

## Repeat Insult (RIPT) - 50 Subject

Objective: to determine the irritation and/or sensitization potential of a test material(s) after repeated application under occlusive, semi-occlusive or open patches to the skin of human subjects.

### Experimental Design

**Test Material Information - please include in your sample submission...**

**1. Sufficient sample -Per 50 subjects:** liquids - approx. 250ml ; powders, semi-solids - approx 250g ; fabrics/fibres - approx 600sq in)

**2. Indicate nature of Product -** LEAVE ON (APPLY NEAT) or WASH OFF (APPLY DILUTED) and dilution.

**3. Indicate patch type -** SEMI-OCCLUSIVE (Default) or OCCLUSIVE (closed patch) or OPEN (no patching).

**Subjects:** Panels of human subjects, male and female, 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).

### Method

#### 1. Induction Phase:

a) The quantity of test material applied per test patch will be approximately 0.2mL or 0.2g of each substance.

b) Test material(s) will be placed on a 2cm square Parke-David Readi-Bandage (occlusive) or to a 2cm square of Webril non woven fabric affixed to Scanpor tape (semi-occlusive) or equivalent coverings. The patch(es) will be applied to the subject's back between the scapulae and waist, or to the inner forearm. Semi-occlusive tape will be used when evaluating known irritating and/or volatile materials.

c) The subjects remove the patches 24 hours after each application. 24 hour rest periods follow each removal. Prior to each reapplication, site(s) are evaluated by a trained staff member. This procedure is repeated until 9 applications of the test material(s) are made.

d) Skin responses are evaluated according to the following 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.

Accompanied edema (swelling) at any test site is recorded with an "e" and is described as mild, moderate or severe compared with normal surface of surrounding skin.

e) if a subject develops a positive reaction of a 2 - level or greater during the induction phase, the patch is applied to a fresh adjacent site for the next application. If a 2 or greater reaction occurs at the second site or application, no further applications of the reactive test material are made for the remainder of the induction phase. However, reactive subjects will be subsequently patched with the test materials at a virgin test site during the scheduled challenge phase of the study.

#### 2. Challenge Phase:

a) Ten to 21 days after application of the final induction patch, challenge patch(es) are applied to previously unpatched (virgin) sites, adjacent to the original induction patch sites. The challenge sites are scored 24 to 48 hours after application. The subjects are asked to report any delayed reactions which might occur after the final challenge patch reading.

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

### References

Standard Operating Procedures, Clinical Trials 930.00, Repeat Insult Patch Test (RIPT).

Based on the method published in Appraisal of the Safety of Chemicals, Drugs and Cosmetics - Association for Food and Drug Officials USA