D E R M A T E S T N E W S

# Dermatest Newsletter

December 2015

## *WISHING YOU AND YOURS A HAPPY NEW YEAR!*

### 'This Issue'



### Standard RIPT Dates 2016

**Start Date End Date**

*1) January 6th – February 12th*
*2) February 29th– April 6th*
*3) April 20th – May 27th*
*4) June 8th – July 15th*
*5) August 3rd –September 9th*
*6) September 26th –November 2nd*
*7) November 14th –December 21st*

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

**We close on 23rd Dec 2015 and reopen on 4th Jan 2016**

**For our latest price list [June 2015] contact us at...**
info@dermatest.com.au.

## Dermatest Re-certified to ISO 9001

We were delighted with the results of our recent Audit by British Standards Institute and look forward to implementing the new Version

**ISO 9001:2008**
**FS 550907**

## ISO Dubai Report

### Water Resistant Sunscreens - Work Extended

### ISO 24444 - Review in Action

This first ISO Sunscreen related document was published in 2010 and has been re-opened for review during 2016.

### ISO 24445 - Cancellation

Work on development of an In vitro SPF method, PW1 24445, which has been ongoing for around 7 years, was cancelled at the Dubai meeting. As many member countries agree that it is important to have an In vitro method available, a further recommendation was agreed upon in order to prepare a guideline of parameters by which future submissions for a method would be considered. This leaves the window open for continuing refinement of the extensive work already completed in this area, as well as for submission of other methodology, such as Direct Reflectance Spectrophotometry, which is also at an early stage of evaluation outside of the formal ISO system. As well, a survey of other methodology is being formally conducted.

### ISO Water Resistance

Projects for the water resistance test method and an additional 'extension" method for percentage wash off are progressing. Most physical parameters are basically agreed and the advancement of the methods now awaits the review of ISO 24444 in order to co-ordinate the inclusion of the SPF test methodology for prod-

uct application and measurement of response (MED and SPF). The objective of the ISO Technical Experts is to arrive at simultaneous release of the W.R. methods co-ordinated with a reviewed ISO 24444.

## A2B for E.U. and Australia.

This new sunscreen active with broad spectrum properties, produced by BASF, is now cleared for use in the E.U. and Australia. TGA approved the active with the name Tris-biphenyl triazine and at a use level up to 10%, in line with the E.U. listing under Annex V1 of the EU Cosmetics Regulation No 655/2013.


## Ozzie Dollar Stays Low

The Austrialin Dollar remains at around 0.70 U.S. - a big incentive for providers of services such as Dermatest.

## Coming Conferences

**Australian Society of Cosmetic Chemists Annual Seminar**
*Wrest Point Hotel, HOBART April 27-29, 2016*
*http://www.ascc.com.au/news.php?id=97*

**Sun Protection & Anti-Ageing Skin Care Conference Asia**
- *Hilton Singapore 6th and 7th July 2016*
http://www.summit-events.com/index.php?&id=39

**IFSCC Congress** *Orlando Florida Oct 30 Oct 30th to Nov 2nd 2016*
https://ifscc2016.com

**ISO Plenary Meeting Series** Sydney Australia 5th to 9th Dec 2016. More later...

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MERRY CHRISTMAS AND A HAPPY NEW YEAR FROM ALL OUR STAFF AT

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# ISO 24443 In vitro UVA (AS Broad Spectrum Test) Explained

## ISO 24443 - Background

The requirement in AS/NZS 2604 (2012), the E.U. and many other countries, for a minimum of one-third ratio of protection in the *In vitro* UVA verses SPF protection in the UV region of the Solar Light spectrum was generated originally from COLIPA (now Cosmetics Europe) (1).

*In vivo* UVAPF testing dates back to 1999, where it was used in Japan (2) to rate the protection performance of sunscreens against tan as well as sunburn. This was later adopted in E.U, where a similar *In vivo* method was published by COLIPA. (3)

In 2006, the European Commission issued a recommendation (3), which was adopted by the cosmetics industry and documented by COLIPA in 2013. This permits the substitution of an *In vivo* method with an *In vitro* method.

The latest versions of these methods, now recognized in all but the USA and Korea, are ISO 24442 (*In vivo*) and ISO 24443 (*In vitro*). If performed accurately, these two methods correlate.

Whilst JCIA (Japan) (see Table 1), still supports classification of sunscreens according to *In vivo* UVAPF testing, for most of the world, the rationale for proportionality of UVA protection relative to SPF i.e. a RATIO, is based on recognition that the SPF implies a RATIO of protection relative to an MED and, rather than chase a second number on pack label, this was set as a minimum requirement i.e. one third of the labelled SPF.

**Table 1. JCIA Classification of PFA - UVAPF Protection (in vivo).**

| UVAPF | Protection grade |
|---|---|
| 2 or more but less than 4 | PA+ |
| 4 or more but less than 8 | PA++ |
| 8 or more but less than 16 | PA+++ |
| 16 or more | PA++++ |

## Why One Third?

In the E.U., both COLIPA and ISO experts agreed that the direct substitution of *In vitro* for *In vivo* would require a correlation and the evidence from both COLIPA and ISO Ring studies supported this. This discussion resulted in the choice of the ratio as now documented in Section 3.3 of the European Union Directive (4). These requirements for both the one-third ratio and a critical wavelength minimum have been adopted in over 50 countries following publication of ISO 24443. This performance standard was mandated in AS/NZS 2604 (2012).
The significance of this higher level of performance requirement can be more clearly seen in the table below.

**Table 2 Comparison of Interpreted SPF Protection relative to JCIA In vivo.**

| UVAPF (In vitro) | PA Grading (In Vivo) | Theoretical SPF<br><br>if 1/3rd Ratio |
|---|---|---|
| 2 to 4 | PA+ | 6 to 12 |
| 4 to 8 | PA++ | 12 to 24 |
| 8 to 16 | PA+++ | 24 to 48 |
| 16 or more | PA++++ | 48 or more |

## USA Situation.

The FDA has NOT adopted the one-third ratio requirement and only requires the Critical Wavelength test to be attained. This is considerably easier to achieve and does not provide the same high level of consumer protection as the AS/NZS 2604 requirement. An additional factor for US formulated sunscreens is that the FDA requirement for photo-stability challenge is also less rigorous.


1. https://www.cosmeticseurope.eu

2. **Japan Cosmetics Industry Association** – *Measurement Standards for UVA Protection Efficacy (1999).*

3. **Cosmetics Europe Recommendation No 25**
   *Use of appropriate validated methods for evaluating sun product protection*

4. **Synthesis Document.** – *Outcome of Public Consultation on the Draft Commission Recommendation on the Efficacy of Sunscreen Products and Claims Related Thereto.*

# Activity on Sunscreen Actives

## 'Im' PASS for Coalition in USA ?

The Public Access to SunScreens (PASS) Coalition, a consortium of sunscreen active suppliers, dermatologists, sunscreen manufacturers, concerned citizens, public health organizations and experts, successfully lobbied the Obama Administration to take some action in an attempt to stimulate activity within the FDA for expediting the approvals of eight sunscreen actives, which have been held up in the Time and Extent Application (TEA) fast track, many for more than 10 years.

The US President signed the Sunscreen Innovation Act (SIA) in December 2014 with the directive to implement action and, subsequent to that, the FDA issued responses to all applicants requesting further evidence.

As the recent FSCC Sunscreen Symposium in Florida, USA, there was a sense of hope that there might be progress. However, Dr. Michelle Walker, when presenting FDA's perspective on the Act [1], pointed out what industry should not expect from the SIA process directives. This was essentially that the due process of full safety assessment still applied – Generally Recognized as Safe and Effective (GRASE) requirements.

FDA have now requested the TEA applicants to provide data based on the MUsT test which involves systemic absorption measurement after application to most of the skin surface over an extended period.

From the PASS perspective, Dr. Olga Dueva-Koganov [2] points out that this test was never applied for the currently approved actives. Molecular weights of 6 out of 8 of the proposed TEA actives was greater than 500 ( the Dalton Rule for skin penetration) compared with currently approved actives, 8 of which have molecular weights below 300.
Dr. Dueva-Koganov also reported that the number of launches of new products in Australia since the signing of the SIA was greater than in the USA. This is an indicator of how the FDA position is stifling innovation.

Latest is that it appears that some of the submissions under TEA will be withdrawn, especially in light of the requirements for additional animal testing data.

## ZnO for the E.U.

Status of this currently is that the E.U. is now massaging the final wording of the approval covering Zinc Oxide for formal use in Europe. Part of the delay was the consideration of the status of nano grade ZnO. [3]

## A2B for E.U. and Australia.

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References.

**1. Sunscreen Innovation Act: FDA's Perspective –** FSCC Sunscreen Symposium Sept 2015

**2. Public Access to SunScreens Coalition Efforts to Support Sun Care Innovation in the United States -** FSCC Sunscreen Symposium Sept 2015

3. http://ec.europa.eu/health/scientific_committees/docs/citizens_zinc_oxide_en.pdf

4. https://www.ulprospector.com/documents/1316618.pdf?bs=1133&b=237766&st=20

# Sunscreen Status by Country

A current **Hot Topic** under discussion and negotiation between Australian industry associations and TGA is the regulatory status of sunscreens. It would appear that the main driver of this interest is the issue relating to costs involved for compliance with Australian requirements, which are above those of most parts of the World.

| Region | Classification |
|---|---|
| Australia | Therapeutic |
| New Zealand | Cosmetic -> Therapeutic |
| European Union 28 | Cosmetic |
| India | Cosmetic |
| China | Therapeutic |
| Japan | Cosmetic |
| Taiwan | Medicated Cosmetics |
| Korea | Functional Cosmetic |
| MERCOSUR 5 (South America) | Cosmetic |
| USA | Therapeutic |
| Canada | Therapeutic |
| ASEAN 10 countries | Cosmetic |
| South Africa | Cosmetic |
| Mexico | Cosmetic |
| Chile | Cosmetic |
| Russia | Cosmetic |

Previously, TGA applied a GMP Code, which was specific to sunscreens. This dates from a 1994 negotiation with industry associations, including ASCC, but TGA had indicated difficulty in auditing to a code, which was at variance with the PIC/S GMP code in use in many countries by mutual agreement. A new version of PIC/S [(1)] is soon to be implemented, moving this guide further still from the Sunscreen GMP Code.

The TGA and NICNAS recognized definition [(2)] of therapeutic includes two clauses which capture sun protection…
(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury.
(b) influencing, inhibiting or modifying a physiological process.

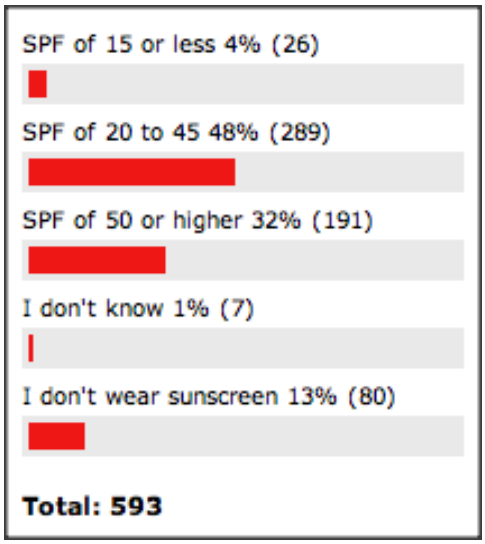
At present, SPF 15 skin care products are Secondary Sunscreens, but many marketers believe that this cut-off should be lifted to at least SPF 30. Countering this argument is the question of their use at this level as Primary, rather than Secondary sunscreens.

The issue for personal care product marketers is the TGA requirements for GMP and premarketing data, particularly stability, make it difficult and expensive to achieve a level of compliance which is above that in their country of origin and manufacture.

A TGA – Industry Working Group on GMP (TIWGG) has been set up and is currently discussing options.

## What is the right SPF for a Sunscreen?

An on line survey of subscribers conducted by ConsumerReports.Org [3] in USA asked a simple question…"Which SPF sunscreen respondents typically use?" Last time I checked, the results looked like this…




The question of the "right" SPF is regularly asked by consumers. It is even more topical since the recent moves to higher SPF categories. At the U.K.Sun Protection Conference in June this year, Dr. Marc Pissavini, R & D Director, Coty-Lancaster Monaco, addressed this very question and reminded us that the choice is not only a question of labelled SPF and amount applied, but also skin phototype, product spreadability, weather, latitude, altitude and general environmental location.

Prof. Brian Diffey [4] has pointed out that SPF 15 rated clothing is adequate to protect and an SPF 15 sunscreen should do the same if applied at 2 mg/sq cm. However, as this is not the case, an SPF 30 should, in the author's view, be recommended. This recommendation should avoid disgruntled consumers who end up with sunburn.

This concept of Spectral Homeostasis, that is , even protection across the spectrum, is gaining popularity and is picked up in the In silico model promoted by BSF on their Sunscreen Simulator website [5].

**Ref:**

**1. PS/INF 69/2014 (Rev. 1) PIC/S GMP Guide Chapter 1 Pharmaceutical Quality System**

2. http://www.nicnas.gov.au/chemical-information/cosmetics/therapeutic-goods-and-uses

3. http://www.consumerreports.org

4.http://www.cosmeticsandtoiletries.com/regulatory/uvfilters/What-Should-the-Minimum-Recommended-SPF-Be-to-Avoid-Sunburn-199882841.html

5. https://www.sunscreensimulator.basf.com