

Test Protocol Outline

SPF Testing - AS/NZS Protocol - 10 subject -

Compliance with this protocol is a mandatory requirement for TGA Listing before marketing in Australia. Both Static (No swim) and Water Resistance testing can be performed, according to label requirement. If water resistance is claimed, the SPF value must be the post swim result at 40 min to 4 hrs as tested. Broad Spectrum claims require testing in-vitro according to Appendix C of the Standard.

Experimental Design

Panel Composition 10 Normal, healthy, adult volunteers who are above 18 years of age.
Individuals are selected from skin types I, II, or III. Informed consent will be obtained.
Individuals free of any dermatological or systemic disorder which would interfere with the results.
Individuals who have completed a preliminary medical history evaluation.
Individuals who have read, understood and signed an informed consent document relating to the specific study to which they are subscribing.
Individuals with no known abnormal response to sunlight.

Standard for Exclusion of a Panelist from a Study

Individuals taking medication which in the opinion of the investigator would mask or interfere with the results.
Individuals with chronic skin allergies.
Individuals with suntan or sunburn.
Individuals with abnormal reaction to the sun.
Pregnant or lactating females.

Method

Solar Simulation

The light source employed is a 150 watt Xenon Arc Solar Simulator, having a continuous emission spectrum in the UVB range from 290 to 320 nm. Exposures are taken at a position within 8 mm from the surface of the skin. The field of irradiation is 1 cm in diameter.

Determination of the Static Sun Protection Factor (Where conducted)

The procedure for this study is outlined in Australian/New Zealand Standard AS/NZS 2604:1998. One test site area served to determine each subject's Minimal Erythema Dose (MED). This was executed by exposing the back to a series of timed incremental UV exposures at 25% intervals. The individual subject's MED is the shortest time of exposure that produces minimally perceptible erythema at 16 to 24 hours post irradiation. The test area is described as the infrascapular area of the back to the right and left of the midline. The appropriate Reference Sunscreen 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/cm².

Determination of Water Resistance (Where Conducted)

This test is employed to determine the substantivity of a test product and its ability to resist water immersion. The procedure is as outlined in section 9 above, and the procedure described in Appendix D4 of AS/NZS 2604 is followed.

Standard requirements and maximum immersion times claimable under the Standard are as follows...

SPF 4 - 7 = 40 min SPF 8 to 14 = 80 min
SPF 15 to 19 = 2hrs SPF 20 to 24 = 3 hrs SPF >25 = 4 hrs.

The water is maintained at an average temperature of 33°C±2°C. The pH of the water is maintained between 6.8 and 7.2.

The test area is air dried prior to exposure from the solar simulator using designated 12.5% or 25% increments. The exact series of exposures given is determined by the control MED and the expected SPF of the product.

References

AS/NZS Standard 2604 : 1998.
Dermatest Standard Operating Procedures Manual.