Dermatest

Newsletter

Dec 2014

"Merry Christmas"

'This Issue'

Standard RIPT Dates 2015

Start Date	End Date
1) January 7th	- February 13th
2) March 2nd	- April 8th
3) April 22nd	- May 29th
4) June 10th	- July 15th
5) July 29th	- September 4th
6) September 21st	- October 28th
7) November 9th	- December 16th

Samples need to be with us one week before!

Our Christmas Shutdown

Close : 23rd Dec Open : 5th Jan 2015

For our latest price list [July 2014] contact us at...
info@dermatest.com.au.

Website Update

A Helping Hand!

The Dermatest website was recently updated and now contains even more information on skin product testing, especially in the sunscreen product development area. Just go to..... http://www.dermatest.com.au/ and click on the intuitive buttons.

US Senate Gives Sunscreens a Boost !!!

The Senate passed a bill on Sept 17th 2014 that aims to improve sunscreen protection. Sen. Jack Reed (D-R.I.) introduced the Sunscreen Innovation Act. This requires a faster tracking of review and approval of OTC sunscreens. A coalition - Public Access to Sun Screens (PASS) - has been lobbying this issue for several years.

A primary objective is to finalise the approval of additional sunscreen actives, which have been with the FDA for up to 15 years. These are U.V. absorbers which now have long (Time) in use and (Extent) of many millions of users in most other countries. President Obama signed off on this bipatisan legislation on November 29th. **However... The FDA New Actives - Many to be Abandoned.**

Following the Action taken by the US Senate to fast track the review of 8 sunscreen actives which have "languished" in the TEA (Time and Extent Application) system of US-FDA for up to 15 years, the Sunscreen Innovation Act directed FDA to act with a view to expediting their consideration. Letters of Initial Determinations were sent to all sponsors of these materials late Aug to early Sept. These advised "determination

that the current scientific record is not sufficient to establish that generally recognized as safe and effective (GRASE) for OTC sunscreens" and advised "data gaps" or "scientific record not sufficient." Of the 8 sunscreen actives involved, It is understood that only 2 may now be proceeded with, the rest seemingly to be abandoned.

TGA Drafts new Labelling Order

A new Therapeutic Goods Order – No 79, has been drafted to replace the current TGO 69. This changes some requirements for labelling of TGA sunscreens and all other therapeutic medicines. TGA have prepared a draft as well as a document that compares the two and highlights the changes. Some variances include requirements to declare additional excipients, type font sizes and information panels. The draft is open until November for submissions. Once implemented, a three to four year transition period will apply.
http://www.tga.gov.au/newsroom/consult-labelling-medicines-140822.htm#.VBp-P1Y99Zg

New Sunscreen Active Approved in E.U.

Tinosorb ® A2B* - INCI name Tris-Biphenyl Triazine - is the first UV filter to be included in the positive list (Annex VI) of the new EU Cosmetics Regulation. "Tinosorb A2B equally protects against UVB and UVAII radiation, thereby making an important contribution to preventing skin cancer and light-induced skin aging. After a long approval process we are delighted that we are now allowed to bring the UV filter to market and that our customers can use it in sunscreen products ," said Dirk Mampe, head of Business Management for Personal Care Specialties Europe.
* Source: BASF Corporate Website

GMP Discussions Ongoing

Negotiations generated as a result of the TGA move from a "customised" Sunscreen GMP' code to adoption of the PIC's GMP Code are still a work in progress. Previously reviewed was the question of the "Release for Supply" process which applies to each and every batch of product manufactured under therapeutic GMP. Six scenarios have been proposed in an attempt to cover all permutations of the steps of manufacture from – bulk to fill – primary packaging - to secondary packaging – to relabeling. Input was sought by end of September before a final guidance which is to be published soon.

The next stage of this process, since the formation of a TGA - Industry Working Group on GMP, is a meeting on Dec 16th to discuss PIC/S GMP Adoption.

Israel Joins ISO Sunscreen Standards Adoption

In August, Israel became the latest country to accept ISO Sunscreen standards, bringing the total to 56. Basically, the E.U. model was picked up. However, one unique requirement appears. Water resistance is required to based on 75% retention after immersion rather than E.U. 50% - a compromise perhaps between Europe and FDA/ Australia !

Sunscreen Application Video goes Viral !

Want to see how well you have applied your sunscreen? A video entitled
"How the sun sees you" has had over 14 million hits since upload to YouTube
https://www.youtube.com/watch?v=o9BqrSAHbTc

Cosmetic or Therapeutic ?

Seems that there is a renewed push to try to down regulate sunscreens from therapeutic status. One of the perhaps little considered consequences of this is very likely to be that new actives would no longer be pursued by chemical suppliers, as they then fall under the "no animal testing" classification which is now supported by the same industry groups who are pursuing down regulation! This issue also applies more broadly for preservatives and other important excipients.

ISO Holds 14th Plenary Meeting in Sri Lanka

A Plenary of ISO was held in Colombo, Sri Lanka first week of Dec. Cosmetic Working Groups held discussions on Sunscreens, Organic and Natural, Microbiology, GMP and Stability.
For Sunscreens, the Preliminary Work Item on Water Resistance advances to the next stage - proposed as a New Work Item.

Water Resistance Test Parameters

This list was prepared here at **Dermatest** and may provide an insight into what may need to be be incorporated into a harmonised test method for water resistance. It is not intended to be interpreted as a document from ISO.

Included into each parameter is a comparative for existing published methods in Australia, USA and E.U.

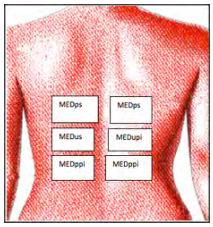
Regional Requirements for Water Resistance

Aust	Allowable Maximum	Measurement
Aust	4 hrs	100% of Post Immersion
USA	80 min	100% of Post Immersion
E.U.	80 min	Static if less than 49% wash off
Mercosure	80 min	Static if less than 49% wash off
Asean	80 min	Static if less than 49% wash off
Israel	80 min	Static if less than 25% wash off

Simulated Swim Test Devices (SSTD) These should be of sufficient capacity to enable complete immersion of all tests sites with no contact between the area and any surface. The position of subjects needs to take into account various shapes of spa baths.

AZ/NZS	COLIPA	FDA
1.8 m	Sufficient Volume	not specified

Test Sample Location The test sites should be configured such that they will be fully immersed when the test subject is located comfortably in the Simulated Swim Test Device.



AZ/NZS	COLIPA	FDA
Scapula to waist	Scapula to waist	not specified

Dry Down Period After Immersion

This is set as 15 to 30 minutes in the ISO 24444 standard.

AZ/NZS	COLIPA	FDA
15 to 30 min	15 to 30 min	Allow to air dry

Test Subject Positioning

Generally accepted as being located out of the direct flow of water jets.

AZ/NZS	COLIPA	FDA
Facing centre	Out of Jets	not specified

Water Flow Rate

A test condition which has had little attention in any published standard. Can have major impact on wash off.

Flow Watch Device

AZ/NZS	COLIPA	FDA
Not specified	not specified	not specified

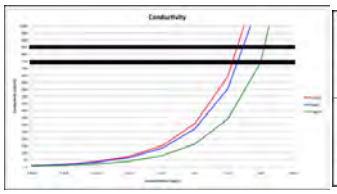
Water Hardness

This is currently only set in the E.U. Water hardness varies between counties as well as between regions of many countries.

AZ/NZS	COLIPA	FDA
Not specified	50 to 500 ppm	40 CFR part 141*

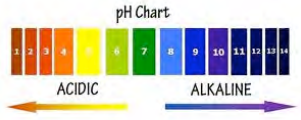
Water Resistance Test Parameters

Water Conductivity
Conductivity is the measure of the total of dissolved salts in the water. Typically, it reflects the total of Calcium, Magnesium and Sodium salts , with other ions being minor components.



AZ/NZS	COLIPA	FDA
Not Specified	Not Specified	Not Specified

Water pH
Only AS/NZS 2604 currently specifies water pH. Important acid soluble actives, such as Zinc oxide are incorporated in the sunscreen. Alkaline water may also emulsify sunscreen films.



AZ/NZS	COLIPA	FDA
6.8 to 7.2	not specified	not specified

Water Temperature
This currently varies slightly between regions. The impact of this has not been fully studied.

AZ/NZS	COLIPA	FDA
31 to 350C	27 to 290C	23 to 320C

Environmental Temperature
Not specified in any current Standard. Needs to be higher for extended water resistance testing in order to support test subject compliance.

AZ/NZS	COLIPA	FDA
not specified	Not Specified	Record

Aeration of SSTD
Only AS/NZS 2604 specifies a period of SSTD water bubbling. General recommendation is to delete this.

AZ/NZS	COLIPA	FDA
Yes 4 min per 6 min	No Bubbles	Moderate Activity

Sanitisation
The impact of various sanitisers has not been studied in detail. If the SSTD is emptied daily, then this is not necessary.

AZ/NZS	COLIPA	FDA
Yes - in Spa Std	Manufact Spec	not specified

Summary
ISO is currently progressing to refinement of the proposed test methodology and all of the above parameters have been considered during the Ring Study validation process for this method development.

Office
Ph 61 2 95562601 Fax 61 2 95563361
Laboratories
20- 22 King St Rockdale N.S.W.
2216 Australia
Phone 61 2 95563835
Postal
P.O. Box 1022 Rockdale N.S.W.
2216 Australia

http://www.dermatest.com.au/