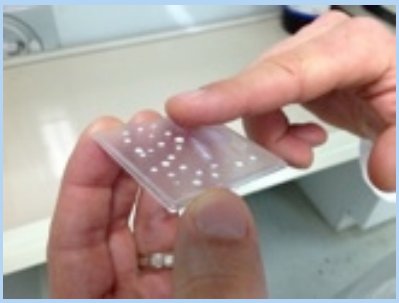
Dermatest

UVAPF In Vitro Broad Spectrum Test

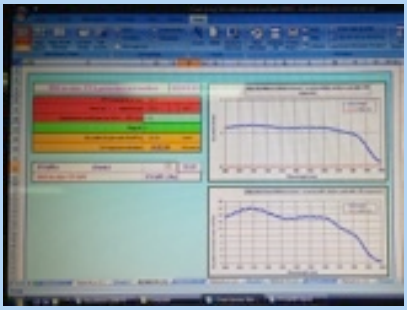
STEPS



1. Film Preparation

2. UV Light Challenge

3. Measurement of UV Absorption



4. Calculation of Results

Measurement of UVA Protection In Vitro

Supportable Claims

- "Broad Spectrum" - Australia
- UVA Circle - E.U
- Broad Spectrum - FDA estimate
- Model for PPD - Japan and Korea
- Premature aging Claims

Principle

The steps of the human UVA tanning test (Persistent Pigment Darkening) can be imitated without the use of test volunteers.

Steps of the Test

A film of sunscreen is applied onto PMMA plates which imitates skin roughness. Drying is completed. The UV Spectrum is measured. Then the plates are subjected to UV light equivalent to the expected in use performance of the sunscreen. The UV Spectrum is then re-measured. The UVAPF, as well as the Critical Wavelength, can be determined and both broad spectrum and UVA ratio calculated from that data.

Validation

The instruments for both solar UV light simulation and for spectrum measurement have to be submitted to regular and rigorous calibration

Reporting

Compliance with all the legislated standards can be certified. The number of markets where this test is accepted in now well over 50.

For AS/NZS 2604 (2012)
For SPF 15 and above, this test is mandatory except for colour cosmetics.The UVAPF/SPF Ratio must be at least 1/3 and the Critical Wavelength must be at least 370 nm.

For Europe
E.U. requires that this test be performed for sunscreens sold in Europe. It is accepted as the alternative to human testing.

PPD - Japan & Korea
Both of these markets still require the In vivo test . This instrumental test does correlate and is very useful in order to predict performance before much more expensive human testing.

References

1. **ISO 24443** - ***Determination of Sunscreen UVA Protection In vitro***

2. **AS/NZS 2604 (2012)** - ***Sunscreen products - Evaluation and classification***
3. ***FDA Final Monograph***

Dermatest Pty Ltd
20 to 22 King St
Rockdale NSW Australia
ph 61 2 9556 2601
info@dermatest.com.au

www.dermatest.com.au

Dermatest

ISO 24443 In vitro UVAPF. Determines both UVAPF Ratio and Broad Spectrum Compliance. Compliance with AS/NZS 2604 and E.U. requirements is also reported.

An *In vivo* SPF value (we recommend at least 3 test subjects) is required for certification. Otherwise, indicative ratio can be reported.

Principle

Transmittance of a dried down film is measured between 290 nm and 400 nm. Requirements can be extrapolated by conversion of the ratios determined.
Challenge of the sample film is required by pre irradiation with a compliant light source which designed to imitate sunlight.
The spectral curve is measured, using a purpose built spectrophotometer which has been fitted with an integrating sphere device.
The substrate for measurement is moulded Polymethylmethacrylate (PMMA) Plates.
A thin film of the test product, at a thickness of 1.3 mg/sq cm, is applied, by a standard application technique.This involves applying a series of around 30 dots over the area of the plate and then rubbing out evenly with the finger which has been pre-impregnated to saturation with the same product. The prepared plates are pre-irradiated in a Xenon Arc solar simulator, filtered to comply with the requirements of the ISO Protocol. The dose of UV light for pre-irradiation is calculated in order to arrive at the required dose appropriate to the expected UVAPF performance of the product.
A Shimadzu UV 2450 Spectrophotometer, fitted with integrating sphere device, is utilised for measurement. The instrument is calibrated on a monthly basis.

Measurements

Measurements are taken against a matching blank glycerin loaded PMMA plate, at increments of 1 nm between the range of 290 and 400 nm. Calculations are completed by input of the data onto the standard ISO spreadsheet.
4 replicate measurements on 4 separate PMMA plates are taken pre-irradiation and a corresponding 16 scans are made post irradiation, on non-overlaying areas of each of the plates. The ISO software manipulates the data to arrive at the ratio relative to the In vivo SPF.

Reporting

An ISO 24443 compliant report is provided in standard spreadsheet format.
UVAPF /SPF Ratio is reported, together with Critical Wavelength.
UVAPF Dx/Labelled SPF value and indication of E.U. compliance.
AS/NZS2604 certification is included as requested.
Spectral and calibration data is provided.
Estimates of Boots Star, FDA Broad Spectrum and JCIA UVAPF are also indicated.