



Test Report

Toxicity testing of a material extract, Cytotoxicity Test

Test report number: ISO 201412-01589A_engl

commissioned by:

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Test material:

Jan 16th 2015

SANMED, PU coated PES knitted fabric Lot no 2014/01487/A for use as waterproof mattress covers, berths and on operating and rehabilitation tables

Test material received: Dec 23rd 2014

Test performed: Jan 09th 2015

Result: The SANMED, PU coated PES knitted fabric Lot no 2014/01487/A didn't cause a cytotoxic effect.

Description of the test procedure:

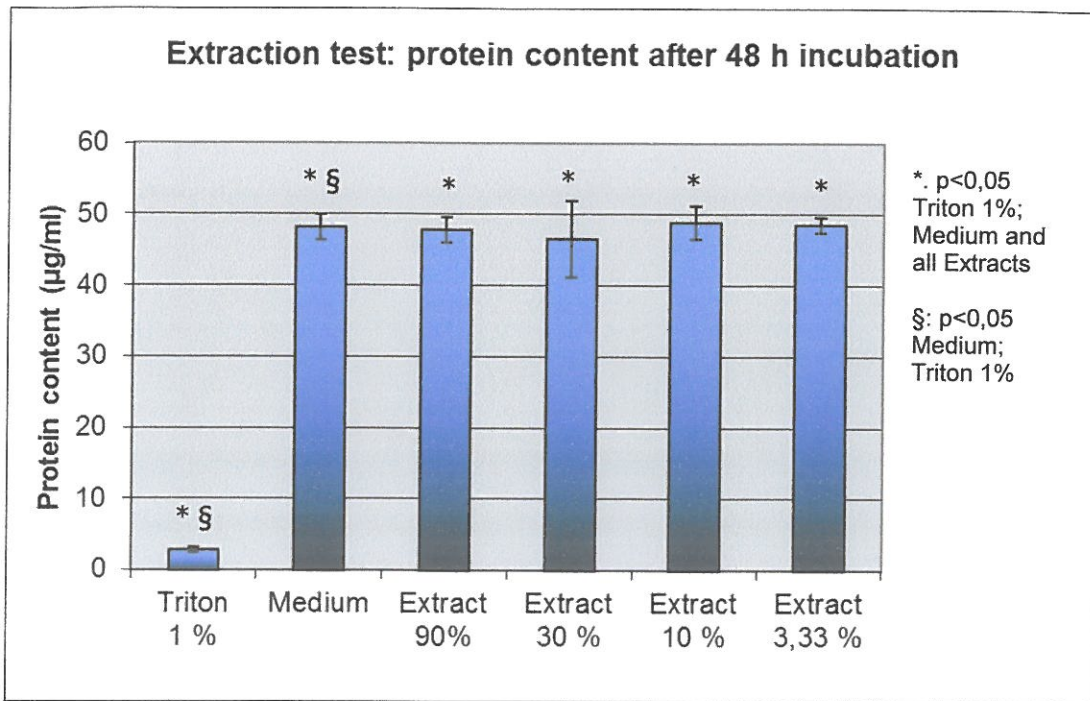
Normative References: ISO 10993-5 (2009); ISO 10993-12 (2012)

The material was extracted for 24 h at 37°C and a partial pressure of 5 % carbon dioxide in extraction medium (DMEM medium with antibiotics, without fetal calf serum [FCS]). According to ISO 10993-12 (2012) the material/extraction volume ratio was 0,1 g/ml extraction medium. After extraction the extraction medium was sterile filtered and supplemented with sterile FCS (concentration of FCS in extraction medium: 10 %). The FCS-supplemented extraction medium was pipetted under sterile conditions on precultivated cells of the mouse fibroblastic cell line L929 and incubated for 48 h at 37°C and a partial pressure of 5 % carbon dioxide. The extract was tested in four dilutions (90 %, 30 %, 10 % and 3,3 %). Each dilution was tested in four parallel experiments.

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Triton X 100 was used as a toxic control substance (concentration in the experiment: 1 % v/v). Cell culture medium was used as a non-toxic control. After the 48 h incubation period the protein content of the cell culture was determined by the method according to Bradford.

Results:



Result data	Protein content n=4					
	Triton 1 %	Culture medium	Extract 90 %	Extract 30 %	Extract 10 %	Extract 3,3 %
µg/ml						
Mean	2,76	48,24	47,87	46,62	48,89	48,48
Standarddev.	0,33	1,79	1,84	5,40	2,28	1,08

In the presence of Triton X 100 in the cell culture medium 5,7 % of the protein content compared to the negative control was reached. This value is within the valid range of 15 % protein content or less compared to the negative control.

Materials are considered cytotoxic, if the material extract leads to a protein content of the test cells of less than 70 % compared to the negative control. This was not the case in this test.

Result: The SANMED, PU coated PES knitted fabric Lot no 2014/01487/A didn't cause a cytotoxic effect.

Explanatory notes:

none

Test performed by: *Dieter Scheddin*

authorized by: *Dieter Scheddin*
(Dr. D. Scheddin / CEO CYTOX)

It is not allowed to publish only parts of this test report without written approval of CYTOX.