



Test Report

Toxicity testing of a material extract

Test report number: ISO 201011-01047B_engl

commissioned by:

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Test material:

Jan 20th 2011

Polyurethane clear lacquer Legnopur 26211 with 10 % PUR hardener 82019, brushed onto glass (120 g/m²)

Test material received: Dec 23rd 2010

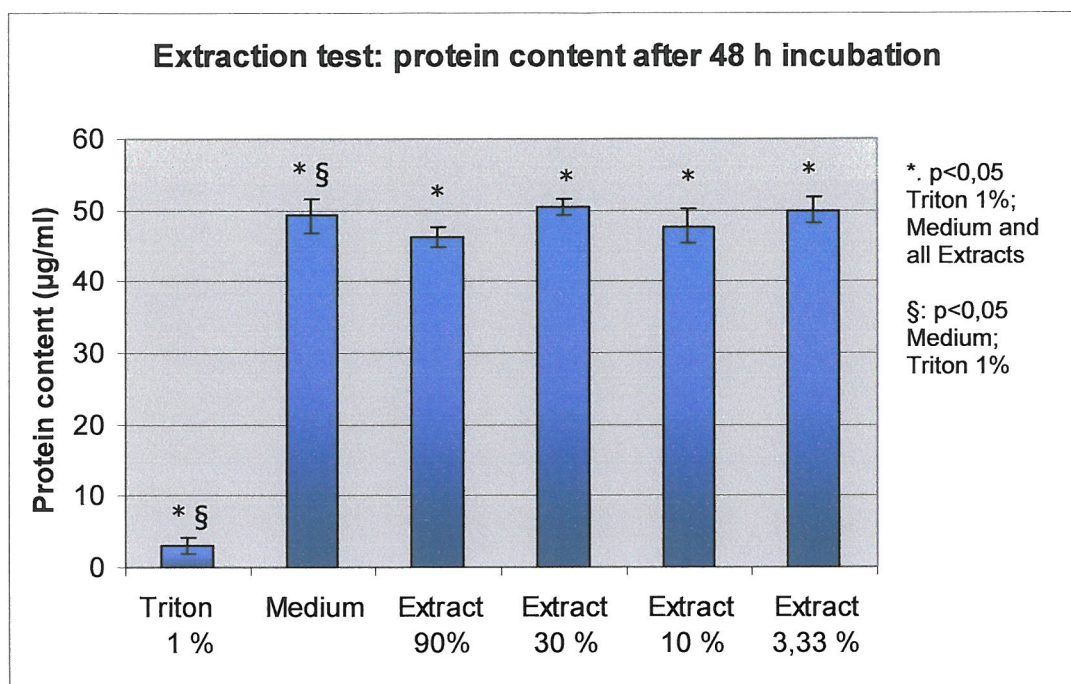
Test performed: Jan 13th 2011

Description of the test procedure:

Normative Reference: ISO 10993-5 (2009)

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 µg/ml	Protein content n=4					
	Triton 1 %	Culture medium	Extract 90 %	Extract 30 %	Extract 10 %	Extract 3,3 %
Mean	3,01	49,26	46,23	50,52	47,76	49,98
Standarddev.	1,15	2,38	1,34	1,19	2,42	1,80

In the presence of Triton X 100 in the cell culture medium 6,1 % 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 70 % compared to the negative control. This was not case in this test.

Result: The Polyurethane clear lacquer Legnopur 26211 with 10 % PUR hardener 82019, brushed onto glass (120 g/m²) 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.