

Test Report

Toxicity testing of a material extract

Test report number: ISO 200407-00289A_engl

commissioned by:

smartfiber AG

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CYTOX

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Test material:

Aug 14th 04

-fiber sample No. 04 07 171

Test material received: Jul 23rd 04

Test performed: Aug 10th 04

Result: The fiber sample No. 04 07 171 didn't cause a cytotoxic effect.



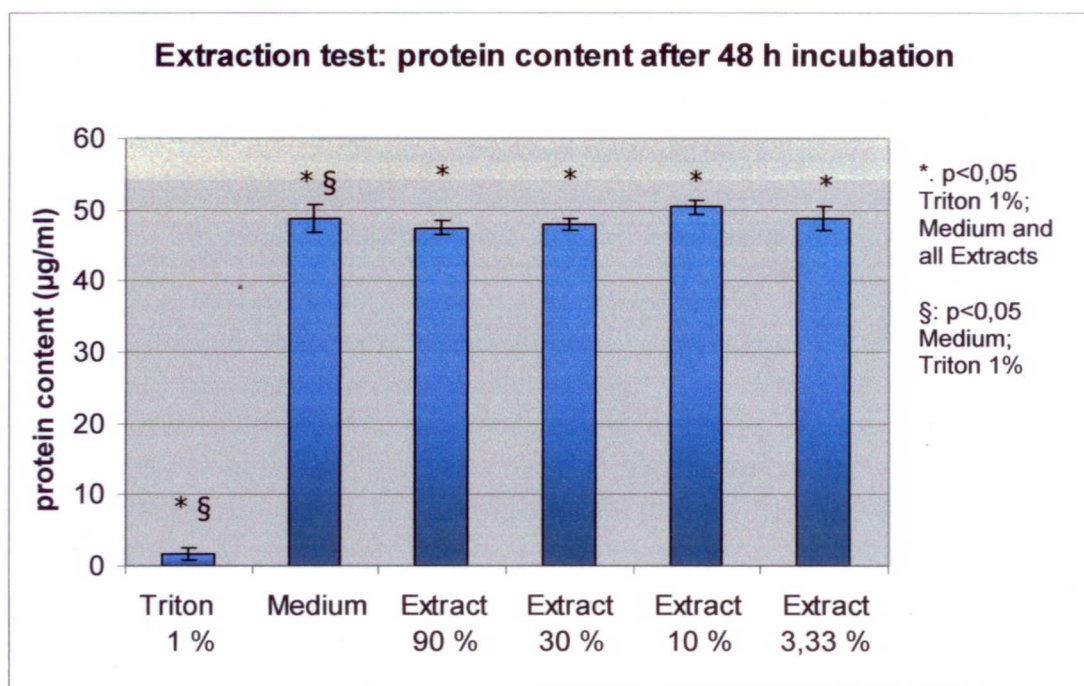
Description of the test procedure:

Normative Reference: ISO 10993-5 (1999), EN 30993-5 (1994)

The material was extracted for 48 h at 37°C and a partial pressure of 5 % carbon dioxide in extraction medium (DMEM medium with antibiotics, without fetal calf serum [FCS]). The material surface/extraction volume ratio was 2 cm² per 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.

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	1,62	48,83	47,48	48,01	50,34	48,89
Standarddev.	0,82	1,91	1,03	0,89	0,97	1,70

In the presence of Triton X 100 in the cell culture medium 3,3 % of the protein content compared to the negative control was reached. This value is within the valid range of 35 % 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 81 % compared to the negative control. This was not case in this test.

Result: The fiber sample No. 04 07 171 didn't cause a cytotoxic effect.

Explanatory notes:

none

Test performed by:

Dietrich Scheddin

authorized by:

Dietrich Scheddin
(Dr. D. Scheddin / CEO CYTOX)

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