

6. RESULTS

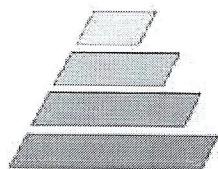
During the study a drop-out case occurred for reasons not correlated with the test, therefore the results are referred to 19 volunteers.

PRODUCT: **FABRIC TREATED WITH NITRO**

Ref. ISPE: 191/13/01 - 283/13

IMMEDIATE SKIN IRRITATION POTENTIAL (ISIP) (30 minutes after product application, T₁)

| TOTAL NUMBER of SUBJECTS: 19 | |
|---|-----------|
| IRRITATED SUBJECTS NUMBER | |
| cases +/- <i>doubtful reaction (light faint homogeneous erythema)</i> | 0 |
| cases + <i>homogeneous pink-red erythema of minimum degree</i> | 0 |
| cases ++ <i>sharp bright-red erythema, of moderate degree, clear limits, possible faint homogeneous oedema</i> | 0 |
| cases +++ <i>strong erythema and spread oedema; possible vesicles and/or follicular pustules</i> | 0 |
| Total irritation cases | 0 |
| Irritation Percentage | 0% |



PRODUCT: **FABRIC TREATED WITH NITRO**

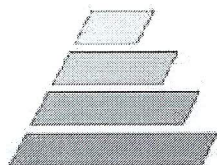
Ref. ISPE: 191/13/01 - 283/13

SKIN IRRITATION POTENTIAL (SIP)

**[48 hours after product application (T₂) and
24 after occlusion removal (T₃)]**

| | |
|---|-----------|
| TOTAL NUMBER of SUBJECTS: 19 | |
| IRRITATED SUBJECTS NUMBER | |
| cases +/- <i>doubtful reaction (light faint homogeneous erythema) perceptible at T2 and keep until T3</i> | 0 |
| cases + <i>homogeneous pink-red erythema of minimum degree</i> | 0 |
| cases ++ <i>sharp bright-red erythema, of moderate degree, clear limits, possible faint homogeneous oedema</i> | 0 |
| cases +++ <i>strong erythema and spread oedema; possible vesicles and/or follicular pustules</i> | 0 |
| Total irritation cases appeared at T3 | 0 |
| Total irritation cases | 0 |
| Irritation Percentage | 0% |

| | |
|--|---|
| Cases +/- perceptible at T2 only (light faint homogeneous erythema) | 0 |
| Allergic reactions | 0 |



7. CONCLUSIONS

During the study a drop-out case occurred for reasons not correlated with the test, therefore the conclusions are referred to 19 volunteers.

The occlusive application of the tested product for 30 minutes (**T₁**) on 19 healthy subjects, did not induce any reaction related to an Immediate Skin Irritation Potential.

The occlusive application of the tested product for 48 hours, on 19 healthy subjects, did not induce any reaction related to a Skin Irritation Potential, as assessed at the occlusion removal (**T₂**) and 24 hours after the product removal (**T₃**).

No allergic reaction was observed.

PRODUCT: **FABRIC TREATED WITH NITRO**

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| | % of IRRITATION |
|------|-----------------|
| ISIP | 0% |
| SIP | 0% |

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