BIOSERV
ANALYTIK UND
MEDIZINPRODUKTE GMBH

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HRB 8996, Amtsgericht Rostock
USt-IdNr. DE 813328752
Steuer-Nr.: 07910604745

Geschäftsführer:
Dr. sc. Udo Meyer

Rostock,
21.01.2021

Study Report

Changed Certificate Version (1)	replaces the original study report from 12.01.2021; Supplement Designation Test material
Test material	**PRO/20/09128** Prod. Date: 14-09-2020; Reference: FRESH
Sample no.	2020121379
Sampling by	Client
Arrival	23.12.2020 12:43:00
Quantity (delivered)	1 piece(s)
Packaging	Transport packaging, no declaration
Start of investigation	23.12.2020
End of investigation	21.01.2021
Sample preparation	Under laminar flow, autoclaved
Method	See attachment

Test Criterion	Exper. Test-Start/ End	Result	Unit
Skin Irritation (DIN EN ISO 10993-10:2014-10)	05.01.2021	fulfilled	
4-09-SOP-11-128	08.01.2021		

End of test results

Evaluation

The test material did not cause skin irritation (P.I.I.= 0.0) under selected test conditions.

21.01.2021

B. Grümmer
Study Director

R. Koslowski 21.01.2021
R. Koslowski
Quality Assurance

Archival storage: A copy of this study report is stored together with the documents of the study in the archive of BIOSERV.
The test and measurement results specified above refer exclusively to the test material as received.

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Attachment to study report 2020121379

Skin Irritation (DIN EN ISO 10993-10:2014-10)

Contents

1 Material and Methods

1.1 Test material

PRO/20/09128; Prod. Date: 14-09-2020; Reference: FRESH

The test material was packed and sent by the client. The test material was sterilized by autoclaving.

The test procedure was performed without extraction of the test material because the test material has an appropriate physical state for direct application and is intended to be used directly on the skin of the patient. (DIN EN ISO 10993-10:2014-10, Annex A.2.)

1.2 Animals and husbandry

Healthy, young adult albino rabbits of female sex with a body weight not less than 2 kg were used (Kaninchenbetrieb Palleit). The animals were nulliparous and non-pregnant. This animal species was used since it is suitable for the test and recommended by DIN EN ISO 10993-10:2014-10.

The rabbits were kept in their cages (single-caged) for at least 5 days prior to test start to allow for acclimatisation to the laboratory conditions.

The animals were permanently controlled by veterinarians according to DIN EN ISO 10993-2:2006-10. They were immunized against Myxomatosis and RHD.

Keeping of animals:

- Temperature: 15°C – 21°C
- Tap water (drinking quality) ad libitum
- Common diet (pellets, sniff Spezialdiäten, Germany) ad libitum
- 12 h light/dark cyclus

1.3 Test procedure

The fur on the backs of three rabbits was closely clipped on both sides of the spinal column (10 cm x 15 cm) 20 hours before the test procedure started. Only animals with healthy intact skin were used.

The test material was applied directly to the clipped skin of the rabbits, together with control gauze patches (25 mm x 25 mm).

Location of skin application sites: see figure 1 of DIN EN ISO 10993-10:2014-10.

The application sites were covered with a non-occlusive gauze patch and wrapped with an occlusive bandage for 4 hours.

At the end of the contact time the dressings were removed and the residual substances were detached.

The application sites were observed (1±0.1) h after removal of the gauzes and after (24±2), (48±2) and (72±2) hours. The skin reaction was described and scored in the following manner:

Reaction	Numerical Grading
Erythema and eschar formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderated erythema	3
Severe erythema (beet-redness) to slight eschar formation	4
Edema formation	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well defined by definite raising)	2
Moderated edema (raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond exposure area)	4
Total possible score for irritation	8

The Primary Irritation Index (P.I.I.) was determined in the following manner:

After the 72 h grading, all erythema grades plus edema grades (24 ± 2) h, (48 ± 2) h and (72 ± 2) h were totalled separately for each test sample and blank for each animal. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).

To obtain the primary irritation index for the test sample all the primary irritation scores of the individual animals were added and divided by the number of animals.

The primary irritation score of the negative control (vehicle) was subtracted from the score of the test material to obtain the primary irritation score.

The primary irritation response in rabbits is categorized as follows:

Response Category	Mean Score (P.I.I.)
Negligible	0.0 - 0.4
Slight	0.5 - 1.9
Moderate	2.0 - 4.9
Severe	5.0 - 8.0

2 Test Results

Symptoms observed: 3 rabbits

Test material in contrast to control

	Symptoms observed after (Numerical Grading)			
Animal	**24h**	**48h**	**72h**	**P.I.I.**
2020-89	0	0	0	0
2020-90	0	0	0	0
2020-91	0	0	0	0
Score P.I.I.:				**0.0**

3 Assessment

The test material did not cause any irritation of skin after the application time of 4 hours in the course of the observation period of 72 h (P.I.I. - 0.0).

21.01.2021