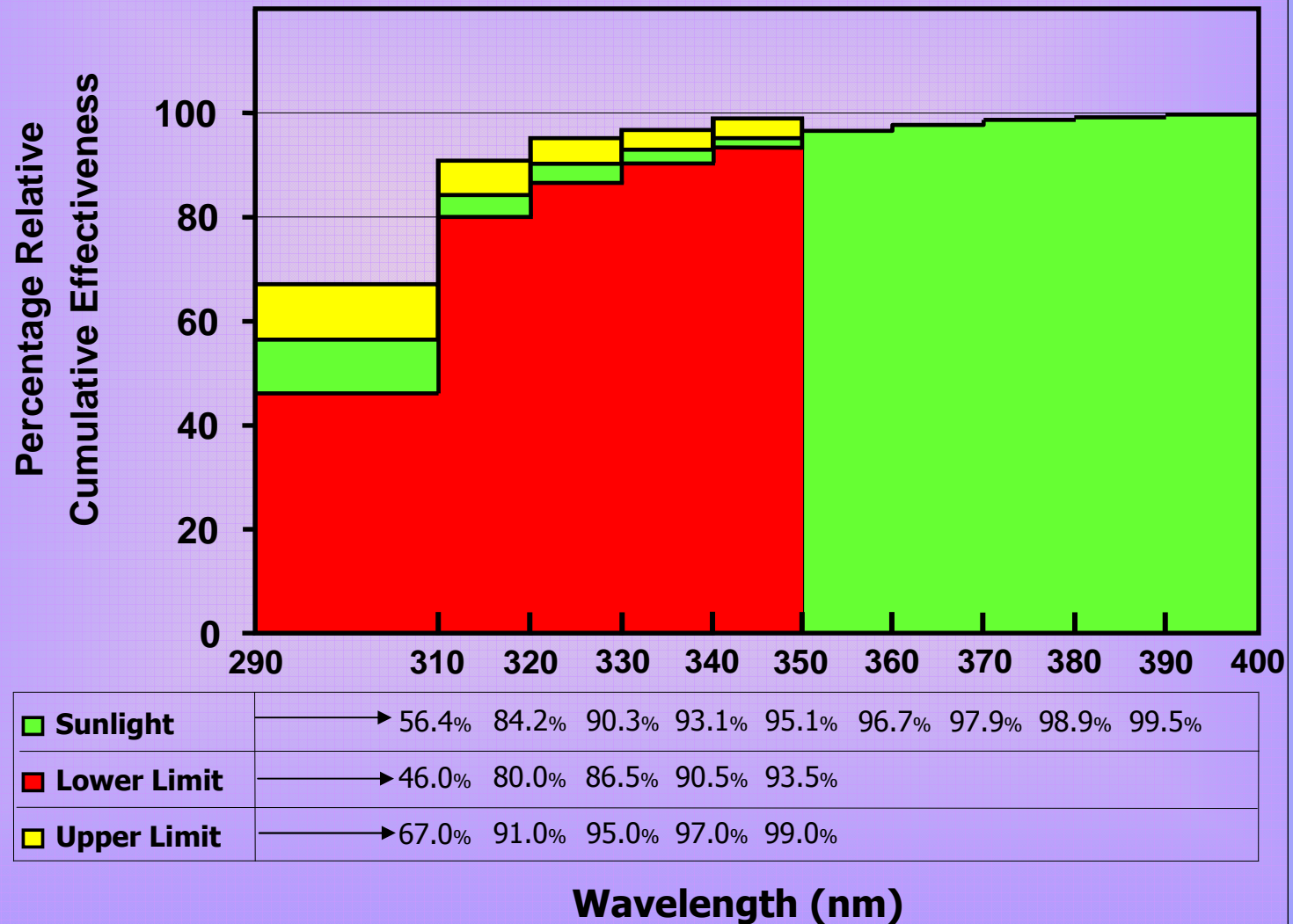


– Spectral Output



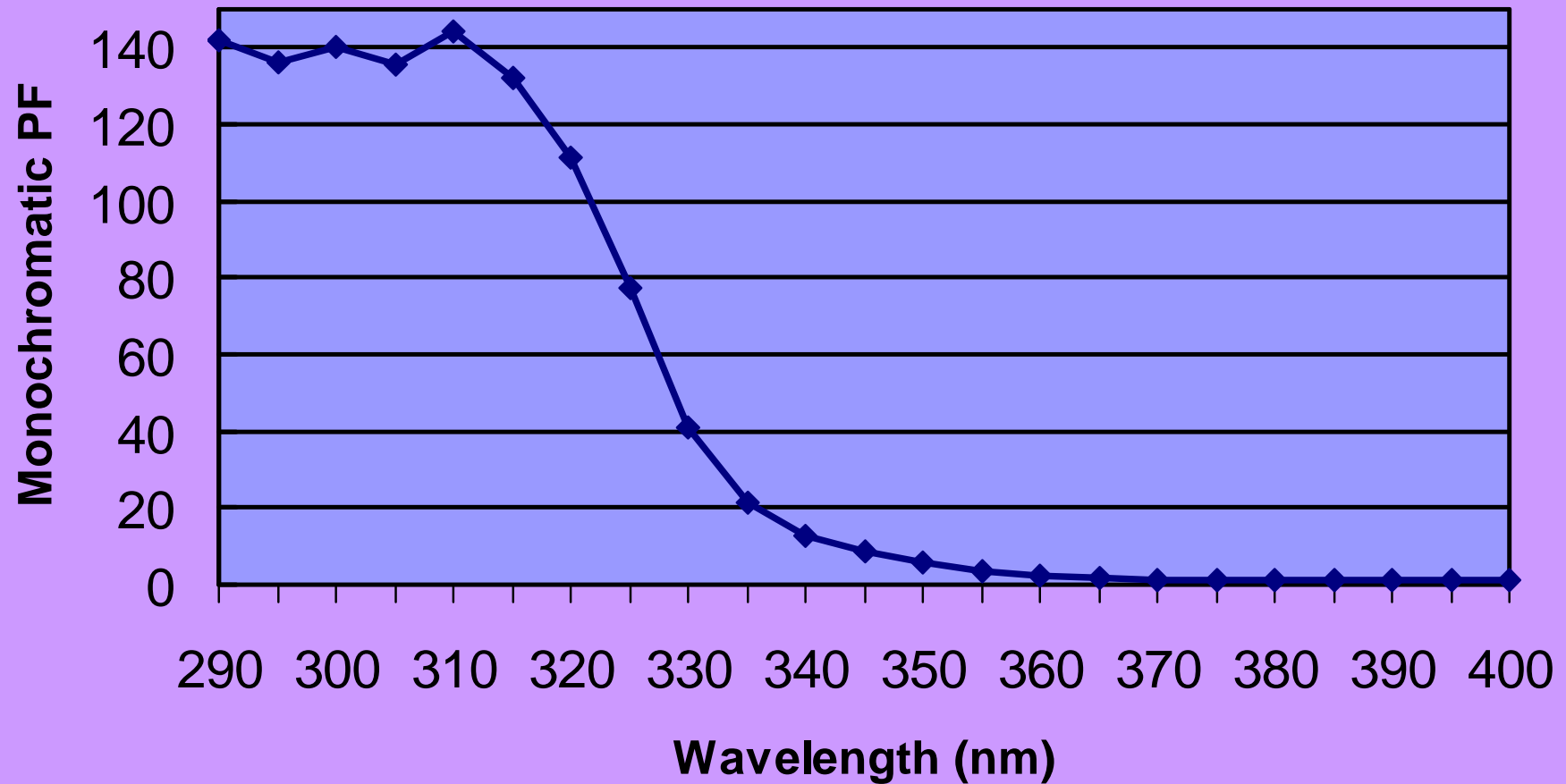
- Spectral Output

COLIPA Solar Simulator Limits



– Spectral Output

Protection Profile for USA SPF45 Sun Product



- Spectral Output

Place cursor on C1 and import file ie / FILE IMPORT NUMBERS

Then PAGE DOWN 5 Times To cell C17 (To add Titles etc.)

Or PAGE DOWN Twice To cell C41 To view data only

PAGE DOWN AGAIN

Trans data for SP#23.1 mPFs Attach 7 minus scan 6 calc using transm transm minus scan 6 RAW IMPORTED DATA

Control values :

Sample values :

PAGE DOWN AGAIN FOR FULL RESULTS

RESULTS TABLE

mPF VALUES

	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(1)	(2)	(3)	(4)	(5)	(6)
1.47E-11	3.52E-09	3.09E-10	9.00E-10	1.19E-08	1.10E-08	6.22E-05	2.25E-10	3.95E-09	4.85E-12	0.00E+00	0.00E+00	3.66E-08	
1.42E-08	1.66E-07	6.11E-08	1.39E-06	6.20E-07	1.04E-06	1.43E-02	3.05E-08	2.53E-07	1.48E-08	5.00E-01	1.00E+00	7.97E-04	
2.42E-07	2.45E-06	5.60E-07	4.02E-07	2.76E-05	3.95E-05	1.11E-02	4.32E-07	1.50E-06	9.66E-08	1.49E+01	6.43E+00	0.30E-03	
6.95E-07	3.11E-06	1.23E-06	3.27E-05	3.34E-05	3.32E-05	2.43E-02	3.78E-07	3.39E-07	6.16E+01	1.84E+01	1.43E-02		
6.37E-07	2.14E-06	9.23E-07	7.34E-05	6.12E-05	7.97E-05	1.22E-02	7.97E-07	1.28E-06	6.12E-07	5.28E+01	1.52E+02	1.27E-02	
4.16E-07	1.26E-06	5.74E-07	3.68E-05	4.57E-05	4.24E-05	9.49E-03	5.05E-07	6.16E-07	3.72E-07	2.98E+01	9.76E+01	7.44E-03	
1.95E-07	5.04E-07	2.69E-07	1.52E-05	1.98E-05	1.83E-05	4.28E-03	2.40E-07	2.69E-07	1.95E-07	1.26E+01	4.57E+01	3.40E-03	
6.41E-08	1.79E-07	1.16E-07	5.71E-06	7.38E-06	7.04E-06	1.57E-03	1.04E-07	1.29E-07	9.71E-08	4.91E+01	1.77E+01	1.55E-03	
4.77E-08	6.54E-08	7.26E-08	2.61E-06	3.67E-06	3.62E-06	1.13E-03	6.56E-08	6.49E-08	6.80E-08	2.45E+00	9.29E+00	6.60E-04	
4.95E-08	7.43E-08	5.89E-08	2.48E-06	3.26E-06	3.23E-06	6.24E-04	5.31E-08	5.21E-08	5.49E-08	2.15E+00	6.17E+00	7.46E-04	
4.78E-08	6.28E-08	5.21E-08	2.14E-06	2.87E-06	2.86E-06	9.89E-04	4.80E-08	4.90E-08	4.34E-08	1.88E+00	7.05E+00	6.57E-04	
4.20E-08	5.63E-08	4.34E-08	1.85E-06	2.45E-06	2.46E-06	6.38E-04	3.89E-08	3.95E-08	3.77E-08	1.65E+00	5.03E+00	5.61E-04	
3.65E-08	4.81E-08	3.62E-08	1.57E-06	2.13E-06	2.11E-06	5.98E-04	3.37E-08	3.65E-08	3.25E-08	1.49E+00	5.21E+00	4.79E-04	
3.12E-08	3.95E-08	3.01E-08	1.33E-06	1.77E-06	1.84E-06	5.13E-04	3.16E-08	2.89E-08	2.99E-08	1.33E+00	4.45E+00	4.09E-04	
2.66E-08	3.22E-08	2.73E-08	1.11E-06	1.55E-06	1.53E-06	4.52E-04	2.41E-08	2.67E-08	2.48E-08	1.18E+00	3.78E+00	3.63E-04	
2.19E-08	2.73E-08	2.78E-08	9.13E-07	1.26E-06	1.27E-06	3.93E-04	2.45E-08	2.70E-08	2.17E-08	1.05E+00	3.25E+00	3.06E-04	
1.62E-08	2.27E-08	2.63E-08	7.20E-07	1.03E-06	9.98E-07	3.72E-04	2.32E-08	2.24E-08	9.42E-01	2.69E+00	2.67E-04		
1.59E-08	1.99E-08	1.91E-08	5.22E-07	7.44E-07	6.89E-07	2.53E-04	1.89E-08	1.85E-08	9.19E-01	2.32E+00	2.31E-04		
1.20E-08	1.63E-08	1.63E-08	3.26E-07	4.71E-07	4.33E-07	2.60E-04	1.63E-08	1.51E-08	2.09E-01	2.03E+00	2.01E-04		
1.11E-08	1.39E-08	1.24E-08	1.67E-07	2.33E-07	2.25E-07	1.96E-04	1.09E-08	1.15E-08	5.72E-01	1.72E+00	1.76E-04		
9.18E-09	1.15E-08	1.30E-08	5.67E-08	8.83E-08	7.68E-08	2.02E-04	1.15E-08	1.04E-08	9.84E-01	4.34E-01	1.47E+00	1.55E-04	
7.83E-09	9.92E-09	9.95E-09	1.14E-08	1.95E-08	1.69E-08	1.71E-04	8.52E-09	8.06E-09	3.10E-01	1.27E+00	1.34E-04		
6.81E-09	8.51E-09	1.23E-08	1.48E-09	2.98E-09	1.95E-09	1.69E-04	1.09E-09	1.51E-09	7.93E-01	1.92E-01	1.07E+00	1.19E-04	

- 7 = COLIPA Lower Limit
- 8 = COLIPA Upper Limit
- 9 = COLIPA Sunlight spectrum
- 10 = TRI SOL SIM SERIAL NO 2994 - 23/8/00
- 11 = TRI SOL SIM SERIAL NO 2994 - 24/08/00
- 12 = TRI SOL SIM SERIAL NO 3646 - 30/08/00
- 13 = Diffey zenith sunlight, 90 degree sunlight (ie max on earth)
- 1 = Albuquerque 1300 hrs spectrum
- 2 = Sayre Alb1300 Blue Limit
- 3 = Sayre Alb1300 Red Limit
- 4 = Boots AFP Sol/Sim (WG320/1mm + UG5/2mm)
- 5 = Boots Crt Sol/Sim (WG320/2mm + Dichroic)
- 6 = Diffey 40N

50.02	48.66	44.29	44.74	49.02	49.76	43.97	26.58	10.56	4.674	2.877	2.207	1.916	1.759	1.678	1.587	1.531	1.487	1.459	1.436	1.399	1.385	1.375
27.52	205.3	149.4	147.9	161.83	70.83	20.73	7.097	3.785	2.582	2.24	2.01	1.893	1.765	1.687	1.627	1.568	1.557	1.508	1.488	1.475		
167.4	152.2	118.8	120.4	143.2	151.7	124	61.5	19.16	6.738	3.636	2.59	2.18	1.964	1.852	1.732	1.656	1.6	1.564	1.534	1.486	1.472	1.456
107.6	108.8	97.07	98.25	109.7	111.7	96.22	62.41	17.2	6.431	3.581	2.6	2.192	1.977	1.868	1.746	1.672	1.614	1.578	1.548	1.5	1.481	1.468
91.73	94.22	85.46	86.86	95.94	96.97	84.02	47.18	15.93	6.094	3.437	2.514	2.133	1.932	1.828	1.713	1.642	1.588	1.554	1.525	1.478	1.465	1.449

290	295	300	305	310	315	320	325	330	335	340	345	350	355	360	365	370	375	380	385	390	395	400	290	295
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106.5	113.5	122.5	106	120.8	104.8	90.97	80.4	49.48	29.35	17.8	11.72	7.783	5.335	3.814	2.828	2.158	1.734	1.461	1.287	1.184	1.123	1.085	MONOCHROMATIC PRK							
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	106.49	113.5					
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	106.49	113.5				
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	106.49	113.5			
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	106.49	113.5		
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	106.49	113.5	
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	106.49	113.5	
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	106.49	113.5
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	106.49	113.5
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	106.49	113.5
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	106.49	113.5
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	106.49	113.5
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	106.49	113.5
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	106.49	113.5

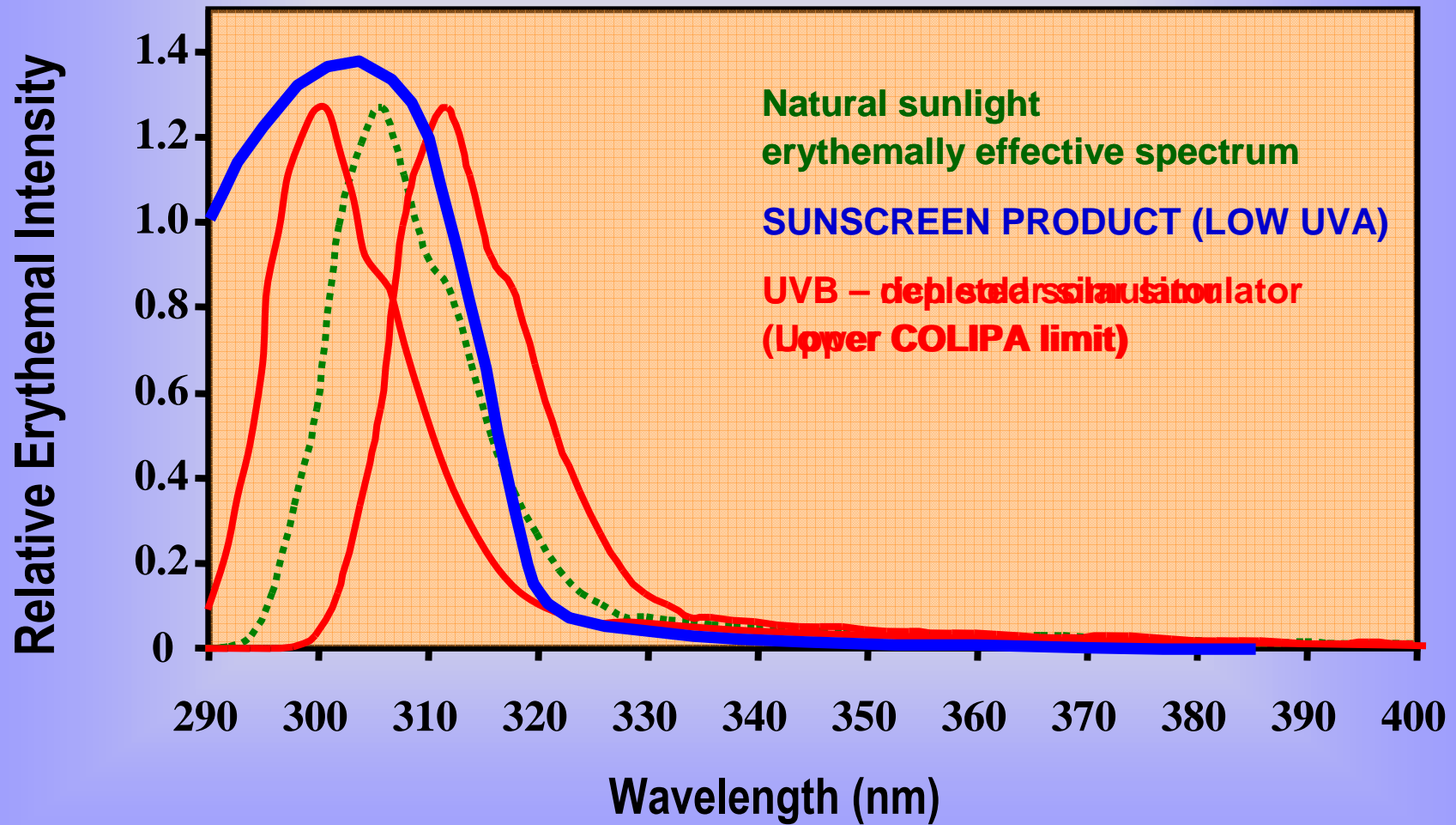
290	295	300	305	310	315	320	325	330	335	340	345	350	355	360	365	370	375	380	385	390	395	400	Simpson's Ratio
106.49	113.50	122.45	105.97	120.79	104.80	90.97	80.40	49.48	29.35	17.80	11.72	7.78	5.33	3.81	2.83	2.16	1.73	1.46	1.29	1.18	1.12	1.08	0.37
106.49	113.50	122.45	105.97	120.79	104.80	90.97	80.40	49.48	29.35	17.80	11.72	7.78	5.33	3.81	2.83	2.16	1.73	1.46	1.29	1.18	1.12	1.08	0.37
106.49	113.50	122.45	105.97	120.79	104.80	90.97	80.40	49.48	29.35	17.80	11.72	7.78	5.33	3.81	2.83	2.16	1.73	1.46	1.29	1.18	1.12	1.08	0.37
106.49	113.50	122.45	105.97	120.79	104.80	90.97	80.40	49.48	29.35	17.80	11.72	7.78	5.33	3.81	2.83	2.16	1.73	1.46	1.29	1.18	1.12	1.08	0.37
106.49	113.50	122.45	105.97	120.79	104.80	90.97	80.40	49.48	29.35	17.80	11.72	7.78	5.33	3.81	2.83	2.16	1.73	1.46	1.29	1.18	1.12	1.08	0.37
106.49	113.50	122.45	105.97	120.79	104.80	90.97	80.40	49.48	29.35	17.80	11.72	7.78	5.33	3.81	2.83	2.16	1.73	1.46	1.29	1.18	1.12	1.08	0.37
106.49	113.50	122.45	105.97	120.79	104.80	90.97	80.40	49.48	29.35	17.80	11.72	7.78	5.33	3.81	2.83	2.16	1.73	1.46	1.29	1.18	1.12	1.08	0.37
106.49	113.50	122.45	105.97	120.79	104.8																		

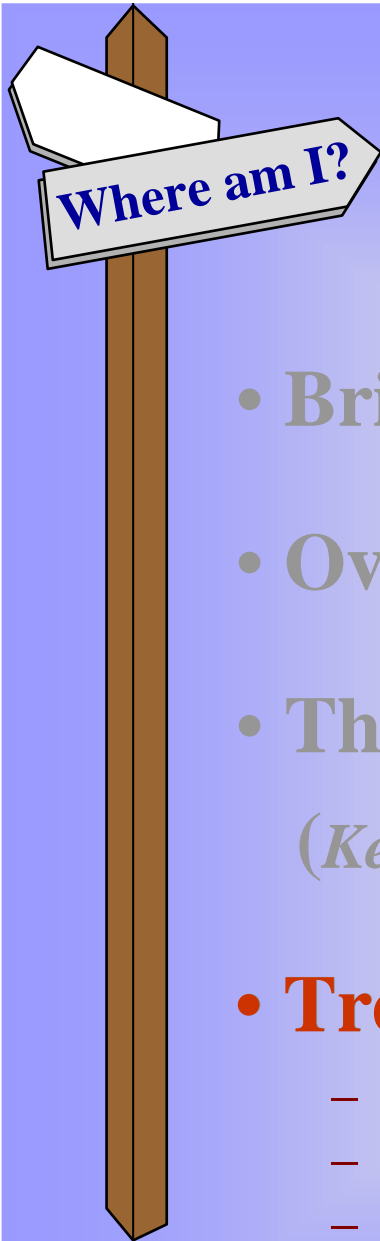
– Spectral Output

Effect of Different Spectra on USA Sun Product SPF25

Labelled SPF (in vivo)	SPF 45
Modelled to COLIPA standard sun	SPF 23
Modelled to COLIPA lower limit	SPF 19
Modelled to COLIPA upper limit	SPF 45
Modelled to 0° Zenith angle	SPF 29

Spectrum Effect on Sunscreen SPF





- Brief history of the COLIPA SPF Test Method
- Overview of the method
- The devil is in the detail:
(Key points of difference from the FDA method)
- **Trends in sun products in Europe**
 - Aesthetics
 - Formats
 - Ingredients
 - Claims

– **Aesthetics**

- ~ **Mainly oil-in-water formulations**
- ~ **Non greasy / Oil Free**
- ~ **Light with easy rub-in**
- ~ **Spray lotions / gels / gelled oils popular**
- ~ **Coloured products for kids**
- ~ **Pack design / Product Positioning**
 - Premium for women**
 - Becoming more commodity for family**
 - Still relatively expensive (4 oz bottle = \$12 approx.)**
- ~ **Becoming increasingly price sensitive**

– Aesthetics



– Formats



Small packs (2 oz) becoming very popular

– Ingredients

- ~ Antioxidants very popular**
- ~ Unique / Patented extracts & additives**
- ~ New sun filters**

UVASorb HEB (3V Sigma) (UVB)

Mexoryl SL (L'Oreal) (UVB)

Mexoryl SX (L'Oreal) (UVA)

Tinosorb M (Ciba) (UVA/UVB)

Tinosorb S (Ciba) (UVA)

Neoheliopan AP (H&R) (UVA)

– Claims

~ UVA Protection

~ Photostable

~ Extended Wear / Water Resistance

~ Hypo-allergenic still popular

~ Unique Biological Claims & Patents

Antioxidant

p53 Protection

Immune system protection

Anti - cellulite !!

~ Still a strong bias to technical/scientific claims but aesthetic claims appearing more

SUMMARY

- **FDA and COLIPA methods are the same in principle.**
- **A joint FDA/COLIPA test can be conducted but certain details of each method must be followed.**
- **A joint test will be more laborious**
- **Flexibility in both methods may still lead to differences in SPF between USA and Europe**

THANK YOU

Mike Brown
Suncare Scientific Adviser



THE BOOTS COMPANY