

Test Protocol Outline

Phototoxicity - 10 Subject

Objective:

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

Experimental Design

Subjects: Panels of 10 subjects, male and female, over the age of 18 years, randomly selected.

- Informed of the nature of the test including possible adverse reactions.
- Written informed consent documents signed by all participants prior to induction.
- Parental consent will be obtained from minors.
- 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).

A bank of four 40W calibrated fluorescent bulbs (Sylvania, 350 blacklight, F40/350BL) with a continuous long-wave UV-A spectrum ranging between 320 and 400 nm (peak 365nm) will be used.

Method

1. The inner left arm will be designated as the control (non-irradiated) site and the inner right arm as the test site. On the initial day of the study, the test site will be wiped clean with alcohol and tape stripped with hypo-allergenic tape 3 times to remove several layers of cornified epithelium. Two-tenths of a milliliter (0.2mL or 0.2g) of test materials will be placed onto a 2cmx2cm Parke-David REDI-Bandage occlusive patch or the equivalent, then applied to the non-irradiated control site (left arm) and will be allowed to remain in place for 24 hours.

2. Test materials will be applied to the right arm directly to the skin. The site will be irradiated with non-erythemogenic ultraviolet (UV-A) irradiation at a distance of 10cm from the source and receiving a UV-A light dosage of greater than 4.4, W/cm². The test site will be covered with a Parke-Davis REDI-Bandage occlusive patch containing additional test materials (0.2mL or 0.2g) for a period of 24 hours, then removed. Hydrophilic ointment USP will serve as the negative control (irradiated and non-irradiated).

Responses

Immediately following and at approximately twenty-four, forty-eight hours and one week post removal all sites will be scored. The subjects are asked to report and delayed reactions which might occur after the final reading.

At the sponsor's request, readings may be taken at additional time periods after application and removal of patches, to follow the course of reversal of reactions.

Adverse Experiences

An adverse experience is defined as any medical event, intercurrent illness or injury which related to study participation. All adverse experiences will be documented and reported to the sponsor. All adverse experiences will be followed to satisfactory resolution.

Results of dermal responses will be presented in tabular form. The Investigator will submit a final report with all data to the Sponsor.

References