

Test Protocol Outline

Hand Irritation - Single Product - 10 Subject

Objective: To determine the relative irritancy potential of the product comparative to a control. Appropriate to surfactant and antibacterial type formulations.

Experimental Design

Subjects - Usually 10, male & female, random selection.

- Informed of nature of test and possible adverse reactions, informed consent docs. (only incl. those who are dependable, able to read, understand and follow directions)
- Prior to initiation, medical history form completed by subject, exclude those who have a history of physical or dermatological condition which would preclude application of the test materials.

Test Materials - Please forward : liquids - approx. 500ml ; powders, semi-solids - approx 500g.

Only 1 material or product may be tested, plus a known high irritation index control or a comparative product. - controls should represent a similar product category to test products, and all should be submitted blindly.

Method

1. Quantity per test. - 10mL or 10g.
2. Placed into a medical sterile glove.
3. Test subject's hand inserted into glove and product left in contact with skin surface for 15 to 30 minutes (depending on range finding results). Product massaged into hands for 10% of contact time.
4. Gloves removed and product washed from hands with water. Air Dried.
5. Response evaluated after 1 hr and after 16 to 24hrs. Measured with Erythema Meter and by visual observation.
6. Sites scored by trained personnel prior to next application.
7. Test is repeated for a total of 2 days or until irritation scored. If/when a reaction of 3 or 4 is observed, test is discontinued and the score attained will be entered for the balance of 21 days.

Scale

0 = no evidence of any effect

? = query

+/- = minimal, faint, uniform or spotty erythema

1= pink uniform erythema covering most or all of the contact site

2 = pink-red erythema visibly uniform in entire contact site

3= bright red erythema with or without petechiae or papules

4 = deep red erythema with or without vesiculation or weeping

Accompanying edema (swelling) is recorded with an 'e' and is described as mild, moderate or severe as compared with the normal surface of the surrounding skin.

Reporting

The final report to the sponsor of the study will include: purpose, test materials, panel selection and demographics, experimental design, results and conclusions. Results of dermal responses in tabular form.

References

In - house protocol.