

Test Report

Toxicity testing of a material extract, Cytotoxicity Test

Test report number: ISO 201506-01698_engl

commissioned by:

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Test material:

Jul 20th 2017

EVA-plastic „EVA SPEZIAL SANDWICH®“

Test material received: Jun 09th 2017

Test performed: Jul 06th 2017

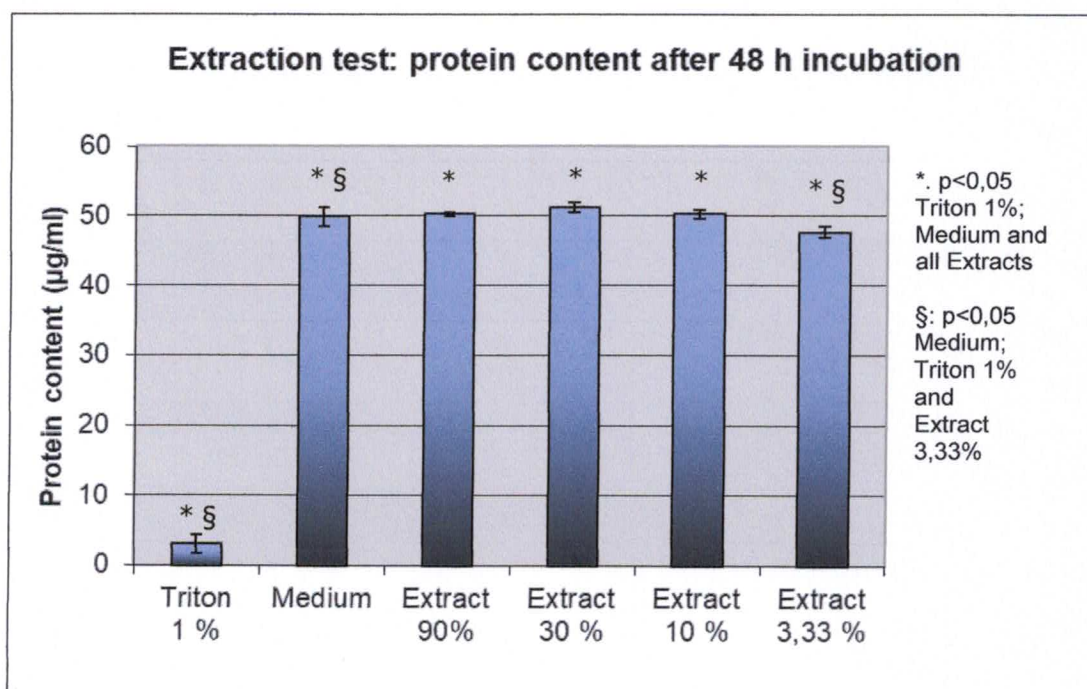
**Result: The EVA-plastic „EVA SPEZIAL SANDWICH®“
did not cause a cytotoxic effect.**

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]). The material /extraction volume ratio was 0,2 g/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	3,12	49,91	50,28	51,27	50,28	47,70
Standarddev.	1,33	1,30	0,33	0,74	0,57	0,81

In the presence of Triton X 100 in the cell culture medium 6,3 % 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. The material did not cause a cytotoxic effect.

Result: **The EVA-plastic „EVA SPEZIAL SANDWICH®“
did not cause a cytotoxic effect.**

Explanatory notes:

none

Test performed by: Dr. D. Scheddin

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

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