LABORATORIO DE INVESTIGACIÓN Y ANÁLISIS

Avda del Carrilet 353 · 1ª planta
08907 L'Hospitalet de Llobregat · Barcelona
Tel 93 260 01 84
limsalab@limsalab.com
www.limsalab.com

Nº INF: 17_006452-25517004

REPORT FROM DERMATOLOGICAL RESEARCH

Patch Test (Normal skin)

VERIFICATION OF THE COMPATIBILITY WITH SKIN, AFTER 48 HOURS OF APPLICATION WITH OCCLUSIVE PATCH IN THE BACK OF ADULTS SUBJECTS.

Product:

Single use soapy sponge

Submitted by:

C.V. Médica S.L.

C/Ponent, 1 (P.I. La Plana)
43424 Sarral, Tarragona

SUBJECT OF TEST:	:	Single use soapy sponge (BATCH 170209)
LIMSA REFERENCE	:	17_006452
REPORT	:	17_0006452-25517004
TEST START	:	JUNE 06TH 2017
TEST END	:	JUNE 08TH 2017

LABORATORIO DE INVESTIGACIÓN Y ANÁLISIS
Avda del Carrilet 353 · 1ª planta
08907 L'Hospitalet de Llobregat · Barcelona
Tel 93 260 01 84
limsalab@limsalab.com
www.limsalab.com

Nº INF: 17_006452-25517004

PROTOCOL

Aim of the test	Checking the good cutaneous compatibility (absence of primary cutaneous irritation), after one application of the studied product for 48 hours, followed by a macrocospic examination realized according to a numerical established scale.
Test type	Occlusive patch test
Preliminary data	-INCI of the product. -Microbiological results. The customer is responsible for compliance with the declared qualitative composition of the product.
Inclusion criteria for volunteers	-Subjects: 13 -Sex: male or female -Age: 18 to 70 years -All type of skin (7 resistent, 6 sensitive) -Negative history of allergy. -Without lesions in the application spot. - Signed an informed consent form for the test, were advised of their purpose, methodology and possible adverse effects.
Methodology	**1)Application of the product:** - Zone: upper back. - Under the supervision of a dermatologist, 20 mg of product is applied to the patch and fixed to the upper back by means of an adhesive patch. A blank test is performed in parallel with a patch without product. - Duration and frequency: 1 application, patch removed after 48 h. **2)Clinical observations**: -Patches are removed and the skin checked by a dermatologist 15-30 minutes later. - Verification by volunteers of absence of reaction 24 hours later. In case of visible reaction the subject must return to be evaluated.
Analysis of the results and interpretation	-**Quantification of the cutaneous irritation: Primary Skin Irritation Index (P.S.I.)**, according to a numerical established scale based on the presence of erythema or edema in the skin (See Appendix table 1) **Interpretation of the results:** **-** The product is classified according to the PSI-class table (see Appendix table 2), on the basis of P.S.I obtained in the Evaluation.

LABORATORIO DE INVESTIGACIÓN Y ANÁLISIS
Avda del Carrilet 353 · 1ª planta
08907 L'Hospitalet de Llobregat · Barcelona
Tel 93 260 01 84
limsalab@limsalab.com
www.limsalab.com

Nº INF: 17_006452-25517004

RESULTS AND CONCLUSION

STUDIED POPULATION

Subjects recruited	13
Subjects that have come	13
Subjects included by the Dermatologist	13
Subjects that left during the study	0
Subjects for the analysis of the results	13

RESULTS

	Volunteers		***Application***	***After 48 hours***	
VOL. Nº	***AGE***	***SEX***	***spot***	***ERITEMA***	***EDEMA***
01	61	Female	Upper back	0	0
02	50	Female	Upper back	0	0
03	50	Female	Upper back	0	0
04	60	Female	Upper back	0	0
05	34	Female	Upper back	0	0
06	52	Female	Upper back	0	0
07	48	Female	Upper back	0	0
08	60	Female	Upper back	0	0
09	54	Female	Upper back	0	0
10	53	Female	Upper back	0	0
11	52	Female	Upper back	0	0
12	46	Male	Upper back	0	0
13	51	Female	Upper back	0	0

P.S.I.	0	0
TOTAL P.S.I.	0	

It has to be noted that the test results may be influenced by factors like lifestyle, stress, diet, environmental conditions, etc

The final P.S.I is: **0.00**

LABORATORIO DE INVESTIGACIÓN Y ANÁLISIS
Avda del Carrilet 353 · 1ª planta
08907 L'Hospitalet de Llobregat · Barcelona
Tel 93 260 01 84
limsalab@limsalab.com
www.limsalab.com

CONCLUSION

The patch test concludes that the product **SINGLE USE SOAPY SPONGE (batch 170209)** used by subjects without allergy to any of its components is well tolerated by the skin as no irritation or allergic reactions were documented in volunteers.

Based on the results obtained with the methodology adopted, **SINGLE USE SOAPY SPONGE (batch 170209)** meets the requirements of the skin compatibility test, and can be classified as **NON-IRRITANT.**

L'Hospitalet de Llobregat (Barcelona) JUNE 12th, 2017.

Revised by: Jose Manuel Carrión Chemical technician	Approved by: Carles Gannau Cases Technical Director	LABORATORIO DE INVESTIGACIÓN Y ANÁLISIS

LABORATORIO DE INVESTIGACIÓN Y ANÁLISIS
Avda del Carrilet 353 · 1ª planta
08907 L'Hospitalet de Llobregat · Barcelona
Tel 93 260 01 84
limsalab@limsalab.com
www.limsalab.com

APPENDIX

Table 1

ERYTHEMA
0: No erythema
0,5: Light erythema
1: Erithema and/or papules
2: Erithema and/or papules, and/or vesicles
3: Erithema and/or papules, and/or vesicles, and or blisters
4: Erithema, Bullous and/or ulcerative reaction, and/or papules, and/or vesicles, and or blisters

EDEMA
0: No edema
1: Very slightly edema, hardly visible.
2: Light edema
3: Moderate edema (about 1 mm raised skin)
4: Strong edema (extended swelling even beyond the application area)

Table 2

PSI	Class
<0.5	Not irritant
0.5 ≤ PSI <2	Slightly irritant
2 ≤ PSI < 5	Moderately irritant
≥5	Highly irritant