



## Test Report

### ***Toxicity testing of a material extract, Cytotoxicity Test***

Test report number: ISO 201702-02108\_engl

commissioned by:

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Test material:

Mar 13<sup>th</sup> 2017

Uncoated Polyamid 12 (PA 2200) test specimen in the colours

DM Black [01]

DM Violet [03]

DM Blue [04]

DM Red [06]

DM Pink [07]

Test material received: Feb 21<sup>st</sup> 2017

Test performed: Mar 03<sup>rd</sup> 2017

**Result: The uncoated Polyamid 12 (PA 2200) test specimen in the colours DM Black [01], DM Violet [03], DM Blue [04], DM Red [06] and DM Pink [07] did not cause a cytotoxic effect.**

Description of the test procedure:

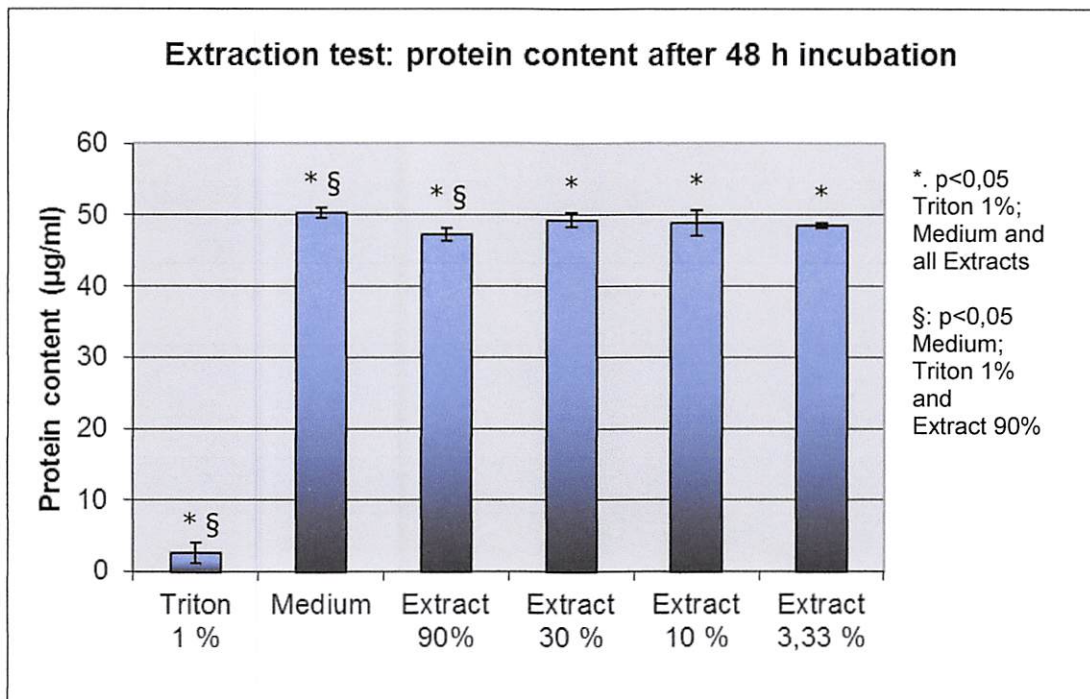
Normative References: ISO 10993-5 (2009); ISO 10993-12 (2012)

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 surface / extraction volume ratio was 3 cm<sup>2</sup> material 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

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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 %
Mean	2,65	50,34	47,34	49,31	48,96	48,58
Standarddev.	1,49	0,78	0,90	1,00	1,81	0,38

In the presence of Triton X 100 in the cell culture medium 5,3 % 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 extract did not show a cytotoxic effect.

**Result:** The uncoated Polyamid 12 (PA 2200) test specimen in the colours DM Black [01], DM Violet [03], DM Blue [04], DM Red [06] and DM Pink [07] did not cause a cytotoxic effect.

Explanatory notes:

none

Test performed by: Dietmar Scheddin

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

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