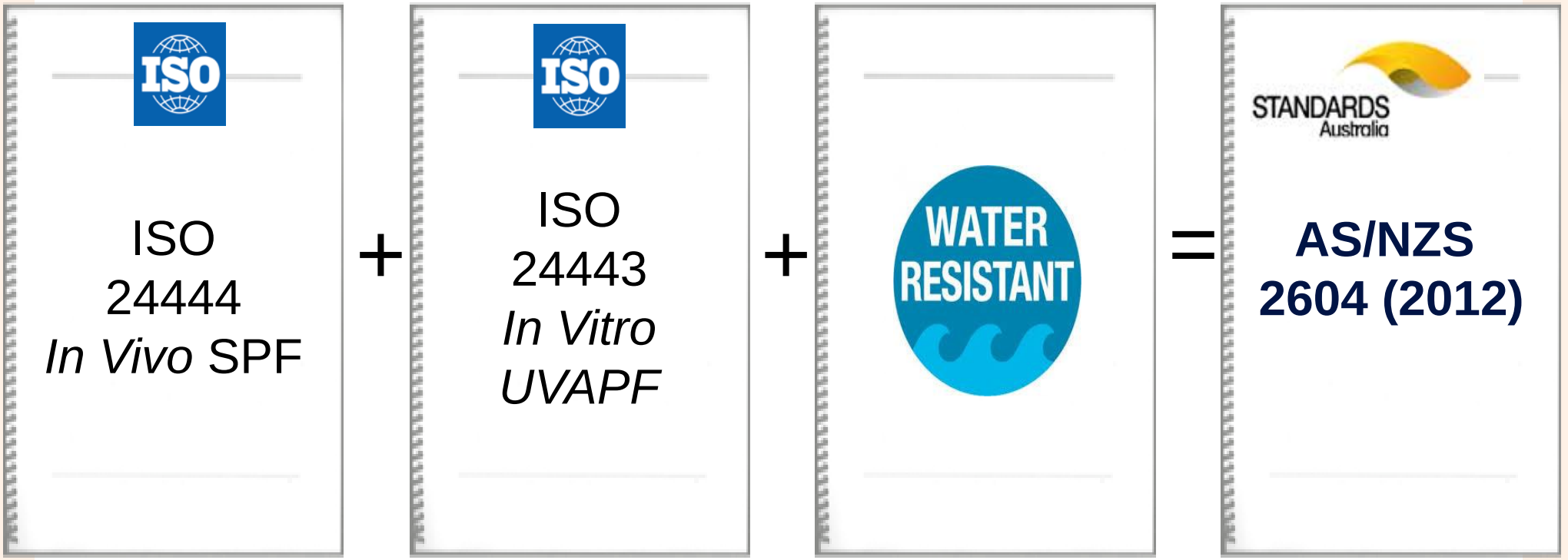
Sunscreen Test and Sunscreen Formulas

John Staton
Eurofins | Dermatest

eurofins | Cosmetics

Sunscreen Testing to ISO Methods



ISO Methods

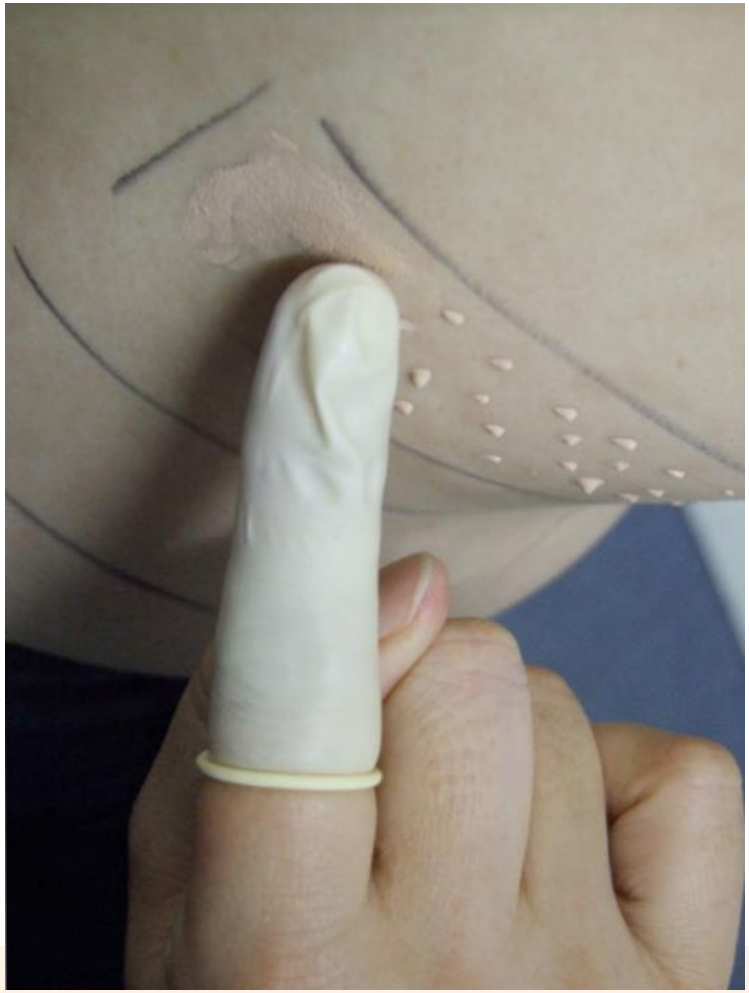
ISO 24444 SPF Test now Accepted in 60 + Countries!

Region	ISO 24444
Australia	YES
New Zealand	YES
European Union 28 countries	YES
India	YES
China	YES (2016)
Japan	YES
Taiwan	YES
Korea	YES
MERCOSUR 6 countries	YES
USA	NO
Canada	YES
ASEAN 10 countries	YES
South Africa	YES
Mexico	YES
Chile	YES
Russia	YES
Israel	YES
India	YES

SPF Test Methodology

Test Sunscreen applied at 2 mg/sq cm

Film dries 15 to 30 minutes



SPF Test Methodology

Solar Simulator Light Challenge

SPF Test Methodology : MED response

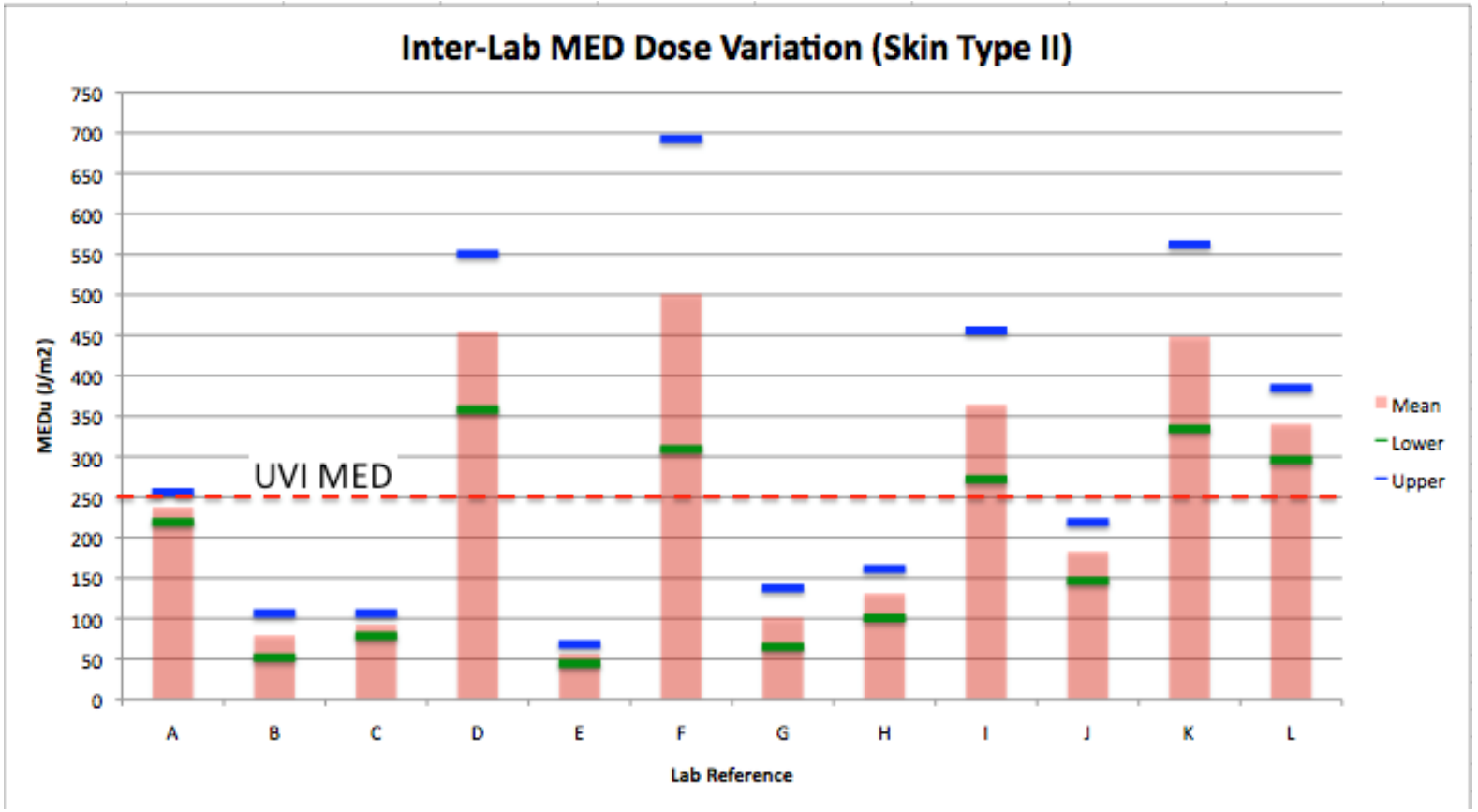
Exposure Series

Protected

Unprotected = SPF

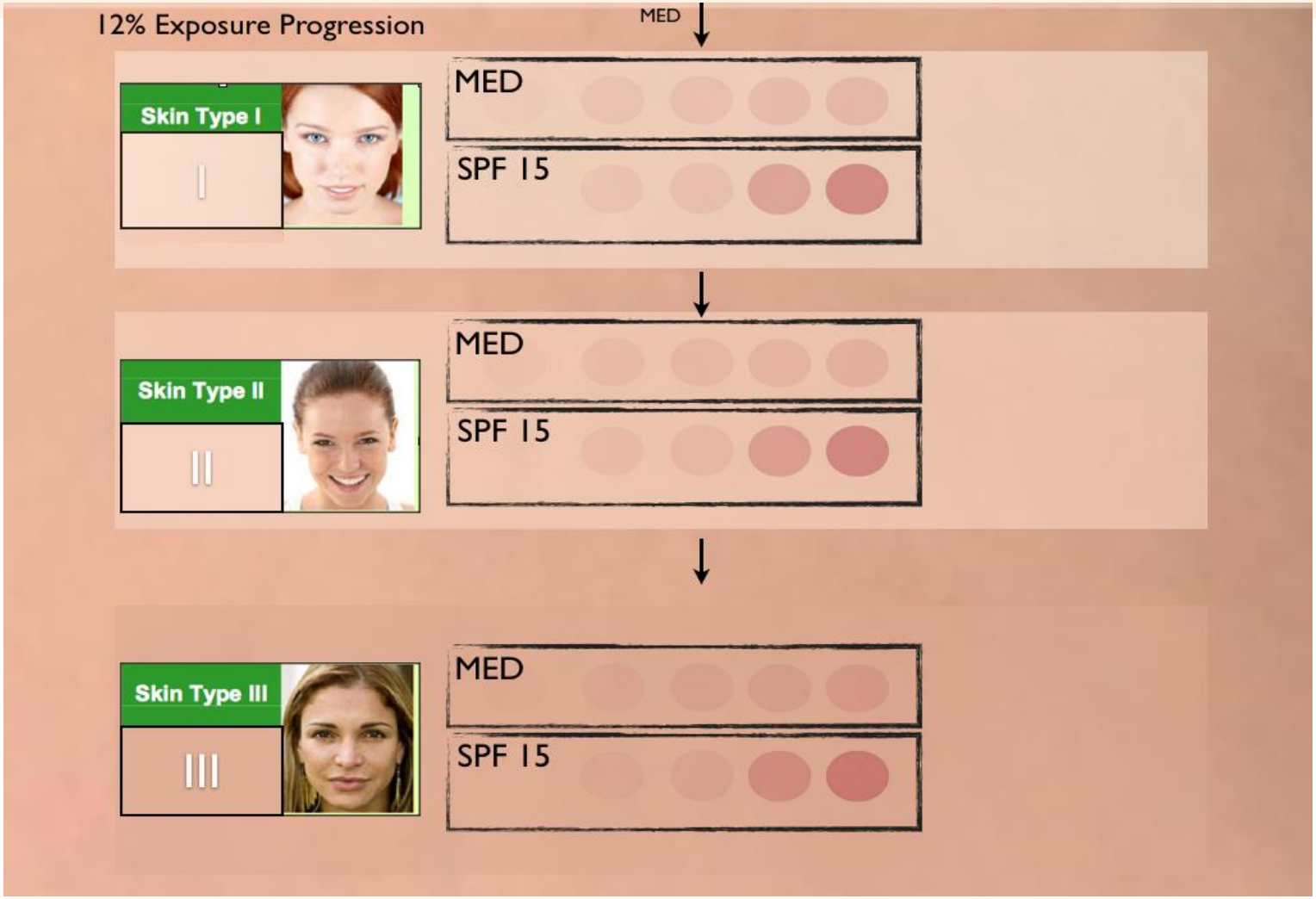
Why Variation in Test Performance?

What is the Right Dose for the MED?

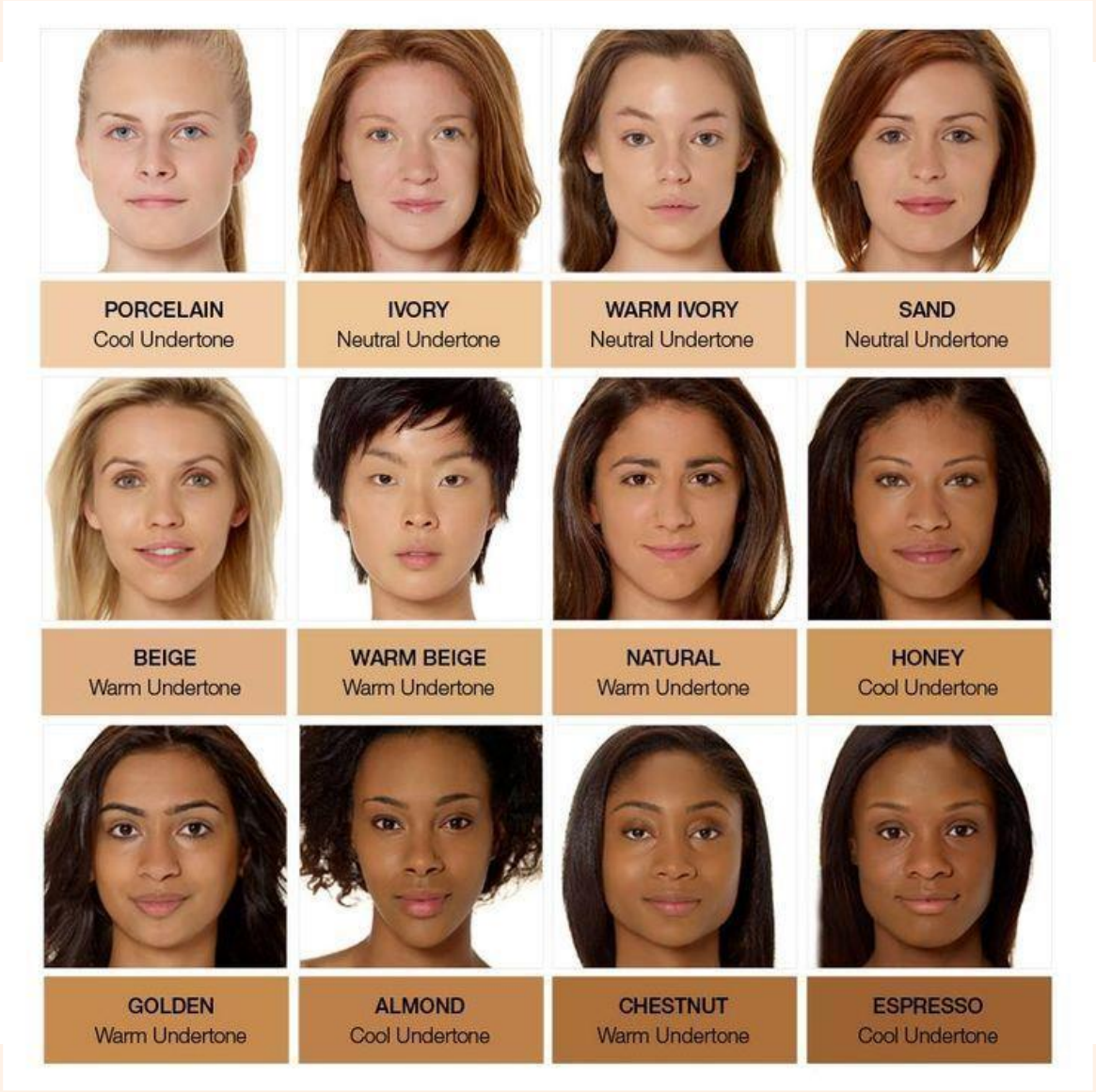


12 of 26 Lab Reports – rest have insufficient data

Skin Type! Fitzpatrick [1975]

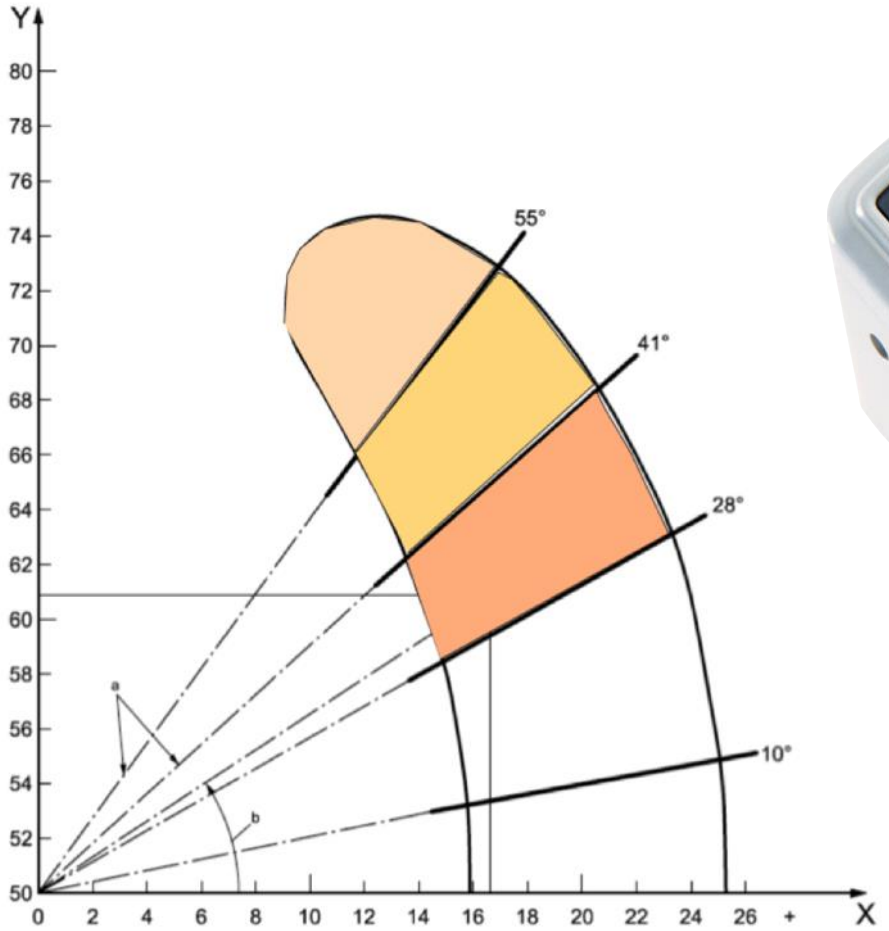


Skin Type – ITAo



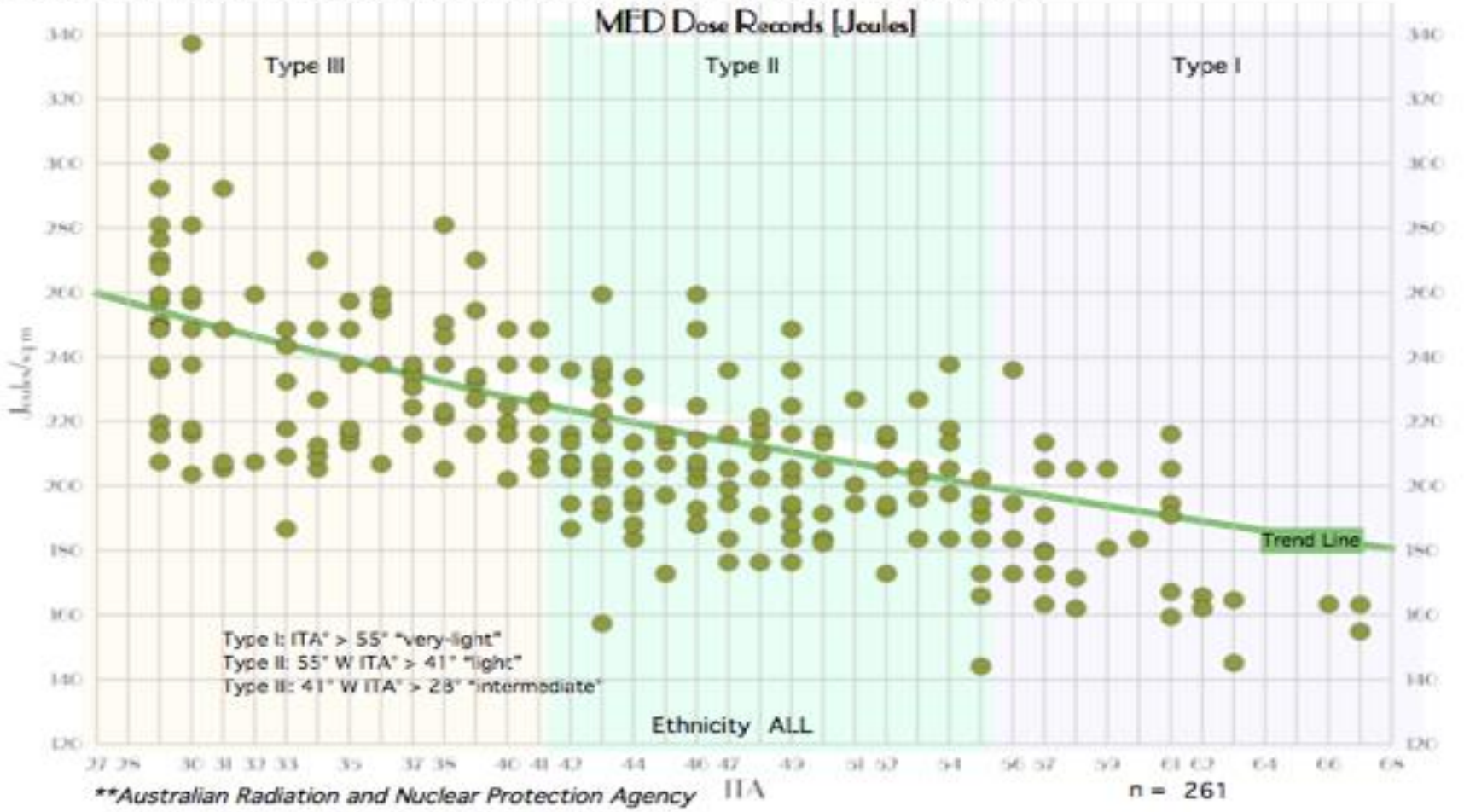
Skin Type – ITAo :Individual Typology Angle

Skin colour is a Continuum

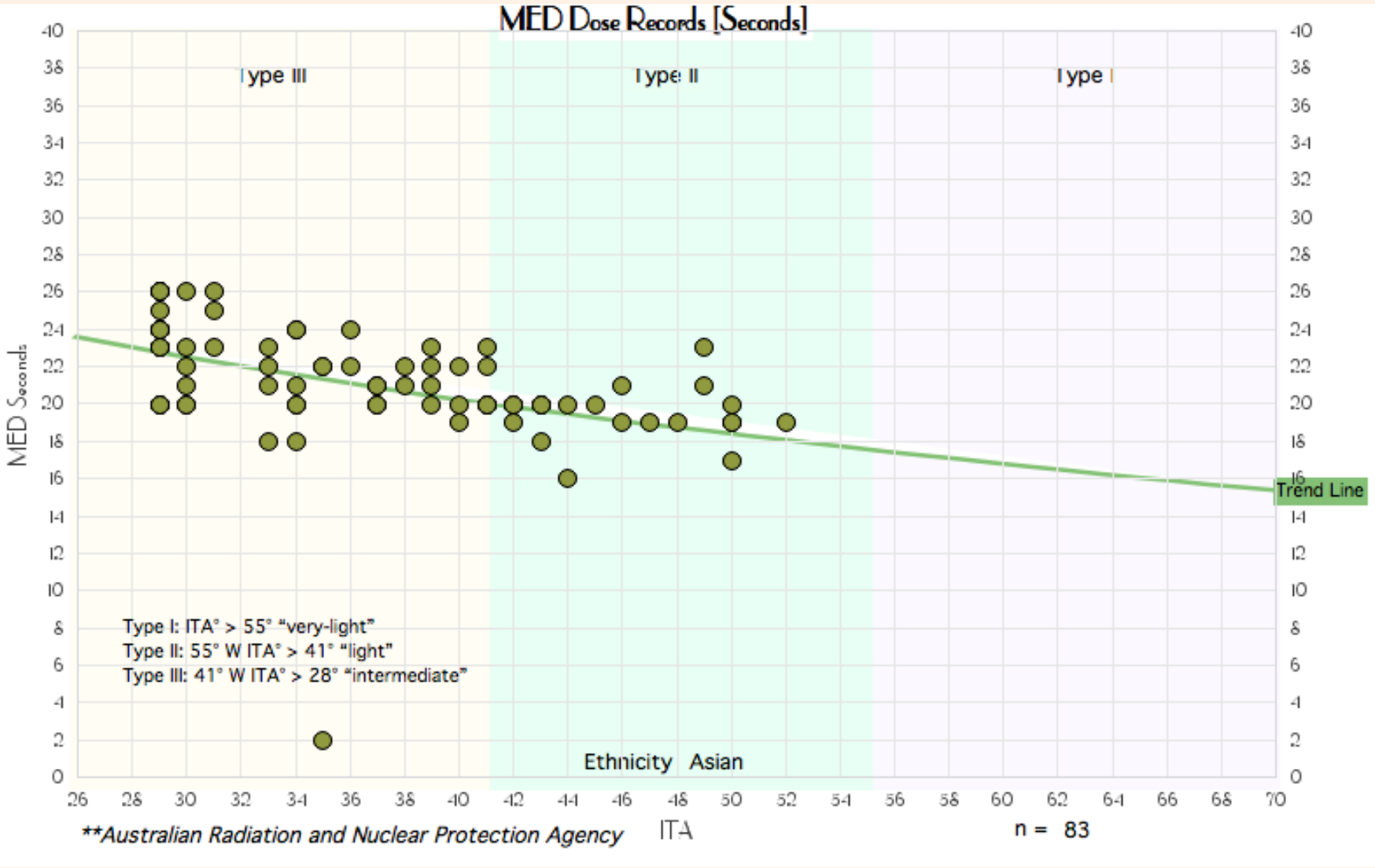


MEDu versus Joules/sqm

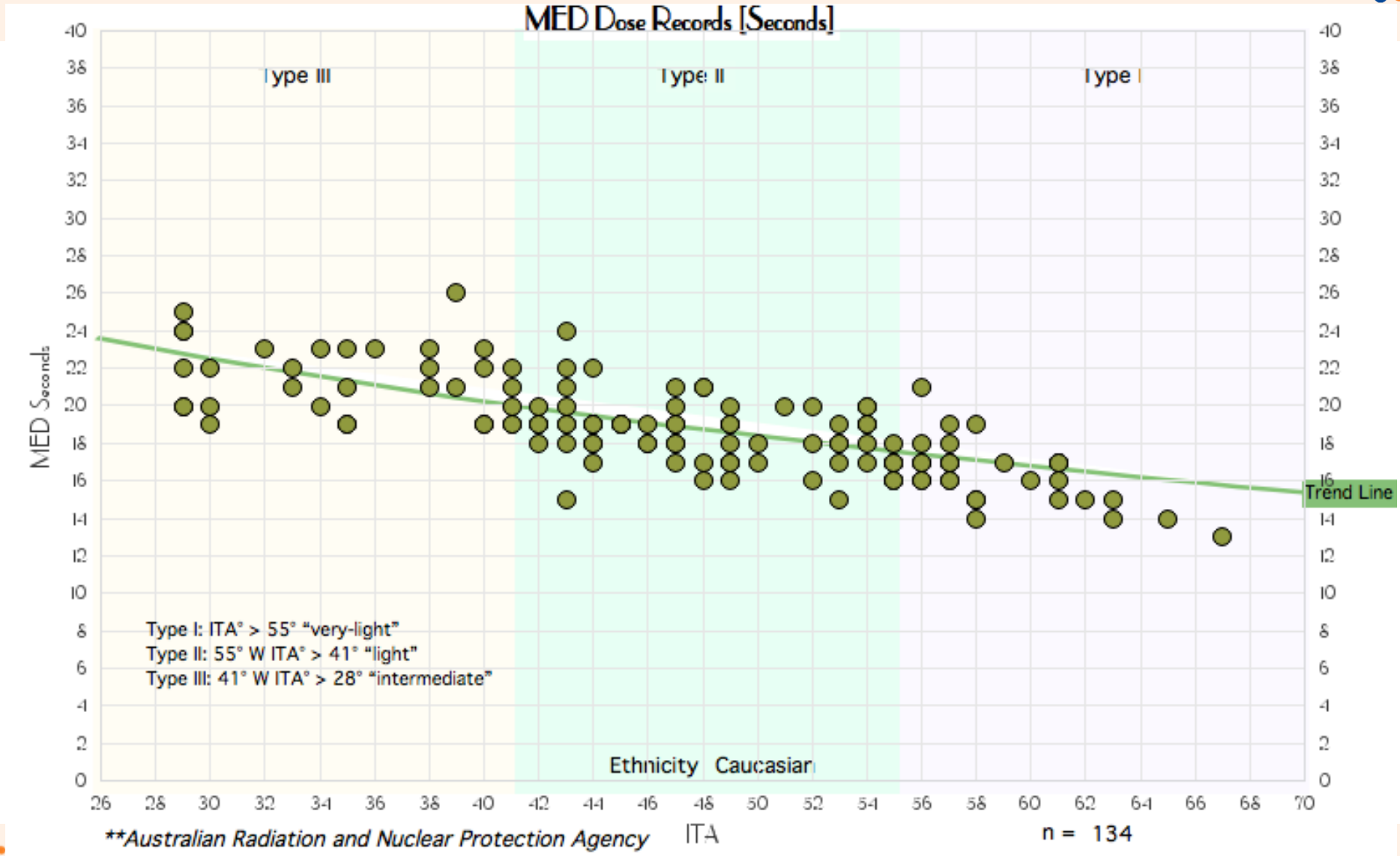
The graph below indicates the total dose of Erythemally Effective radiation applied to Dermatest test subjects for exposure of unprotected skin for calculation of Minimal Erythemal Dose (MED) . The values corellate with the Joules/sq m used by ARPANSA** and other metrology authorities for the calculation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



MEDu versus Joules/sqm ASIAN



MEDu versus Joules/sqm CAUCASIAN



Efficacy of Formulations?

Sun Protection Factor is a product of...

- Percentage of Actives
- Efficiency of Actives
- Film Formation on Skin
- Substantivity (water resistance)

Permitted % Limits: e.g. Ensulizole

INCI Name Phenylbenzimidazole Sulfonic acid — **Efficiency** 2.00

AAN Phenylbenzimidazole sulfonic acid

USAN Ensulizole

EC & USA/FDA name 2-Phenylbenzimidazole-5-sulphonic acid --> Ensulizole

UV Action
UVB filter when converted into a salt.

UV Absorption Range

λmax 302

Solubility
Water-soluble when neutralised with base; soluble in alcohols, glycols.
Insoluble in oils and esters.

Brand Names / (Suppliers)

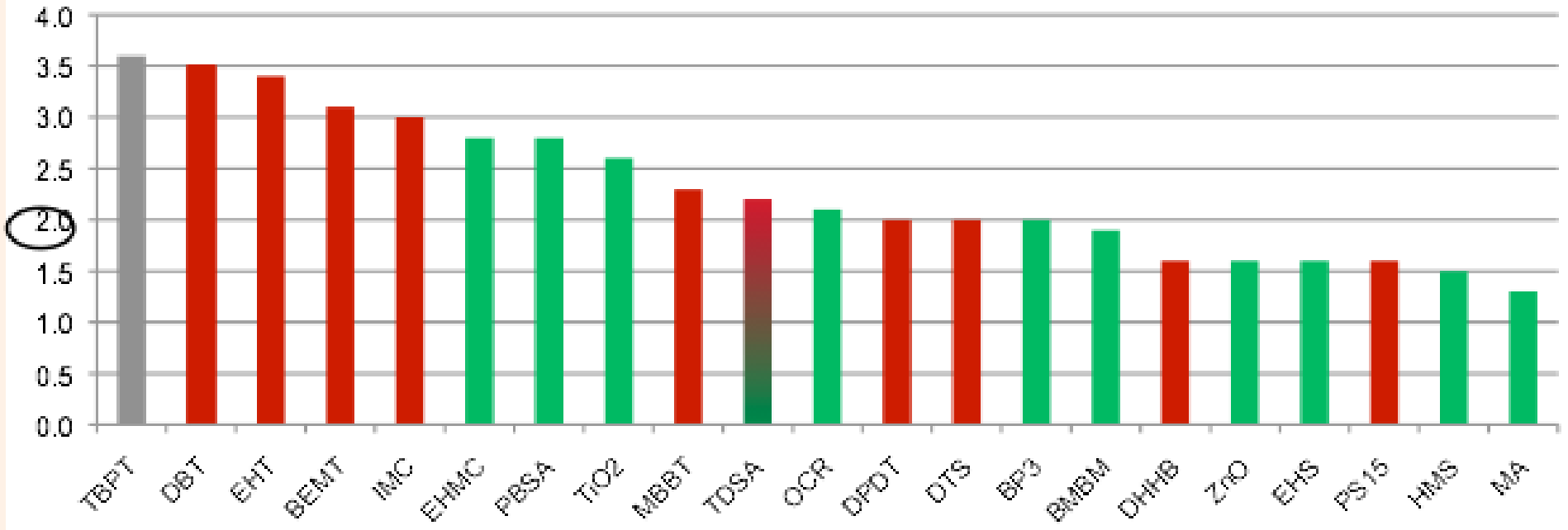
Parsol HS	(DSM Nutritional)
Neo Heliopan hydro	(Symrise)
Eusolex 232	(Merck)
Bio-Gir-PISA	(Girindus Chemie)
Novantisol	

◉ Yes ○ No	F	**Universal**	3%	Compilation April 2011
◉ Yes ○ No	F	**USA**	4%	FDA Federal Register, June 17, 201[illegible]
◉ Yes ○ No	F	**Canada**	4%	Sunscreen Monograph [illegible]y 7, 2013
◉ Yes ○ No	F	**Aust**	4%	Australian Reg Guidelines for Sunscreens V1.0 Nov. 2012
◉ Yes ○ No	F	**E.U.**	8%	EC Cosmetics Regulation (v.2). (1223/2009) Annex VI
◉ Yes ○ No	F	**Japan**	3%	Pharmaceutical Affairs Law (No.145)
◉ Yes ○ No	F	**Asean**	8%	ASEAN Cosmetic Directive Annex VII (June 2010)
◉ Yes ○ No	F	**Mercosur**	8%	MERCOSUR/GMC/ Resolution No. 25/05 (2007)
◉ Yes ○ No	F	**China**	8%	Hygienic Standard for Cosmetics (January 2007)
◉ Yes ○ No	F	**Korea**	4%	Positive List of approved sunscreen actives (KFDA)
◉ Yes ○ No	F	**India**	8%	IS 4707 Standards
◉ Yes ○ No	F	**South Africa**	8%	SANS 1557:2012 Edition 3.1
◉ Yes ○ No	F	**Russia**	8%	Custom Union Commission. Decree No. 526 of 28.01.11

% limits vary between countries

Universal Limit 3% w/w

Actives Efficiency



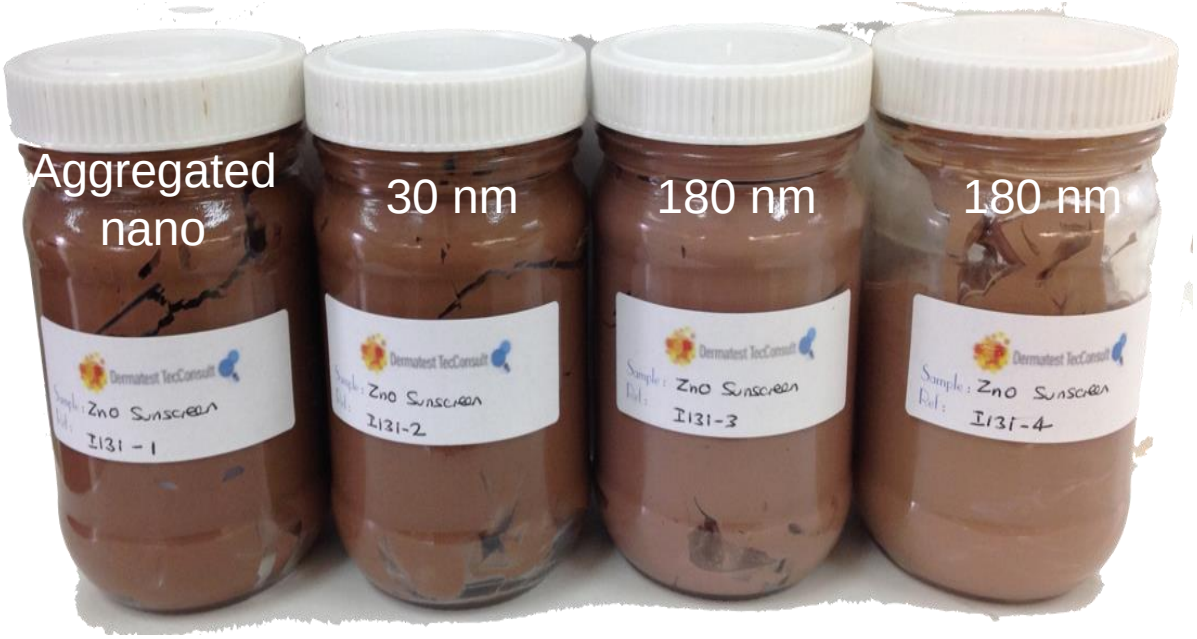
Most commonly used UV filters worldwide

Courtesy BASF Personal Care 2014

Efficiency of Inorganics: varies greatly

Zinc Oxide Balms Non-aqueous

ZnO 16%	ZnO 16%	ZnO 17.5%	ZnO 25%
Aggregated nano	30 nm	180 nm	180 nm



SPF 59	**SPF 55**	**SPF 10**	**SPF 10** (no increase)

Dose Form – Film Thickness Effect

Applied film thickness is 20 microns

Dried film thickness is 20 microns

Stick or Balm

100% Non Volatiles

Dose Form – Film Thickness Effect

Applied film thickness is 20 microns

Dried film thickness is 10 microns

Lotion or Cream

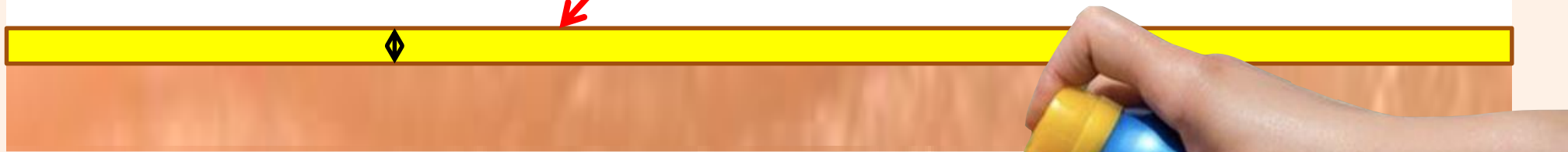
50% Non Volatiles

Dose Form – Film Thickness Effect

Applied film thickness is 20 microns

Dried film thickness is 4 microns

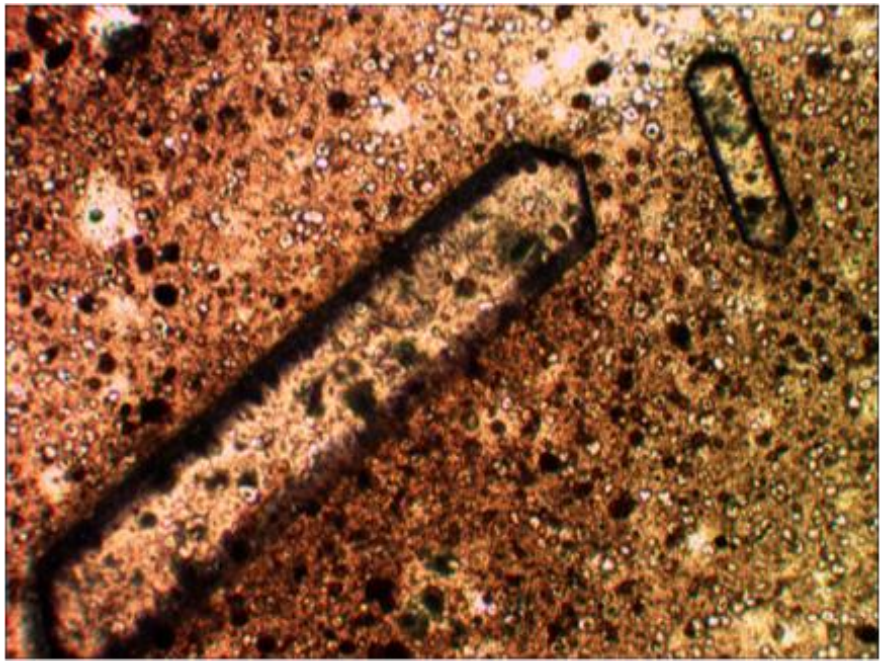
Spray or Aerosol



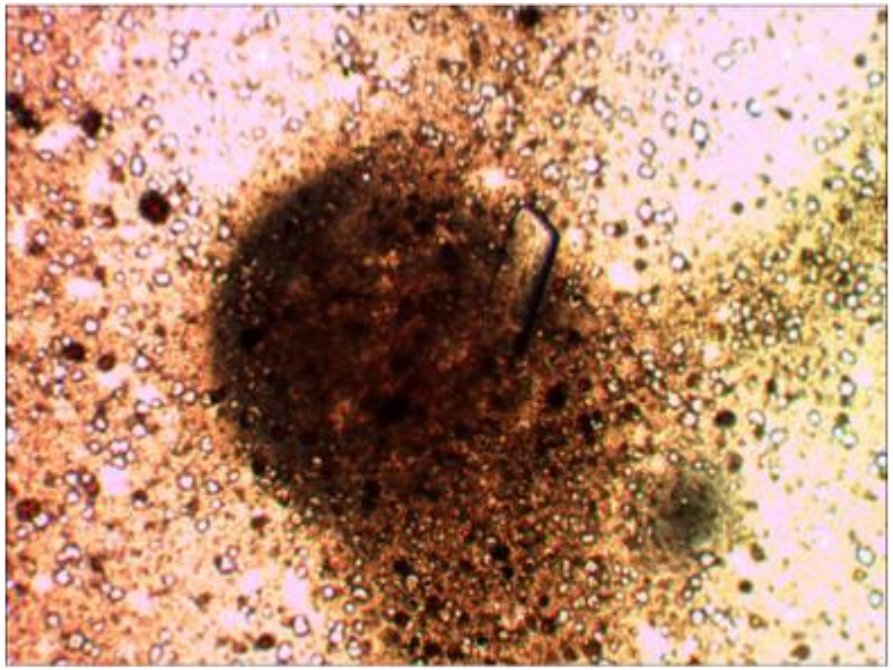
20% Non Volatiles

Incompatibility and Stability Issues

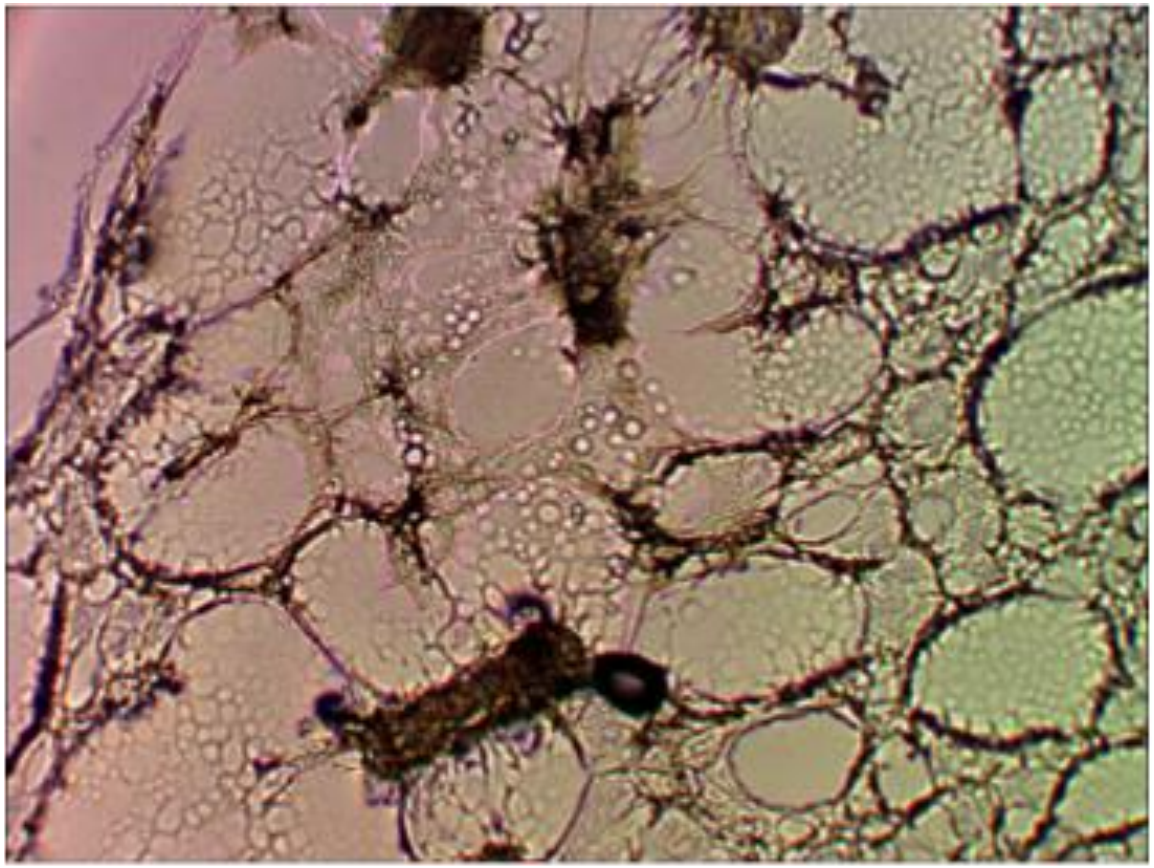
Crystalisation



Agglomeration



Discontinuity of Film



Substantivity:Water Resistance

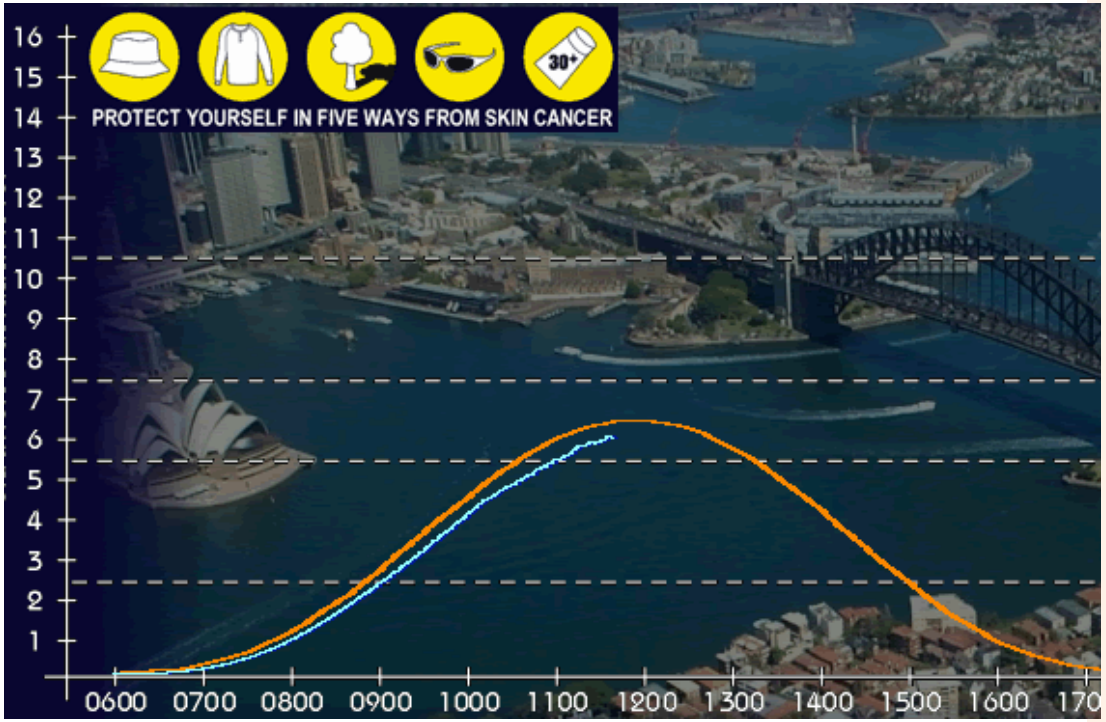
By testing in Spa

- E.U. Method – 50% discount then **static SPF claim**
- AS/NZS 2604 Method – **post immersion SPF Claim**

Bridging the Gap - Sim to Sun

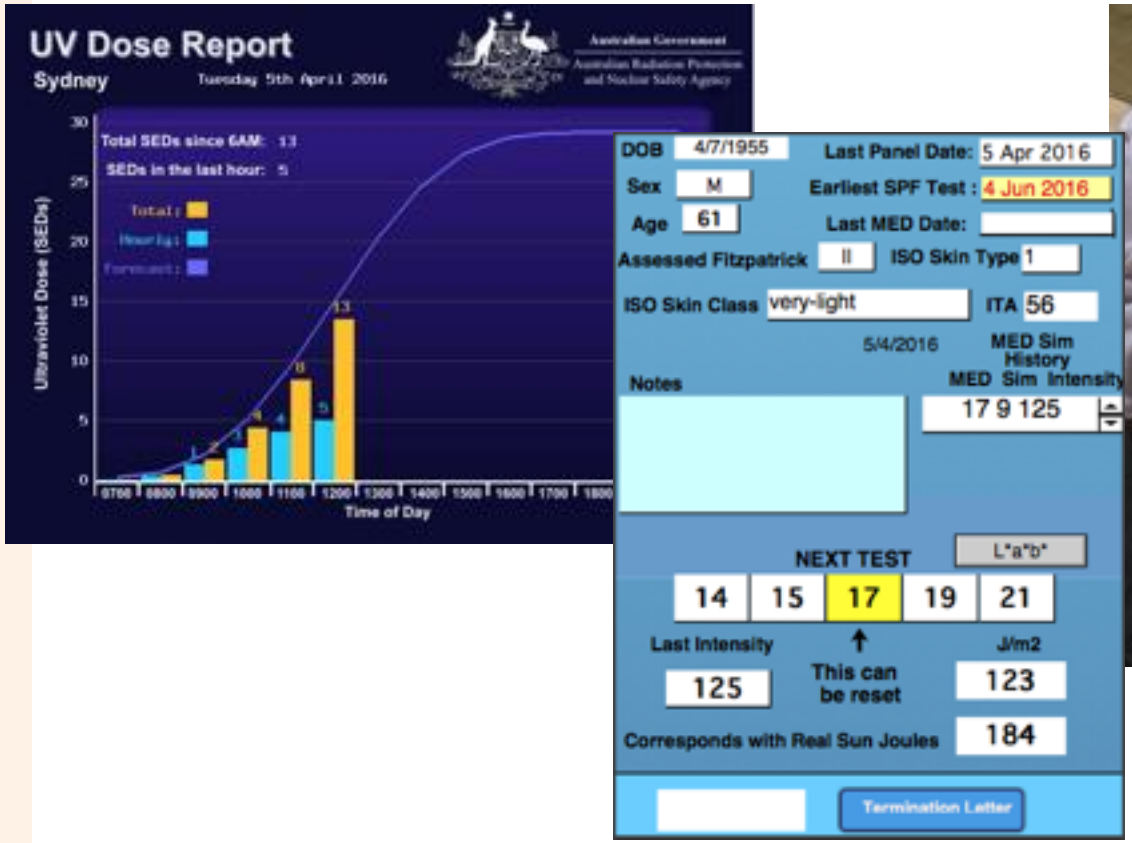
The Solar Sim Tells us…

The UVI index tells Consumers…

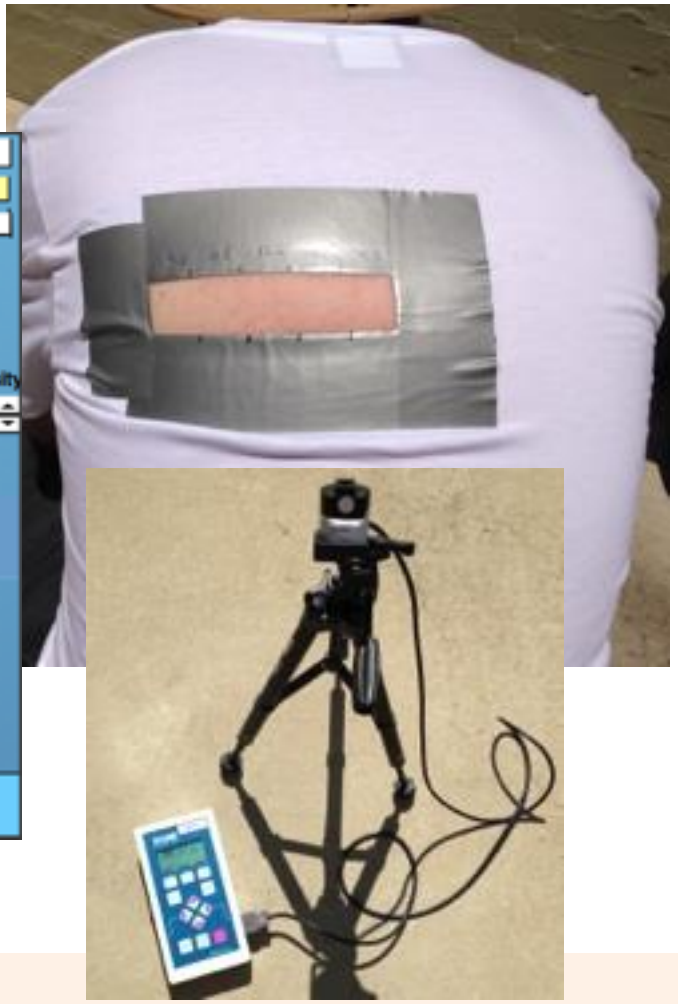


Bridging the Gap - Sim to Sun

UV Dose Report



Sun versus Sim



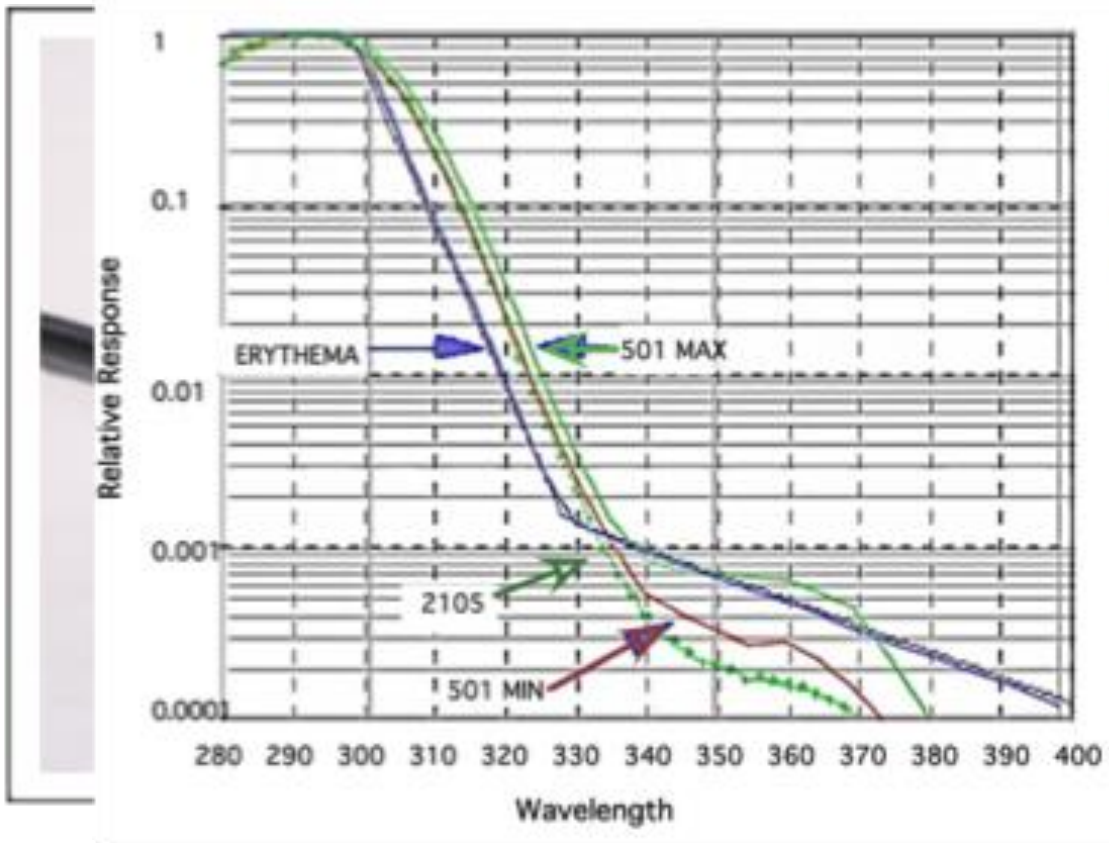
Bridging the Gap - Sim to Sun

Solar Sensor in Lab

Solar Sim for UV Index

Bridging the Gap - Sim to Sun

Solar Sensor in Lab

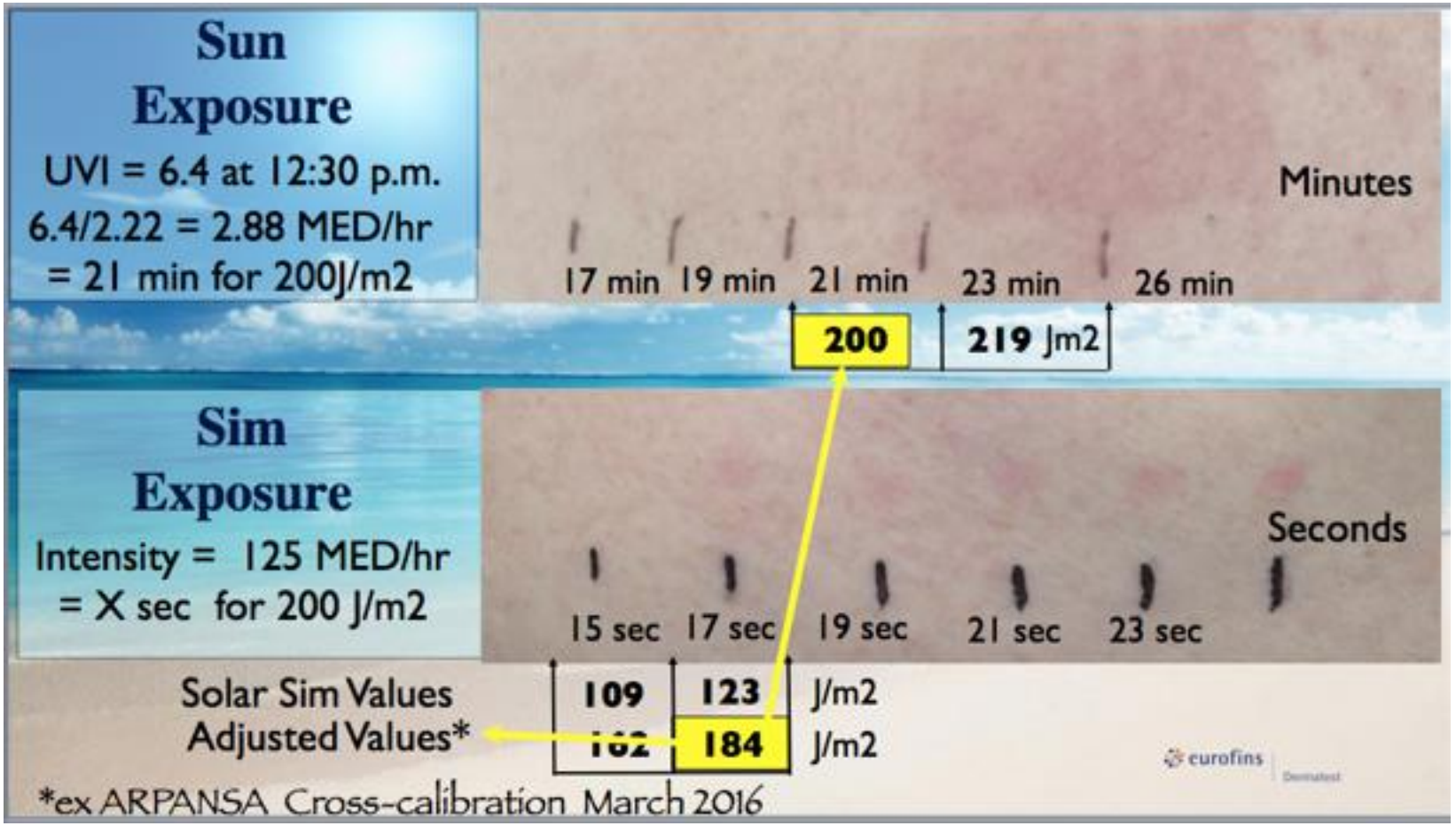


Solar Sim for UV Index

Bridging the Gap - Sim to Sun

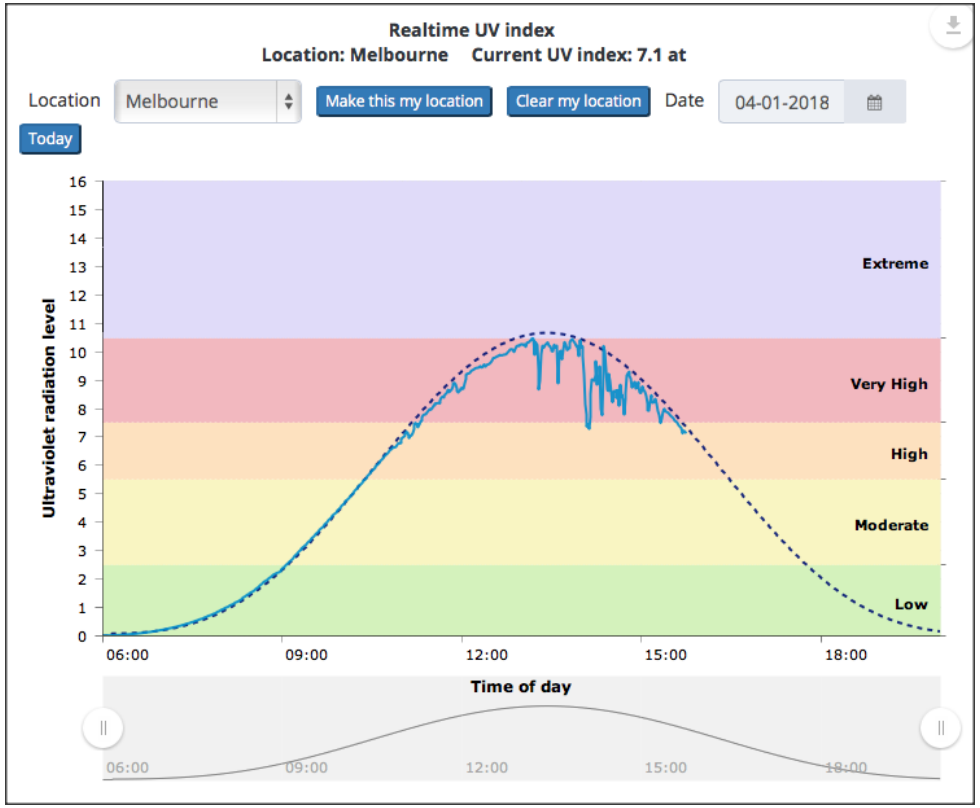
UV Dose Report

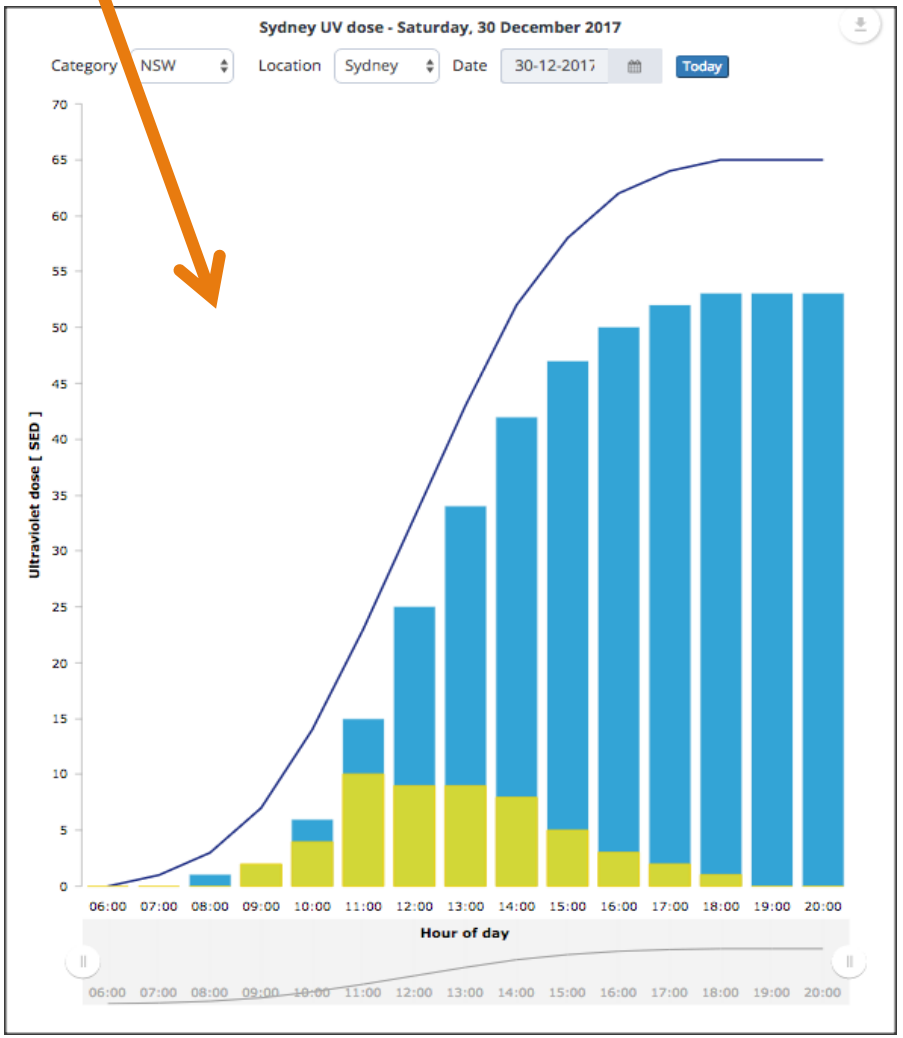
Sun versus Sim



Bridging the Gap - SED or MED?

ARPANSA on line 2018





Relationship between the Test and the Formulation

- The label claimed SPF MUST be supportable by ISO test compliance
- The product should be formulated to pass the test!

Sunscreen Test and Sunscreen Formulas

euroFINs

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