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SUPPORTING SKINCARE

Dermatest

Testing”

ISO 24442 *In vivo* UVAPF Testing

This ISO 24442 method is is mandated in Japan and Korea and an accepted option for E.U. and some other Countries.

Supportable Claims

- UVA Protection
- UVA Circle logo
- JCIA PA++++
- Premature Aging and Skin Cancer protection in some markets.

UVAPF measurement is performed on a panel of at least 10 human adult volunteer test subjects with selected skin types who only tan, and are usually darker skin. The test panel is selected from volunteers who do not have any history of sensitivity to skin product ingredients and who who have an appropriate health history. The requirements of the test are now the same for all regulated markets.

Product Application

A very accurately measured and controlled amount (2 mg/sq cm) of product is applied to a marked out area of skin. The product is evenly spread, using a standardised technique. The product is then allowed to dry for 15 to 30 minutes.

Solar Simulation

A Solar simulator, which has been designed and calibrated to imitate the spectrum of the UVA component of sunlight, is used to apply small incremental doses of light energy to the protected area. An unprotected area and an area with a Standard Sunscreen applied, are exposed and in 3 to 6 hours, a tanning reaction known as Persistent Pigment Darkening develops at test sites where the UVA Protection has been exceeded.

Reading of Results

The results are read around 3 to 6 hours after the exposures are made. The test value taken is the point where there is a slight but clearly visible tanning of the skin.

The UVAPF is a simple ratio of the number of seconds or accumulatderd Joulles/sq m of light exposure, divided by the value for the unprotected exposure seconds.

References

[Monographed Methods}

ISO 24444 : 2012

JCIA UVAPF Method 2013.

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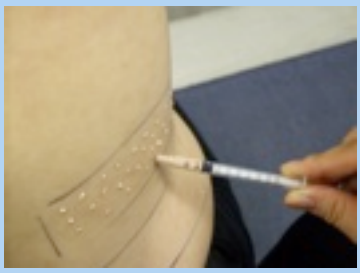
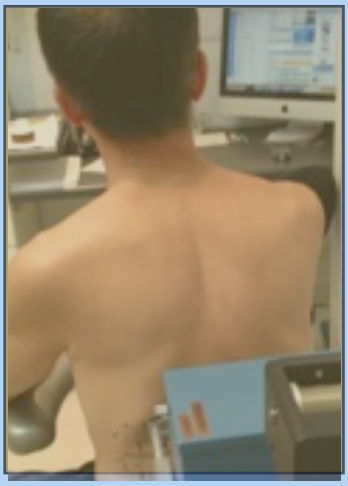
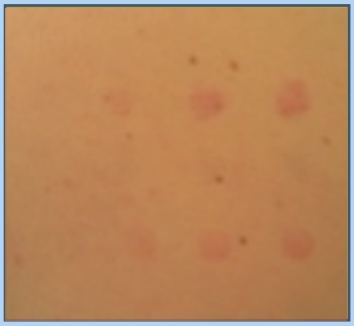
STEPS



3. Product Application



2. Solar Simulator Exposure



3. Reading of Results

Dermatest Pty Ltd

UVAPF TEST ACCORDING TO THE ISO 24442 PROTOCOL

1. Objective:

The test panel will be convened to evaluate the effectiveness of a test material as a sunscreen product by determining the Sun Protection Factor (SPF) on human skin as described in the document: International Standard ISO 24442 - Cosmetics — Sun protection test methods — In vivo determination of sunscreen UVA protection

2. Test Material Handling

The record of the sample is entered into a log identifying the lot number, sample description, batch number, sponsor, date received and tests requested. Samples are retained for a period of two years beyond final report generation.

3. Ethical Principles for Conduct of Study

3.1 The study will be conducted in accordance with the principles as described in the document WMA Declaration of Helsinki – for Medical Research Involving Human Subjects.

4. Standard for Inclusion of a Panelist in a Study

4.1 Individuals over the age of consent.
4.2 Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the investigator.
4.3 Individuals who have completed a preliminary medical history evaluation.
4.4 Individuals who have read, understood and signed an informed consent document relating to the specific study to which they are subscribing.
4.5 Individuals with no known abnormal response to sunlight.

5. Standard for Exclusion of a Panelist from a Study

4.1. Individuals taking medication which in the opinion of the investigator would mask or interfere with the results.
4.2. Individuals with chronic skin allergies.
4.3. Individuals with suntan or sunburn.
4.4. Individuals with abnormal reaction to the sun.
4.5. Pregnant or lactating females.
4.6 Subjects accustomed to using sun beds.
4.7 Subjects who have participated in a UVA study within the last two months.
4.8 Subjects who have had UV exposure to the back area within the previous 4 weeks.

6. Informed Consent and Medical History Forms

An informed consent will be obtained from each volunteer prior to initiating the study describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability. Panelists sign and date the informed consent document to indicate their authorisation to proceed and acknowledge their understanding of the contents. Each subject is assigned a permanent identification number and completed an extensive medical history form. These forms along with the signed consent forms, are available for inspection only on the premises of Dermatest Pty Ltd and during normal office hours.

7. Panel Composition:

A minimum of ten healthy volunteers, between the age of consent and 70 years will be recruited for this study. The panel consisted of fair skin individuals with Fitzpatrick skin types II, III or IV.

8. Solar Simulation

The light source employed is a small beam 150 watt Xenon Arc Solar Simulator (Solar Light Co., Philadelphia, Pennsylvania, Model 16S or Model 601) having a continuous emission spectrum in the UV range from 290 to 400 nm and compliant with the spectral performance requirements of the Section 6 and ANNEX B of the ISO protocol. Xenon arc is selected on the basis of its black body radiation temperature of 6000oK which produces continuous UV spectra (all wavelengths) substantially equivalent to that of natural sunlight. This device is equipped with a dichroic mirror (which reflects all radiation below 400nm) and works in conjunction with a 1 mm thick Schott WG335 filter to produce simulation of the solar UVA spectrum. A 1 mm thick UG 11 filter (black lens) is added to remove reflected (infrared, greater than 700 nm) heat and remaining visible radiation. UV radiation is monitored continuously during exposure using a Sunburn UV Meter/Dose Controller System (Solar Light Co) . Measurements are taken at a position within 8 mm from the surface of the skin. The field of irradiation is >0.5 cm in diameter, with at least 1 cm between each adjacent site. Realignment of the Light Sources and calibration of the sunburn meters are conducted by independent certification facilities and adjustment to light source power supply only by the Director.
The amount of UVA II (320-340 nm) is set to be between 8 and 20 % of the total UV irradiance (UVAII / UVA = 8-20 %). < 0.1 % of UVB is contained in the source beam.

Acceptance Limits for Solar Simulator Output.

Spectral Range (nm)	Measured % (%)	
	Lower limit	Upper limit
< 320		< 0,1
320 – 340 nm	8	20
340 – 400 nm	80	92
Visible + Infrared	< 5 % of total ir radiance	

10. Determination of the UVA Protection Factor

The test area is described as the infrascapular area of the back to the right and left of the midline .
One test site area of 40 sq.cm serves to determine each subject's Unprotected pigment darkening dose (MPPDDu). This is executed by exposing the back to a series of 5 timed incremental UV exposures at 125% intervals. The individual subject's MPPDD is the shortest time of exposure that produces perceptible pigment darkening at 2 to 24 hours post irradiation.. The application area is 40 sq.cm. The product is delivered to the test site through plastic volumetric syringes. The material is evenly applied to a rectangular area for a final covering of 2.0 mg/sqcm +/- 2.5%.
The product is deposited in a series of evenly distributed spots and then spread evenly with a fingercot. Product application, UV exposures and measurements of responses will be conducted in stable environmental conditions with the room temperature maintained between 18oC and 26oC.
15 to 30 minutes after application, a series of 5 UV light exposures in geometric progression of 25% increments will be administered from the solar simulator to subsites, each with an area of not less that 1 cm sq and spaced at 1 cm separation within the treated area. On the actual day of testing another series of exposures is administered to an adjacent untreated site of unprotected skin to re-determine the

MPPDDu. An adjacent test site is then selected to perform a static determination on the test substance.
A reference sunscreen, as described in Annex c of the ISO 24442 Standard, is also applied to each of the test subjects, utilising an application exposure procedure which is the same as that utilised for the test product.
Following UV exposure to all test sites, the product is gently removed using moist soft tissue together with ethanol if needed.

11. Evaluation of Response
The volunteers are instructed to return to the testing facility 2 to 24hr hours post exposure, for evaluation of delayed tanning response. The smallest exposure or the least amount of energy required to produce unambiguous redness (PPDp) in the treated site is recorded. The UVAPF is then calculated by the equation
UVAPFi = MPPDDpi
MPPDDui

12. Calculations and Statistics
The UVAPFi values from an initial panel of the first 10 test subjects are sequentially evaluated in order to determine a provisional mean UVA Protection Factor. The statistical criteria described in the test method are then applied to determine a confidence interval and statistical variance. Where necessary, additional subjects will be tested according to the protocol if the first 10 results are not found to be within the specified range.

13. Rejection Criteria
Panelist's results will be rejected and the panelist replaced if:
8.1. The responses on the treated test site are randomly absent or out of sequence. This is an indication that the products are not spread uniformly.
8.2. An MPPDDu could not be obtained due to elicited response at all exposure sites.
8.3. The exposure series failed to elicit a response on either the untreated or the applied skin areas.
The test is then considered a technical failure and the subject's data is discounted.

14. Individual Panelist Results
These will be set out in the attached report in ISO 24442 compliant format.

15. Observations
Adverse effects or unexpected reactions of any kind will be recorded.
16. Archiving: All original samples, raw data sheets, technicians notebooks, correspondence files and copies of final reports and remaining specimens are maintained on premises of Dermatest Pty Ltd in limited access storage files. A duplicate disk copy of final reports is archived separately off site.

17. Colour Discrimination Test
All technical employees of Dermatest Pty Ltd who are involved in scoring of exposed skin spots are required to take and pass a visual colour discrimination examination using the Farnsworth-Munsell 100 Hue Test.
Certification for J.C.I.A. Compliance
Where requested, an additional certification, indicating JCIA compliance can be provided.

UVAPF Protection Grade
2 to less than 4 PA+
4 to less than 8 PA++
8 to less than 16 PA+++
16 or more PA++++

References

1. Dermatest SOP – 027 Procedure for Conducting a UVA Study – ISO 24442 Method.
2. International Standard ISO 24442 - Cosmetics — Sun protection test methods — In vivo determination of sunscreen UVA protection
3. WMA Declaration of Helsinki – for Medical Research Involving Human Subjects.