

## Photoallergy - Single product - 25 Subject

To determine the photoallergenic potential of a topically applied product under maximization conditions.

### Experimental Design

**Subjects:** Panels of 25 subjects, fair skinned, male and female, randomly selected. Subjects with abnormal response to sunlight are excluded. • Informed of the nature of the test including possible adverse reactions. • Written informed consent documents signed by all participants prior to induction. • Only subjects that are considered dependable and able to read, understand and follow directions will be requested to participate. • Prior to initiation of a test, each subject will complete a medical history form. The subjects will not exhibit any physical or dermatological condition which would preclude application of the test material(s).

**Test Materials:** A sufficient quantity of each test material should be submitted by the sponsor. Approximately 250gm of test material is required for a panel of 25 persons. A hydrophilic ointment control, without sodium lauryl sulfate is provided by Dermatest.

**NOTE:** it is strongly advised that the product be tested for contact sensitization prior to any photobiological evaluations.

### Method

**Light Source :** 150 Watt Xenon Arc Simulator (Solar Light Company, Philadelphia, Pennsylvania 19126) having a continuous emission spectrum in the UV-B range (290 to 320 nanometers) is used. Long ultraviolet light (UV-A, 315-400 nm) is obtained by filtering the radiation through a 2mm Schott WG 345 Filter (50% transmission @ 345nm) or a 1mm Schott WG 320 Filter.

**Method:** Prior to the testing of sunscreen product(s), the sensitivity of the unprotected skin of each subject, i.e. the Minimal Erythema Dose (MED), is determined by exposing 1 cm.sq. areas of untreated skin to the solar simulator for increasing periods of time in 25 % increments. The MED of each individual is determined in seconds, based on the length of exposure which first elicits a slight reddening of the skin, as observed 24 hours following exposure. Duplicate test areas to which the test substance has been evenly applied (at a density of 10 ul or mg/sq.cm.), are delineated on the subjects back. Sites are covered with patches of nonwoven cotton cloth and occluded using overlapping strips of hypoallergenic tape. After 24 hours the test sites are wiped dry with gauze and one set are exposed to 3 MED's of solar simulating radiation while the remaining set is left unirradiated. After a 48 hour rest period during which the site is left uncovered a similar occlusive application is made for another 24 hours to the same sites and again one set is exposed to 3 MED's immediately upon removal of the dressing while the alternate set is again left unirradiated. This sequence is repeated for a total of 6 exposures twice weekly (usually Tuesday and Friday).

**Challenge:** panelists are challenged 10-14 days after the final induction exposure. Similar occlusive applications are made for 24 hours to a previously unexposed untreated area of normal skin. The sites are then irradiated with 4.0 joules/cm<sup>2</sup> of UV-A radiation. Reactions are scored 48 and then 72 hours post challenge irradiation.

**Controls:** five sites are selected a. normal intact skin untreated, b. patch materials only - no product - no exposure, c. patch materials with UV-A exposure only, d. Hydrophilic Ointment - patched; unirradiated, e. Hydrophilic Ointment USP - patched and irradiated.

**Scoring:** The irradiated and non-irradiated sites are scored 48 hours after exposure to the light source as follows:  
0 = no evidence of any effect      ? = query  
+/- = minimal, faint, uniform or spotty erythema    1 = pink uniform erythema covering most or all of the site  
2 = pink-red erythema visibly uniform in entire site    3 = bright red erythema with or without petechiae or papules  
4 = deep red erythema with or without vesiculation or weeping

### References

Contact Dermatitis 1980:6:161-160 - "Photomaximization test for identifying photoallergic contact sensitizers", Kaidbey, K.H., Kligman, A.M.