Coronati lab

Consulenza di Laboratorio per la Qualità Biomedicale

SENSITIZATION TEST ON GUINEA PIG

(DELAYED CONTACT HYPERSENSITIVITY – BUEHLER TEST METHOD)

"Soletta con lamina in lega"

According to
ISO 10993-10

REPORT N. 149-12

Customer:

MACROLAB S.r.l. per conto di MEDIKA s.r.l.
Via Lea Cazzuoli, 15 - 41037 Mirandola (MO)

TIME SCHEDULE

Acceptance N.	11-3180
Samples receiving date:	07/12/11
Start test date:	27/12/11
End test date:	25/01/12

TEST LABORATORY
Coronati Consulting Sas via L. Gavioli, 3 I-41037 Mirandola (MO)

The test has been commissioned to:
Eurofins Biolab S.r.l. (MI) Italy

Mirandola	*Prepared by:* Dr. ssa C. Pellegrini	*Verified and apporoved by:* Dr. R. Coronati
26-01-12		

Coronati Consulting sas -Tel. 0535-611533 Fax 0535-410441- E-mail: info@coronaticonsulting.it Web: www.coronaticonsulting.it

REFERENCE DOCUMENTS

- UNI EN ISO 10993-1:2010 "Biological evaluation of medical devices: Evaluation and testing"
- UNI EN ISO 10993-2:2006 "Animal welfare requirements"
- UNI EN ISO 10993-10:2009 "Tests for irritation and sensitization"
- UNI EN ISO 10993-12:2009 "Sample preparation and reference materials"

SAMPLE

Sample:	Soletta con lamina in lega
Code:	Taglia 40
Article:	N.d.
Lot:	N.d.Campione 2011
Manufacturing date:	N.d.
Expiry date:	N.d
Sterilization method:	N.d.
Sterilization lot:	N.d.

TEST METHOD

Characterisation

Species: Albino guinea pigs
Strain Hartley
N. 15
Sex: Female Weight: 300-400 g at the arrival at the centre
Supplier: Bettinardi-Momo (Mo)

Caging

The animal were caged, in group of ten, in transparent polycarbonate cages (dimensions: 590×385×200H mm). Stabling rooms have been lighted with fluorescent lamps and kept with cycles of 12 hours of light and 12 hours of darkness. Temperature and humidity, controlled by air conditioning system, have been continuously registered.

Cleaning and disinfection

The cages and the housing room were cleaned before the animals were accommodated, then disinfected periodically.

Feeding

Animals have been fed with standard pellet complete diet supplied by the authorised breeder Harlan Italy.

Watering

Filtered tap water from local network was supplied ad libitum from an automatic watering system.

Quarantine

Before allocation to the study, the animals were kept in quarantine for five days. During this period they were observed daily.
At the end of the quarantine week the animals were carefully examined in order to evaluate their suitability for the study.

PREPARATION FOR THE ASSAY STUDY

The test product has been used neat for all test phases.

EXPERIMENTAL DESIGN

Experimental design consisted of one group of 10 treated animals and one group of control animals. The animals were allocated into groups as follows:

GROUP	INDUCTION PHASE DAY 0, 1,2 DAY 7, 8,9 DAY 14, 15, 16	CHALLENGE PHASE Day 28
1	Test product	Test product
2	WFI	Test product

The animals allocated to the study were selected randomly from those suitable, available at that time.
At maximum 5 animals for each cage; cages have been identified via a tag.

TREATMENT

Skin preparation

24 hours before testing, fur was removed by shaving a 50 cm2 wide area on the back of the animals.

Administration

The test sample was used neat.
25×25 mm of the test sample were applied directly on back of the animals made humidify with sodium chloride injection.

Induction phase

The test sample was administered by topical application to the clipped left upper back region of each animal. Each side was covered by an occlusive dressing.
The dressing was removed after 6 h.
This procedure was performed on three days a week for three weeks.
The control animals were treated using WFI in the same way.

Challenge phase

Fourteen days after the last induction application, all test and control animals were challenged with the test sample.
The test sample was administered by a single topical application to a clipped untested area of each animal.
Each side was covered by an occlusive dressing.
The dressing was removed after 6 h.

OBSERVATIONS

24 hours after removal the patch, and 48 hours after removal the patch all the animals treated and controlled were evaluated for a skin reaction.
The intensity of erithema and/or edema were evaluated according to the follow scale:

PATCH TEST REACTION	*GRADING SCALE*
No visible change	**0**
Discrete o pacthy erythema	**1**
Moderate and confluent erythema	**2**
Intense erythema and swelling	**3**

INTERPRETATION OF RESULTS

Magnusson and kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals. If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.
If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.
The outcome of the test is presented as the frequency of positive challenge results in the test and control animals.

RESULTS

Animals treated with the sample extract			Animals treated with Negative control		
Animals	Reaction at 24 h	Reaction at 48 h	Animals	Reaction at 24 h	Reaction at 48 h
	Erythema	Erythema		Erythema	Erythema
1	0	0	1	0	0
2	0	0	2	0	0
3	0	0	3	0	0
4	0	0	4	0	0
5	0	0	5	0	0
6	0	0	-	-	-
7	0	0	-	-	-
8	0	0	-	-	-
9	0	0	-	-	-
10	0	0	-	-	-

No abnormalities were observed in treated and control animals.

% sensitising guinea pigs treated: 0%

DEVIATIONS

No deviation has been detected during the study.

CONCLUSIONS

On the basis of the results, interpreted according to ISO 10993-10:2010, the product "SOLETTA CON LAMINA IN LEGA" must be considered **NON SENSITIZING**.

⇒ *The present test report refers only to the samples examined.*