



# Dermatest

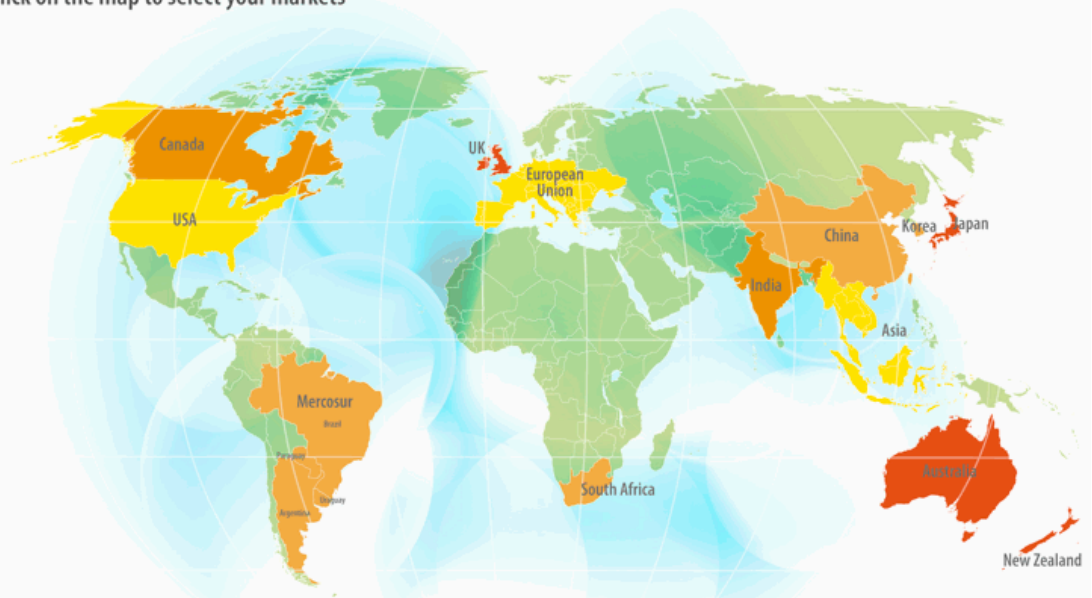
Newsletter

Nov 2011

- TESTING SERVICES**
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- UVA
- Water Resistance
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## Which Dermatest? To find the testing requirements for your Sunscreen product

click on the map to select your markets



- ASEAN
  Australia
  Canada
  China
  EU
  India
  Japan
  Korea
  Mercosur
  New Zealand
  SouthAfrica
  UK
  USA

then indicate your claims:

- SPF
  UVA
  Water Resistant
  Sweat Resistant
  Photostability
  Sand Resistant



## ANNOUNCING ... "Which Dermatest?"

Our website has recently been updated so that it can be used as a comprehensive database for an extensive reference of requirements for SPF, UVA and associated testing. We have included regulatory information on ALL the markets where information was available! You simply ... click on the geographical location of your market/s ... select the claims you intend to make ... and click to <submit>. You can even construct a cost estimate for your SPF study!!!

Give it a try at...

[www.dermatest.com.au](http://www.dermatest.com.au)

**'This Issue'**

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**Patch Test Dates: 2012**

Start Date	End Date
9th Jan	15th Feb
27th Feb	4th April
16th April	23rd May
6th June	13th July
25th July	31st Aug
12th Sept	19th Oct
2nd Nov	12th Dec

*Samples need to be with us one week before!*

# Sunscreen News

## “Future Proofing” Your Sunscreen!

AS/NZS 2604 2012 will require your attention to two main areas...

1. For UVA, the new definition of “Broad Spectrum” which is based on a test which is essentially “tougher” than present.
2. For SPF, a one method fits all technique for applying the sample to the test subject’s back.

We recommend that you review the timing of product launch from here on in and order these protocols when testing new or modified formulations.

### Australian New Zealand Sunscreen Standard on FINAL timeline

Standards Australia Sunscreen Committee CS-042 met 1<sup>st</sup> and 2<sup>nd</sup> Sept for almost 2 full days to finalise the drafting of the new AS/NZS 2604 Sunscreen Standard. Now at the stage of edits only before this document goes to ballot in Nov. A similar process will also occur in New Zealand. It is possible that the final document will be in print prior to Christmas, but a more likely date is Feb/March 2012. As the AS/NZS document will incorporate ISO 24443 (UVA in vitro) and ISO 24444 (SPF in vivo), this means that Australia will be the first country to adopt the new Internationally harmonized documents.

Once AS/NZS 2604 2012 is in print, TGA and NICNAS will begin to adopt this into regulations. Unlike the USA, currently marketed products will have to be retrospectively tested. However, a cut off date might appear for the UVA “Broad Spectrum” claim support, as this method has changed substantially, whilst SPF has not. Water Resistance

### Proposed Categories for AS/NZS 2604 (2012)

Tested SPF	Label SPF Claim	Category Description	Broad Spectrum Claim		
			Primary Sunscreen	Secondary Sunscreen	
			Not Allowed	Not Allowed	Not Allowed
1 to 3	Not Allowed		Not Allowed	Not Allowed	Not Allowed
4 to 14	4, 6, 8, 10	Low Protection	Compulsory	Compulsory	Optional
15 to 29	15, 20, 25	Medium or Moderate Protection	Compulsory	Compulsory	Optional
30 to 59	30, 40, 50	High Protection	Compulsory	Compulsory	Compulsory
60 or higher	50+	Very High Protection	Compulsory	Compulsory	Compulsory

requirements will remain unchanged in the 2012 document.

For TGA Listed Sunscreens, the Electronic Lodgment Facility (ELF) will be modified to allow up to SPF 50+. TGA has also flagged that more scrutiny will be conducted regarding stability testing.

#### ISO Gets Closer !

New Zealand will be the venue of the next round of ISO discussions, with a wide range of meetings scheduled for the week of 14<sup>th</sup> to 18<sup>th</sup> Nov 2011. With ISO 24442 (in vivo UVA) and ISO 24444 (in vivo SPF) now in print, sunscreen work will cover in-vitro UVA and SPF, Water Resistance and Photostability.



### Boots Star Method Updated October 2011

The Boots Company PLC have just released a new version of their Boots Star Rating procedure. This incorporates similar changes to those adopted by COLIPA as a result of techniques to improve in-vitro UVAPF methodology during the process of ISO 24443 development.

The Boots Star® Method 2011 allows flexibility such that products tested to the previous version will still be compliant.

The main differences are...

- Dry down time after product application is now extended (15 to 30 minutes).
- The wavelength intervals for plotting of the spectral curve are now 1 nm - previously 2 nm or less.
- The minimum substrate surface area measured on the plate has to correspond to 10% of the whole substrate surface area. Previously it was minimum substrate surface area of 2cm<sup>2</sup>.
- The frequency of calibration of the test instrument is less restrictive - 12 mths in place of 3 months.
- The substrate (now PMMA permitted) plate roughness has changed in line with the substrate materials currently available - 2 - 6um.
- The method allows for different (appropriate) product application rates to match the variance in substrate roughness.
- Changes to the total irradiance to open the limit to 90Watts per square meter.

### Sunscreen Symposium Florida USA - Sept 15<sup>th</sup> to 17<sup>th</sup> 2011

This very popular event is held in Florida every two years. Timing was perfect as it followed closely on the release of the FDA Rules, but gave sufficient time for digestion of these and focus on some of the issues generated for USA sunscreen marketers by the agency.

### Dermatest Achieves Export

### Sunscreen Forum Stimulates Heavy Discussion!!

During the Florida SCC Symposium, the organisers convened a 3 hr open forum, which covered 6 “hot” topics for sunscreens. Are in vitro SPF Methods Viable? : Does a Critical Wavelength of 370 nm or higher provide adequate UVA Protection? : Should SPF be labeled as Tested? : Should the Percentage of Actives allowed be Limited? : Should SPF's be Capped to 50? : Are Sprays Adequate Dosage Forms?

After hearing argument for both sides of each issue, the over 300 participants present actively exchanged opinions on all of these issues, especially those generated as a result of FDA Rules or requests for further submissions.



### Recognition

Dermatest was recently recognised for export achievement with our nomination as a Finalist in the Premier's New South Wales Export Awards. The awards are given for export sales achievement over a sustained period and criteria include ...

- Quality of export marketing strategy
- Innovation in exporting
- Technological influence in export expansion
- Company's commitment to international business
- Level and sustainability of export sales

Holly Feng and George Orban accepted the award on behalf of the Director - who was overseas

on - you guessed it - export business!!

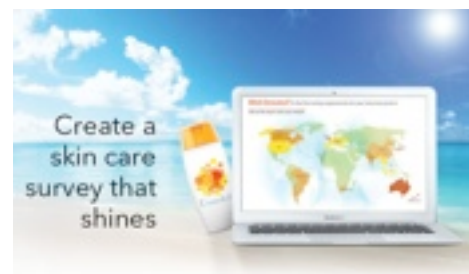


### Sunscreen Forum Participants - Left to Right:

- Dr. Joseph Stanfield : Suncare Research Laboratories USA
- Dr. Dominique Moyal : L'Oreal France
- Mr. John Staton : Dermatest Australia
- Dr Reynold Tan : FDA USA
- Dr. Michael Brown : Boots UK
- Dr. Olga Dueva-Koganov : Integrated Botanical Technologies USA
- Mr. Dennis Lott : Florida Suncare Testing USA
- Dr. Nadim Shaath : Consultant USA

Our website and most of Dermatest is run by FileMaker® Pro software!

To find out more about what is behind our new home pages, click on this link!



[http://filemaker.newo.com.au/newsletter/2011/q4/FM\\_pages/page\\_03/FM-News\\_pg-03.html](http://filemaker.newo.com.au/newsletter/2011/q4/FM_pages/page_03/FM-News_pg-03.html)

### Christmas Close Down

Dermatest will close for our well earned break on 22nd Dec and reopen on 2nd Jan 2012

*We Wish  
YOU and  
YOURS All  
the Best for  
CHRISTMAS AND  
THE NEW YEAR*



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