

Evaluation of the irritation potential and ‘reservoir effect’ of mild soaps using Occlusive patch-test followed by TEWL measurements

Test aim: The aim of the present study is to evaluate possible differences in irritation potential and reservoir effect of cosmetic products containing surfactants after occlusive application onto healthy skin. The inherent capacity of the products to induce irritation and reservoir effect is evaluated using the conventional occlusive patch-test and non-invasive instrumental measurements (TEWL).

Subjects undergoing the treatment:

- ❑ Nr 15-20 volunteers, aged 18-60 years, sex: M/F
- ❑ Criteria of volunteers selection:
 - Good health condition
 - Absence of skin pathologies
 - Absence of topic pharmacological treatment in progress
 - Negative anamnesis for atopy
 - Volunteers shall not to use any bodycare products on their forearms for at least 3 days before the test started.
 - Exclusions: women during pregnancy or lactation, minors

Every volunteer is given a form to fill in and subscribe in order to express free consent to the test and confirm that no condition of test exclusion is present.

Testing plan

aqueous solution of SLS will be used as positive reference and distilled water will used as negative control.

Scheme of test performance

1TH STEP: EVALUATION OF IRRITATION POTENTIAL

- ❑ Occlusive Patch-test : on the volar forearm apply 50µl 10% aqueous solution of the products in aluminium chamber (Finn Chambers) containing a filter paper for 24h with adhesive tape. After the removal of the chamber.
- ❑ 1h after the removal of the chambers the areas will be visually evaluated by a dermatologist using score scale from 0 to 4 (0: negative; 0.5: doubtful, very weak erythema or minute scaling; 1: weak, weak erythema, slight oedema, slight scaling and/or slight roughness; 2: moderate, moderate degree of erythema, oedema, scaling and/or roughness; 3: strong, marked degree of erythema, oedema, scaling and roughness; 4: very strong/caustic, as 3 with necrotic areas).
- ❑ 24h after the removal of the chambers (48h after the application) the areas will be visually evaluated by a dermatologist using the scale previously described.

2ND STEP: EVALUATION OF RESERVOIR EFFECT

- ❑ Apply 20 µl of the products and gently move using a finger cot for 5 seconds on the wet volar forearm. Rinse the test area for 5 seconds with water and pat dry using soft tissue paper.
- ❑ 2 minutes later, apply the aluminium chambers on all the test area for 24h.
- ❑ 1h after the removal of the chambers the areas will be assessed visually by a dermatologist using the same scale previously described.
- ❑ 24h after the removal of the chambers (48h after the application) the areas will be visually evaluated by a dermatologist using the scale previously described and measured the TEWL on the 5 test areas and on the 3 controls.

Instrumentation

The measurement is carried out by TEWAMETER TM 210. The tube is equipped with sensors for the detection of the relative humidity and temperature, electronic control equipment and chip with all the calibration values. The

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measuring head is composed by an empty cylinder (10 mm diameter, 20 mm height) to prevent air influence and turbulence.

Guidelines: "Assessment of water evaporation through skin (Trans Epidermal Water Loss) according to Guidelines for TEWL measurement." Contact Dermatitis 1990; 22: 164-178

Analysis and assessment of results:

- Assessment of criticality
- Statistic treatment of data: Wilcoxon test (significance level α : 5%). To compare the sample test used is products F as Friedman.

Documentation: a report is compiled with the following structure: identification — objective — significance — work plan — protocol — results — statistics — discussion of results — signature of the dermatologist.