Dermatest

Newsletter June 2010

Sunscreen News

'This Issue'

Patch Tests 2010

Start Date	End Date
Jul 26TH	Sep 1ST
Sep 15TH	Oct 22ND
Nov 5TH	Dec 15TH

Samples need to be with us one week before!

Sunscreen News

ISO Sunscreen Update.

The Sunscreen Working Group of ISO met for two days early in June. The two main purposes of this gathering were to advance the drafting of the test method for in-vitro UVA testing and to review results of a ring study of proposed methodology for the standard for in-vitro SPF testing. For the document entitled CD24443 Cosmetics – Determination of sunscreen UVA photoprotection in vitro. More than 80 technical comments on the first draft of the document were considered and debated. The committee resolved to redraft the reviewed document as a Draft International Standard for further comment. The target is to have majority comment on this prior to the next Plenary ISO meeting in October 2010.

The major parameters which now appear to be settled are the choice of PMMA substrate roughness (6 um), application dose (1.3 mg/sq cm) and use of the actual measured SPF as the basis of a pre-irradiation dose of UV light to be applied to the test sample before measuring for film changes (post irradiation value). From a commercial viewpoint, the move to the use of additional replicates will have an impact on test cost.

For the standard for in-vitro SPF testing, ISO 24445, the results of the ring study were reported as disappointing and the conclusion was that there was no correlation with the SPF values determined for the same products when tested in-vivo. Progress on this project is now very much stalled.

The two new in-vivo ISO Standards are now final and soon to be published. These are ISO 24444 (SPF) - and ISO 24442 (UVA). Both are currently in the process of finalisation after having received 100% "in favour" voting on the drafts. Australia will consider adoption of ISO 24444 to replace the static SPF test method in Australian New Zealand Standard 2604, but will not be adopting ISO 24442.

Sunscreen Water Resistance

The first of these new standards covers Water Resistance testing of Sunscreens. Working Group 7 of TC 217 is charged with the responsibility of harmonising the current test methods - essentially those of Australia, COLIPA and FDA in the USA. It is anticipated that the development of this test method will not be a lengthy process, as it is intended only to cover the water immersion procedure and the conditions of the test pool and not require any pass/fail or aspects related to interpretation into labeling.It is proposed that much of the validation of the variable factors for test conditions may be achieved by the use of in-vitro experimentation. Here at Dermatest, we have been developing this methodology using a standard dissolution apparatus. If you would like more information on this then email us at ... info@dermatest.com.au

In-vitro Water Resistance Apparatus

More New ISO Standards Initiated!

At the same June meeting in Monaco, ISO Technical Committee (TC) 217 - Cosmetics initiated two new work items. One of these falls into the sunscreens working Group and the other to another Working Group focused on cosmetic terminology. (see Organic and Natural below).

Organic and Natural

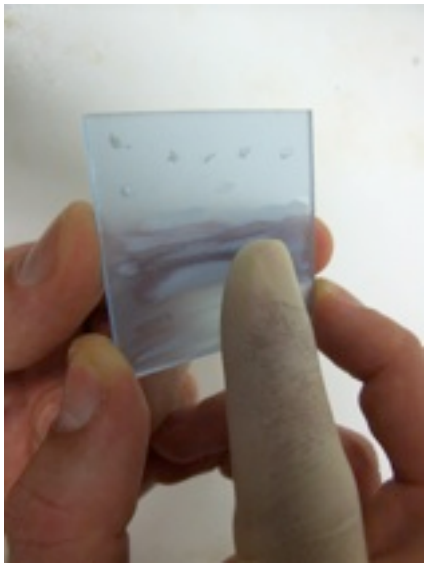
When is an ingredient organic, natural (or herbal) and where is the cut-off? The second standard discussed at the same meeting comes under the responsibility of W.G. 4 Terminology and will consider the definition of "natural" and "organic" as these relate to both cosmetic ingredients and cosmetic products. Delegates from South Africa, Spain, Denmark, India, Australia, U.K., France, Iran, Japan, Netherlands, Poland, U.S.A and Italy as well as COLIPA and P.C.P.C (USA) attended.
The approach to this document will be scientific and technical and not consumer perception driven. It will only relate to cosmetic/personal care products. It is currently intended that the document will not cover associated environmental considerations, such as sustainability, green or biodegradable as these are covered in other ISO documents.

As it is early days and this is a complex topic with considerable variation in interpretation from country to country, as well as legal implication, there is no doubt a long process ahead before issue of any drafts for wider circulation.

New Price List Soon

Clients will receive our updated price list to apply from August 2010. This replaces the previous version dated March 2008. If you would like a copy, email us at ...
info@dermatest.com.au

Product application - in-vivo



Product application - in-vitro

How do I evidence photostability?

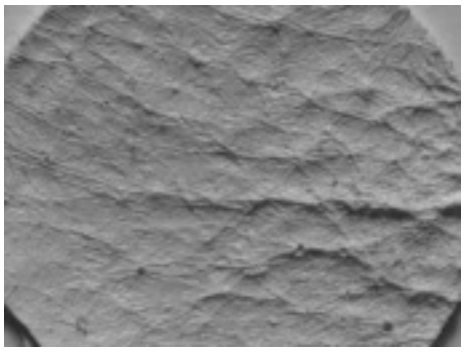
There are a number of published methods suggesting protocols for the evaluation of photostability. The principle of these is essentially the application of UV light to a sunscreen – generally in a thin film – and the comparison of pre and post irradiation effects on the quantity and quality of the sample. The proposed ISO 24443 Cosmetics – In vitro determination of UVA Protection is an example. Although not intended to define photostability, the method does discriminate the effects as they relate the relationship of the UVA protective contribution of the product once it has been light challenged.

However, the only true measure of photodegradation of a sunscreen is the impact on the chemical content of the actives. This analytical approach has been used for substantiation by several major marketers of brands promoting the claim. This is an HPLC, rather than UV measurement, which is stability indicating when fully validated analytical methods are utilised. G.C. M.S. can also be utilized for further investigation of chemical degradates.

A New Line on Wrinkles and Skin Roughness

The process of validation is now underway following our recent purchase of a Visioline VL 650 digital imaging system.
The system utilises a high resolution camera and digital imaging system. This instrument is flexible and has a wide range of applications, from wrinkle and skin roughness studies, to sebum production and desquamation.

Skin Roughness image as recorded by the Visioline camera.



About ARGOM and Stability

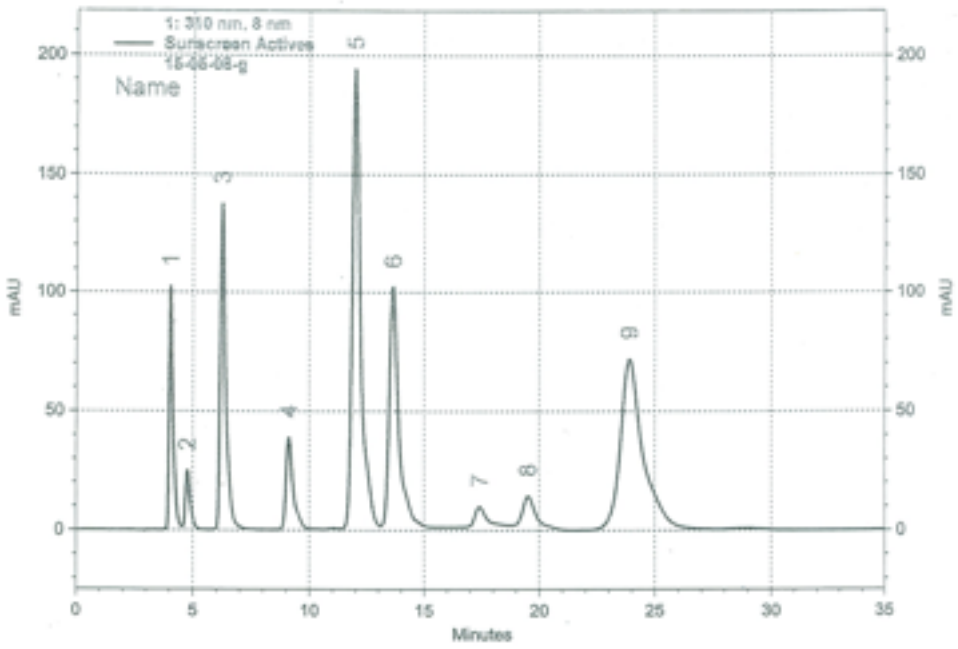
The public consultation period for Chapter 10 of the Australian Regulatory Guidelines for OTC Medicines ended on 18th June 2010 and the document is now in its final stages for release. ARGOM is a comprehensive document for TGA regulated sunscreens and includes requirements for labelling, SPF testing, stability, microbial control and manufacture as well as lists of permitted actives and the process for proposing new actives.

The implementation of ARGOM will occur during the remainder of 2010 and beyond, including some changes to the naming of actives on labelling. As part of the ARGOM and regulatory review "package" sunscreen manufacturers (including those outside Australia) will now be required to implement GMP under PIC's Guidelines, in place of the previous GMP Code for (TGA) Sunscreens. For GMP, the most significant changes will be the requirement to conduct a quality review for each product. This is quite a comprehensive undertaking, involving "past reviews, in-process controls, failed batches, deviations and non-conformities, process or equipment changes, marketing authorisation variations, stability results, complaints and recalls, and technical agreements to identify improvements" according to the TGA.

PIC's also requires the monitoring of product stability over the shelf life of the product ARGOM Chapter 10 give guidance on how to conduct such studies. Dermatest is able to conduct these stability tests and we have developed analytical methodology to comply with the requirements. (see example HPLC multi-active analysis example below). Please contact john@dermatest.com.au if you need assistance or a costing.

At the time of publication of this newsletter the ARGOM Draft could still be down loaded from... www.tga.gov.au/npmeds/consult/cons-argom-sunscreens.htm#happen

Multi-active HPLC of sunscreen



1) 2-Phenylbenzimidazole-5-sulfonic acid
2) Benzophenone-3
3) Octocrylene
4) Ethylhexyl dimethyl PABA
5) Butyl methoxydibenzoylmethane
6) Ethylhexyl methoxycinnamate
7) 2-Ethylhexylsalicylate
8) Homosolate
9) Drometrizole trisiloxane

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