



Test Report

Toxicity testing of a material extract, Cytotoxicity test

Test report number: ISO 201302-01259B_engl

commissioned by:

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Test material:

May 21st 13

Pure synthetic resin test specimen consisting of epoxy resin "L" and hardening agent "EPH 500"

Test material received: May 13th 13

Test performed: May 20th 13

Result: The pure synthetic resin test specimen consisting of epoxy resin "L" and hardening agent "EPH 500" didn't cause a cytotoxic effect.

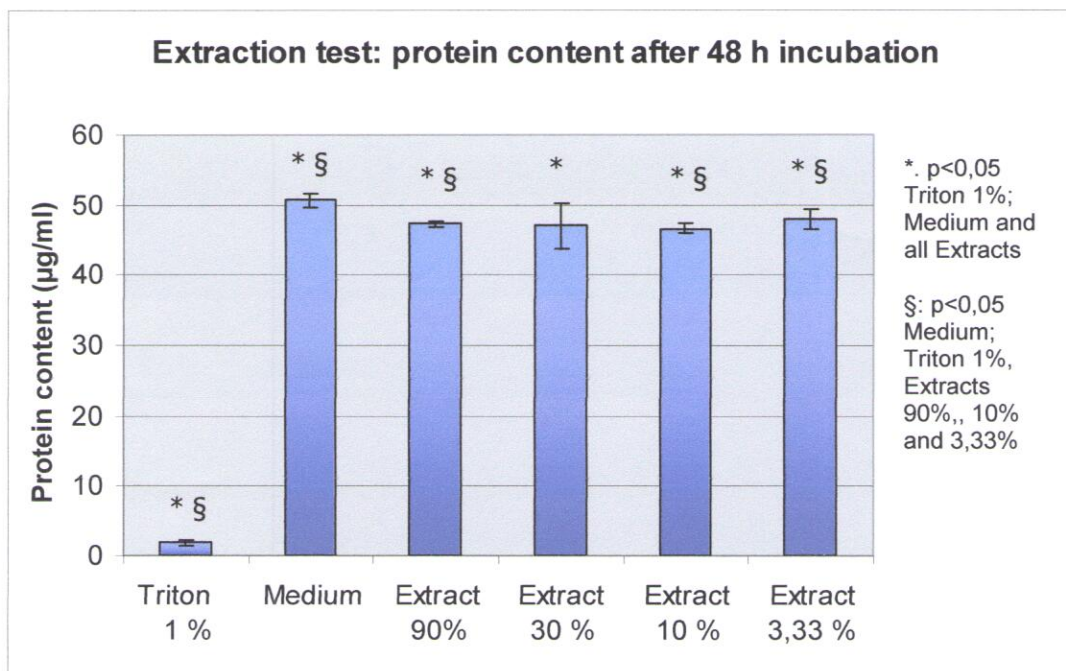
Description of the test procedure:

Normative Reference: 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 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 | 1,88 | 50,67 | 47,29 | 46,97 | 46,68 | 47,95 |
| Standarddev. | 0,47 | 0,91 | 0,33 | 3,20 | 0,66 | 1,48 |

In the presence of Triton X 100 in the cell culture medium 3,7 % 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 case in this test.

Result: **The pure synthetic resin test specimen consisting of epoxy resin "L" and hardening agent "EPH 500" didn't 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.