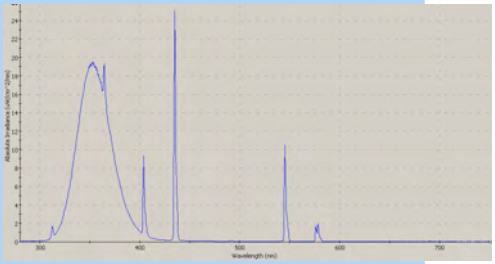
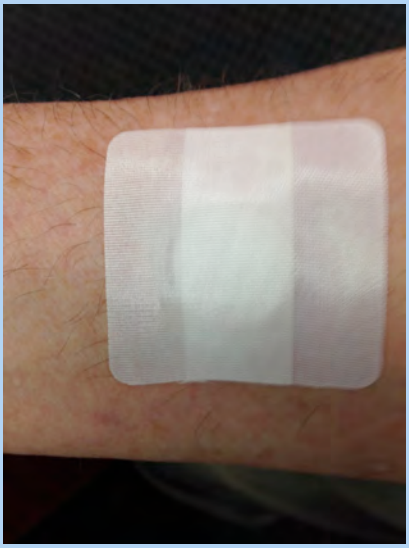
eurofins | Dermatest

Phototoxicity Testing

To determine the phototoxic potential of topically applied product, under occlusion, to the skin of human panelists.



1. NEC Light Source Spectrum



2. Hill Top Chamber

3. Light Box (option)

Phototoxicity is defined as a toxic response that is elicited when skin is first exposed to certain chemicals and then exposed to light.

Supportable Claim

•Product Safety Profile

•Not Photo-toxic

Method

Several methods can be utilised in order to provide the source of light simulation.

Firstly, a solar simulator can be set up with appropriate filter.

Alternatively, a light box which is fitted with UV “Black Light” tubes can be used.

Recruitment

Over the age of 18 years, randomly selected.

- Informed of the nature of the test
- Written informed consent prior to induction.
- Prior to initiation of a test, each subject completes a medical history form.

Study Procedure

On the first test day of the study, sixty (60) µl/ cm2 of each test product is applied to duplicate skin sites (approximately 2 x 2 cm each) on the lower or mid-back.
After the test articles have dried for 5 to 15 min, the sites are covered by 25mm Hilltop chambers or Hypoallergenic patches. Twenty-four (24) hours later, one set of patches is removed. Sixty (60) µl/ cm2 of the test product is reapplied to the test site and then the test site is exposed to UVA radiation
For the Solar sim method, the exposure is 0.5 MED of UVA/UVB and then 20J/cm2 of UVA radiation.
For the Light Box method, a bank of four 20W calibrated fluorescent bulbs (Sylvania, 350 blacklight, F40/350BL) with a continuous long-wave UV-A spectrum ranging between 320 and 400 nm (peak 365nm) are used. The site irradiated with non-erythemogenic ultraviolet (UV-A) irradiation receives a UV-A light dosage of greater than 4.4W/ cm2.
The other patch serves as an un-irradiated control. Also at this same time, another site on the back is similarly treated with a 24 hour occlusive patch but without any test articles and irradiated as described above. This serves as an irradiated control site.

Evaluation of Response

All test sites are graded immediately, twenty-four (24) and forty-eight (48) hours after irradiation. Scores are recorded on the appropriate Case Report Form.

References

Marzulli, N, Maibach, I. *Photoirritation(Phototoxicity) testing in Humans - Dermatotoxicology Methods 1997.*

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