

Facial Discomfort Assay - 10 Subject

To determine facial discomfort potential of a topically applied product as determined by stinging/burning.

Ophthalmologist Certification

Additional option - Registered Ophthalmologist will review protocol, oversee study and certify test results.

Experimental Design

Subjects: Panels of 10 subjects, male and female (or as client requests). Panelists are pre-screened for their sensitivity to topically applied lactic acid. Only those subjects exhibiting cumulative scores of 1.0 to 2.0, representing "sensitive to extra sensitive, will be inducted into the study.

- 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

Product is submitted on a blinded basis.

Only pre-screened and selected test subjects are recruited for the study.

Panelists are made familiar with the descriptive terminology to be used for the subjective evaluation.

One or other side of the face is randomly assigned for application of the test product.

Prior to application of the test product, panelists are instructed to wash their face with Dove Beauty Soap, rinse gently, and pat dry with paper towels, in the presence of a technician.

1 mL or gm of the test product is applied to a cotton swab and rubbed over the surface of the skin, starting at the nasolabial fold and working in a smooth motion across the upper cheek area.

Panelists sit quietly in an environmental chamber set at 95 -100oF (37 to 40oC) and 70 -80% R.H. and record all sensations to the test area at the specified time intervals (0, 2.5, 5 minutes). Panelists rate the intensity of the response.

The following parameters are reported.

Burning	Stinging	Tingling	Warm/cold
Itching	Drying	Smarting	Prickly

Discomfort is evaluated to the following scale

- 0 = none
- 0.5 = barely
- 1.0 = slightly perceptible
- 1.5 = definitely perceptible
- 2.0 = moderately perceptible
- 2.5 = dramatically perceptible
- 3.0 = severely perceptible

References

1. Frosh,P.J and Kligman A.M. A method for Appraising the Stinging Capacity of Topically Applied Substances Journal of Society of Cosmetic Chemists 28 p 197-209 May 1997
2. Test protocol MS01.PROT.FDAT.FORMAT