HeiQ Viroblock NPJ03
48hr Closed Patch Test

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HeiQ Viroblock NPJ03 treated fabric:

Human Patch Test

Dear Valued Customer,

By means of this letter we inform you that HeiQ Viroblock NPJ03 treated fabric has been DERMATOLOGICALLY TESTED at Farcoderm srl (in collaboration with the University of Pavia) and demonstrated a perfect skin compatibility.

The subsequent test report sets out that the HeiQ Viroblock NPJ03 treated fabric shows to be *"NON IRRITANT"*.

In reference to the test: "Fabric sample 8" is a polypropylene non-woven fabric sample that was finished with the surface treatment "HeiQ Viroblock NPJ03".

HeiQ Materials AG

Mark Mckay
Director of Compliance and Quality

In collaboration with:
University of Pavia
Prof. FULVIO MARZATICO
Laboratory of Pharmacobiochemistry
Pharmacology and Toxicology Division

REPORT ON A HUMAN PATCH TEST

48 hour closed patch test under occlusion

Skin test to evaluate potential skin irritation after contact with a non-woven fabric

HEIQ MATERIALS AG

FABRIC SAMPLE "8"

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KEY PERSONNEL

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RESUME PATCH TEST

L'objet de l'étude est l'évaluation de la tolérance cutané d'un tissus sur volontaires humains.
Le principe du test est le suivant :
- Application occlusive du produit à l'essai, dans le dos de 10 volontaires à l'aide de patch spécifique (Finn Chamber).
- Le produit est laissé en contact avec la surface de la peau pendant 48 heures.
- Les réactions cutanées (érythème, œdème...) sont évaluées par le dermatologue 15 minutes, une heure et 24 heures après l'enlèvement du patch.

Au regard des observations réalisées, le produit été testé sous contrôle dermatologique et nous pouvons classer le produit

FABRIC SAMPLE "8"

HEIQ MATERIALS AG
NON IRRITANT

STUDY DESIGN

Title
REPORT ON A HUMAN PATCH TEST
Skin test to evaluate potential skin irritation after contact with a non-woven fabric.

Aim of the study
This study assesses the potential side effects (skin erythema and oedema reactions) that may occur after applying a non-woven fabric to evaluate whether the topical product is safe for consumer use.

Tested Product
Information provided by the Customer

- Product name:

FABRIC SAMPLE "8"

The product consists of polypropylene non-woven fabrics that have been impregnated with a surface treatment.
The composition of the formulation on the fabric is in proportion to the of the fabric weight (filed).

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Ethical requirements

The study was carried out in compliance with the following ethical requirements:

- All of the subjects participating in the study are healthy volunteers at least 18 years old.
- All of the subjects participating in the study are selected under the supervision of a dermatologist according to inclusion/non inclusion criteria (see respective paragraph "Inclusion criteria" and "Non inclusion Criteria").
- Volunteer participation in the study is totally free.
- All of the subjects participating in the study are informed of the aim and the nature of the study..
- All of the subjects participating in the study are informed of the potential risks involved.
- All of the subjects participating in the study give their informed consent signed at the beginning of the study.
- Before volunteers were exposed to the product to be tested, all relevant safety information about the product itself and each ingredient were collected and evaluated.
- All of the study procedures are carried out in accordance with the ethical principles for the medical research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and successive amendments)
- All necessary precautions were taken to avoid adverse skin reactions.
- If unexpected/adverse skin reactions occur, the dermatologist evaluates the severity of the reaction (and report it in the data collecting sheet) and if necessary proceed with the appropriate therapy.

Subject selection

Volunteer recruitment

10 volunteers were recruited to take part in the test in accordance with customer's request and with the following inclusion and non-inclusion criteria:

Inclusion criteria

- ☑ Male and female subjects
- ☑ Subjects between 18 and 60 years old
- ☑ Healthy subjects
- ☑ Subjects informed about test purposes

Non- inclusion criteria

- ✘ Subjects who do not fit the inclusion criteria
- ✘ Pregnant or breastfeeding women
- ✘ Subjects with marks (for example tattoos, scars, burns) in the tested skin region, which might interfere with clinical evaluation
- ✘ Subjects with dermatological problems in the test area
- ✘ Subjects with medication which may affect skin response
- ✘ Subjects undergoing pharmacological treatment (both locally or systemically)
- ✘ Subjects with past history for contact dermatitis
- ✘ Positive anamnesis for atopy

Withdrawal criteria

Participants are withdrawn if

- ✘ They do not follow the conditions of the Study Information Sheet that they receive after the recruitment
- ✘ They suffer any illness or accident or develop any condition during the study which could affect the out come of the study
- ✘ They no longer wish to participate in the study.

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Behavior of volunteers during the test
Through patch application and 24 hours after patch removal volunteers must avoid situations or activity that could interfere with clinical evaluations:

- Exposition to sun or solarium
- Sport
- Immersion in water or steam bath
- Chafing and mechanical or thermal stress in the area in which patch is/has been applied.

Materials and Methods

Tested product and concentration

name……..FABRIC SAMPLE "8"
sponsor……..HEIQ MATERIALS AG
concentration……..as it is
application method……occlusive

Sample preparation and application

The skin area involved in the product application (dorsal) is cleaned with a 70% alcoholic solution to make it more sensitive to product application. The non-woven fabric is applied as it is by using the Finn Chamber, a 8 mm diameter aluminium disk. The fabric was cut and placed in the Finn Chamber. The Finn Chamber is fixed to the skin with a tape already been tested for its safety that ensure the occlusive application of the product.
Applied quantity is sufficient to saturate the pad without overflowing from it when applied on the skin. The product is left in contact with the skin surface for 48 hours. The cutaneous reactions are analysed 15 minutes, one hour and 24 hours after Finn Chamber removal. A Finn Chamber containing a blotting paper disk soaked with distilled water is applied and used as a negative control.

Clinical examination and scoring

Skin reactions are evaluated 15 minutes, 1 hour and 24 hours after patch removal according to the scores reported in table 1, that describes the severity of erythema, oedema or other types of skin irritation. The results are collected in a table and represented graphically. For each experimental time Mean Irritation Index (IIM) is calculated by adding erythema mean value and oedema mean value. The tested product is then classified following table 2 which is based on the Mean Irritation Index.

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Table 1 - *Clinical score of skin reactions*

No erythema	0
Light erythema (hardly visible)	1
Clearly visible erythema	2
Moderate erythema	3
Serious erythema (dark red with possible formation of light scars)	4

No oedema	0
Very Light oedema	1
Light oedema	2
Moderate oedema (about 1 mm raised skin)	3
Strong oedema (extended swelling even beyond the application area)	4

Table 2 - *Classification of the medium irritation index (according to the amended Draize classification).*

Mean Irritation Index (IIM)	**Product classification**
< 0,5	non irritating
from 0.5 to 2.0	slightly irritating
from 2.0 to 5.0	moderately irritating
from 5.0 to 8.0	highly irritating

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RESULTS

Summary of the data obtained and evaluation of the product irritation potential

OEDEMA AND ERYTHEMA REACTIONS

Panellist name	Sex	ERYTHEMA 15'	OEDEMA 15'	ERYTHEMA 1h	OEDEMA 1h	ERYTHEMA 24h	OEDEMA 24h
1 D046G	M	0	0	0	0	0	0
2 D004G	F	0	0	0	0	0	0
3 G032T	F	0	0	0	0	0	0
4 P093C	F	0	0	0	0	0	0
5 S030E	F	0	0	0	0	0	0
6 D041L	F	0	0	0	0	0	0
7 S093S	M	0	0	0	0	0	0
8 L025G	M	0	0	0	0	0	0
9 L109C	F	0	0	0	0	0	0
10 P090D	M	0	0	0	0	0	0

MEAN VALUES FOR OEDEMA AND ERYTHEMA

IIM Er 15'	IIM Ed 15'	IIM Er 1h	IIM Ed 1h	IIM Er 24h	IIM Ed 24h
0,00	0,00	0,00	0,00	0,00	0,00

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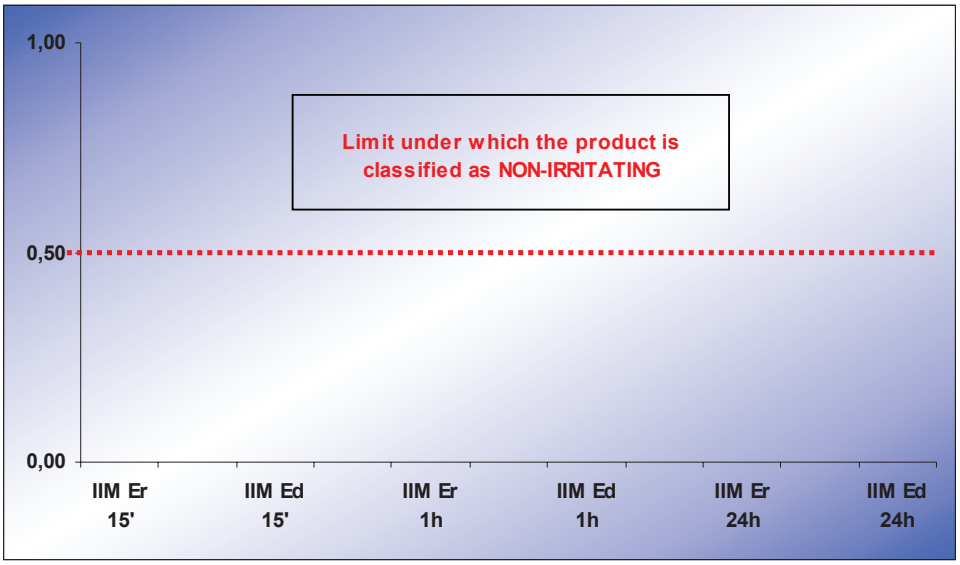

IRRITATION INDEX MEAN VALUES

IIM 15'	IIM 1h	IIM 24h
0,00	0,00	0,00

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CONCLUSIONS

The table and the graphs listed above contain the values of the erythema and oedema indices recorded for each of the 10 volunteers. Potential skin irritation of the product has been assessed according to the amended Draize classification.

On the basis of the data obtained we deem the non woven fabric:

HEIQ MATERIALS AG

FABRIC SAMPLE“8”

NON IRRITATING

“DERMATOLOGICALLY TESTED”

S.Martino Siccomario – 30th September 2011

Experimenter

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Quality control

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Scientific supervisor

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