

# REPORT ON A HUMAN PATCH TEST

## 48 hours closed patch test under Occlusion

Skin test to evaluate potential skin irritation after contact with a cosmetic product

**MEDIMEX**

**SQ2 SKIN**

**COMPLIFE Italia S.r.l.**

[info@complifegroup.com](mailto:info@complifegroup.com)  
[complifeitalia@legalmail.it](mailto:complifeitalia@legalmail.it)  
[complifegroup.com](http://complifegroup.com)

GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 | +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 | +39.0382.25504



Customer	<b>MEDIMEX</b>
Record no	<b>H.S.HU.MP.NTC00.010.00.00_IT0003182/20</b>
Date	<b>10/11/2020</b>

## INDEX

<b>KEY PERSONNEL</b> .....	<b>3</b>
<b>STUDY DESIGN</b> .....	<b>4</b>
Title .....	4
Aim of the study .....	4
Tested Product .....	4
Ethical requirements .....	5
Subjects selection .....	5
Materials and Methods .....	6
<b>RESULTS</b> .....	<b>8</b>
<b>CONCLUSIONS</b> .....	<b>10</b>
<b>BIBLIOGRAPHY</b> .....	<b>11</b>

### COMPLIFE Italia S.r.l.

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

Sede legale: Via Guido Rossa, 1 20024 Garbagnate M.se (MI) Italy, I.P.I./C.F. 11093320155  
Capitale Sociale € 161.834 i.v., C.C.I.A.A. MI 1437929 - Registro Società N. 342215  
Centro di Saggio operante in BPL - Sistema di gestione qualità certificato ISO 9001  
Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N 030015309008)  
Laboratorio di Prova Accreditato ACCREDIA LAB N 1318L (UNI CEI EN ISO/IEC 17025:2018)  
L'elenco delle prove accreditate è consultabile su [www.accredia.it](http://www.accredia.it)



Customer	<b>MEDIMEX</b>
Record no	<b>H.S.HU.MP.NTC00.010.00.00_IT0003182/20</b>
Date	<b>10/11/2020</b>

## KEY PERSONNEL

### Customer

**MEDIMEX**  
1 Allée Alban Vistel  
69110 Sainte-Foy-lès-Lyon  
France

### Experimenter

**Dr. Enza Cestone**  
Degree in Medicine and Surgery, Specialist in Dermatology and Venereology  
Consultant Complife Italia S.r.l.

### Analisi dati e Report / Data analysis and Report

**Dr. Cristina Scilironi**  
Biologist  
Complife Italia S.r.l.

### Complife Italia Srl

Location  
Via Angelini, 21  
27028 San Martino Siccomario (PV)  
Italy  
tel. +39-0382 25504 - fax +39-0382 536006  
Mail: [info@complifegroup.com](mailto:info@complifegroup.com)

### COMPLIFE Italia S.r.l.

[info@complifegroup.com](mailto:info@complifegroup.com)  
[complifeitalia@legalmail.it](mailto:complifeitalia@legalmail.it)  
[complifegroup.com](http://complifegroup.com)

GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504



Customer	<b>MEDIMEX</b>
Record no	<b>H.S.HU.MP.NTC00.010.00.00_IT0003182/20</b>
Date	<b>10/11/2020</b>

## RESUME PATCH TEST

L'objet de l'étude est l'évaluation de la tolérance cutané d'un produit cosmétique sur volontaires humains.

Le principe du test est le suivant :

- Application occlusive du produit dans le dos de 10 volontaires.
- 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.

**MEDIMEX**  
**SQ2 SKIN**

**NON IRRITANT**

## STUDY DESIGN

### Title

REPORT ON A HUMAN PATCH TEST

Skin test to evaluate potential skin irritation after contact with a cosmetic product.

### Aim of the study

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

### Tested Product

#### Information provided by the Customer

- Product name:

**SQ2 SKIN**

The tested cosmetic product conforms to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) and to its annexes.

- Qualitative INCI formula:  
filed

### COMPLIFE Italia S.r.l.

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504



Customer	<b>MEDIMEX</b>
Record no	<b>H.S.HU.MP.NTC00.010.00.00_IT0003182/20</b>
Date	<b>10/11/2020</b>

## 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.

## Subjects selection

### Volunteers recruitment

10 volunteers were recruited to take a part in the test in accordance with the following inclusion and non inclusion criteria:

#### Inclusion criteria

- Male and female subjects
- Subjects between 18 and 70 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 that may affect skin response
- Subjects undergoing pharmacological treatment (both locally or systemically)
- Subjects with 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.

## COMPLIFE Italia S.r.l.

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504



Customer	<b>MEDIMEX</b>
Record no	<b>H.S.HU.MP.NTC00.010.00.00_IT0003182/20</b>
Date	<b>10/11/2020</b>

### Behaviour 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 activity
- ✗ 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	SQ2 SKIN
Sponsor	MEDIMEX
Study start (first enrolment date)	26/10/2020
Study end (last evaluation date)	29/10/2020
Concentration	as it is
Application method	Occlusive

#### Sample preparation and application

The product is applied as it is by using the Finn Chamber, an 8 mm diameter aluminium disk containing a blotting paper disk soaked with the sample to be tested.

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 demineralized water is applied and used as a negative control.

#### Clinical examination and scoring

Skin reactions are evaluated at 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.

### COMPLIFE Italia S.r.l.

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504



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
Light oedema (hardly visible)	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
$0.5 \leq \text{IIM} < 2.0$	slightly irritating
$2.0 \leq \text{IIM} < 5.0$	moderately irritating
$5.0 \leq \text{IIM} \leq 8.0$	highly irritating

**COMPLIFE Italia S.r.l.**

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504



## RESULTS

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

### OEDEMA AND ERYTHEMA REACTIONS

ID Vol	Sex	ERYTHEMA 15'	OEDEMA 15'	ERYTHEMA 1h	OEDEMA 1h	ERYTHEMA 24h	OEDEMA 24h
1 A2112L	F	0	0	0	0	0	0
2 B4523A	F	0	0	0	0	0	0
3 C4222V	F	0	0	0	0	0	0
4 F3716A	F	0	0	0	0	0	0
5 M3265G	F	0	0	0	0	0	0
6 P2126A	F	0	0	0	0	0	0
7 P4226C	F	0	0	0	0	0	0
8 V1341A	F	1	0	1	0	1	0
9 Y4276N	F	0	0	0	0	0	0
10 Y4277V	F	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
0,10	0,00	0,10	0,00	0,10	0,00

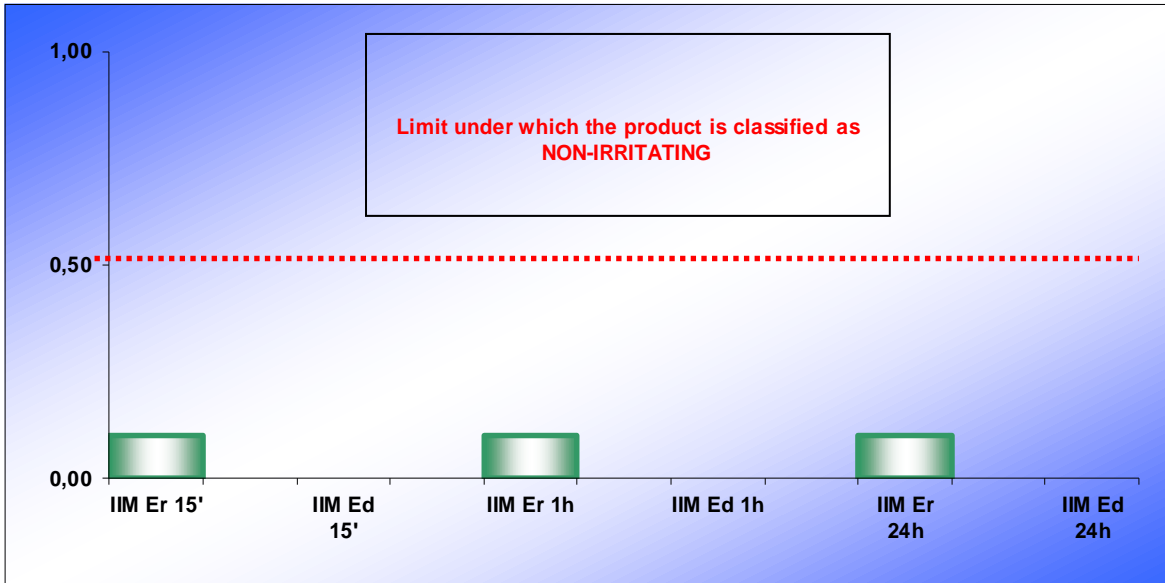
#### COMPLIFE Italia S.r.l.

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504







**IRRITATION INDEX MEAN VALUES**

IIM 15'	IIM 1h	IIM 24h
0,10	0,10	0,10

**COMPLIFE Italia S.r.l.**

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504



Customer	<b>MEDIMEX</b>
Record no	<b>H.S.HU.MP.NTC00.010.00.00_IT0003182/20</b>
Date	<b>10/11/2020</b>

## CONCLUSIONS

The table and the graphs listed above contain the values of the erythema and oedema indices recorded for each volunteer. 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 product:

**MEDIMEX**

**SQ2 SKIN**

**NON IRRITATING**

**“DERMATOLOGICALLY TESTED”**

### Report change record

The table here below reports the change log of all approved changes made to the document that make up the course after initial approval.

Rev. no	Date	Description
0	10/11/2020	First release

**Experimenter**

**Dr. Enza Cestone**

**Data Analysis and Report**

**Dr. Cristina Scilironi**

### COMPLIFE Italia S.r.l.

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504



Customer	<b>MEDIMEX</b>
Record no	<b>H.S.HU.MP.NTC00.010.00.00_IT0003182/20</b>
Date	<b>10/11/2020</b>

## BIBLIOGRAPHY

Berger, R.S., and J.P. Bowman, 1982, "A Reappraisal of the 21-day Cumulative Irritation Test in Man," *J. Toxicol. - Ot. & Ocular Toxicol.*, 1(2);109-115.

Holdiness, M.R., 1989, "A Review of Contact Dermatitis Associated with Transdermal Therapeutic Systems," *Contact Dermatitis*, 20(1);3-9.

Lanman, B.M., E.B. Elvers, and C.J. Howard, 1968, "The Role of Human Patch Testing in a Product Development Program," Joint Conference on Cosmetic Sciences, The Toilet Goods Association (currently, the Cosmetic, Toiletry and Fragrance Association), Washington, D.C., April 21-23, 1968.

Patel, S.M., E. Patrick, and H.I. Maibach, 1976, "Animal, Human, and In Vitro Test Methods for Predicting Skin Irritation," *Dermatotoxicology*, Chpt. 33, 5th Ed., Eds. F.N. Marzulli, H.I. Maibach, Taylor, and Frances.

- 
- The result of the study reported in this document is only referred to the tested sample and the specific experimental conditions.
  - Any part of this report can only be reproduced with the consent of Complife Italia S.r.l.
  - A copy of this report is kept on file at Complife Italia S.r.l.
  - Both the informed consent and the information forms are kept on file at Complife Italia S.r.l. for 10 years after the date of issue of the report.

### COMPLIFE Italia S.r.l.

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

