

Occlusive patch test-single application- test performed in collaboration with the dermatological department of the University of Padua

Test aim: the test allows the assessment of cosmetic formulations compatibility destined to come into contact with human skin. Usage conditions are amplified (occlusive patch until 24 hours) in order to confirm that the product is not irritating in normal or reasonable expectable usage conditions. In fact the test can be carried out only after a safety surveyor has attested that no significant risk to volunteers is expected in method conditions.

Subjects undergoing the trial:

- n 20 subjects, sex: M/F.
- Criteria of volunteers selection:
 - Good health condition
 - No participation in analogous trials in the two previous months
 - Negative anamnesis for allergenic skin reactions
 - Absence of skin pathologies
 - Absence of topic pharmacological treatment in progress
 - 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 to the above mentioned conditions.

Scheme of test performance:

After cleaning skin with alcohol 70%, it is necessary to apply blasters (Finn chambers on scanpor or Curatest F) on paravertebral area, at scapular level, or on the forearm and let them on site for 24 hours, reminding the volunteer not to wash the area during the whole test. After this interval of time, blasters are removed by a dermatologist, who will clean application areas from all eventual product residue. After 15 minutes, period of time which is necessary to extinguish blaster irritation, the dermatologist performs a first assessment of the eventual irritation, scoring both erythema and edema according to a scale from 0 to 4. After 24 hours from blaster removal, the dermatologist carries out a second assessment of erythema and/or edema in the same conditions and modalities of the first lecture.

Expression of results:

The average irritation index is defined as the sum of the assessment score of both erythema and edema. The values of irritation index at 15 minutes and at 24 hours are indicated in the experimental report completing the form concerning the volunteers.

Analysis and assessment of results:

It is necessary to calculate - for every product - the mathematical average of all irritation indexes obtained for the 20 volunteers recruited for this test. According to the index, the product is classified as *not irritating, lightly irritating, moderately irritating or strongly irritating*.

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