Test Report

Toxicity testing of a material extract

Test report number: ISO 201007-01000_engl

commissioned by:

R & G Faserverbundwerkstoffe GmbH
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Test material: Sep 30th 10

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

Test material received: Sep 06th 10 Test performed: Sep 24th 10

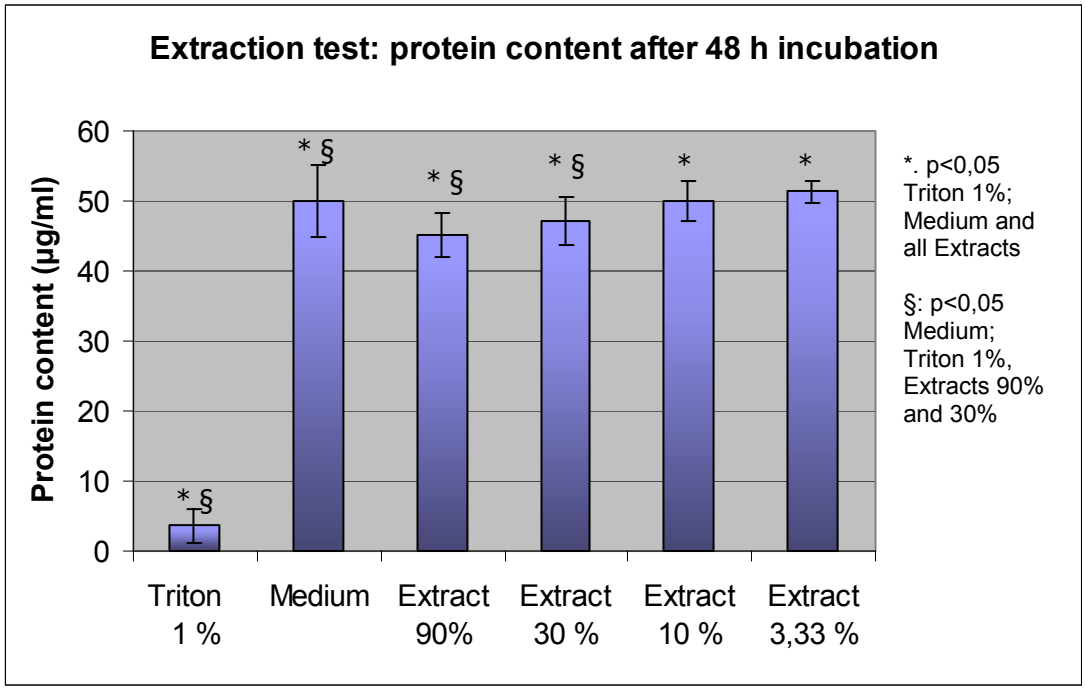
Result:	**The pure synthetic resin test specimen consisting of epoxy resin "L" and hardening agent "L" didn´t cause a cytotoxic effect.**

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 cm^2 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					
µg/ml	Triton 1 %	Culture medium	Extract 90 %	Extract 30 %	Extract 10 %	Extract 3,3 %
Mean	3,59	49,96	45,12	47,13	49,90	51,40
Standarddev.	2,47	5,14	3,07	3,36	2,84	1,57

In the presence of Triton X 100 in the cell culture medium 7,2 % 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 pure synthetic resin test specimen consisting of epoxy resin "L" and hardening agent "L" didn´t cause a cytotoxic effect.**

Explanatory notes:

none

Test performed by:_____

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

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

Test Report

Toxicity testing of a material extract, Cytotoxicity test

Test report number: ISO 201302-01259B_engl

commissioned by:

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May 21st 13

Test material:

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

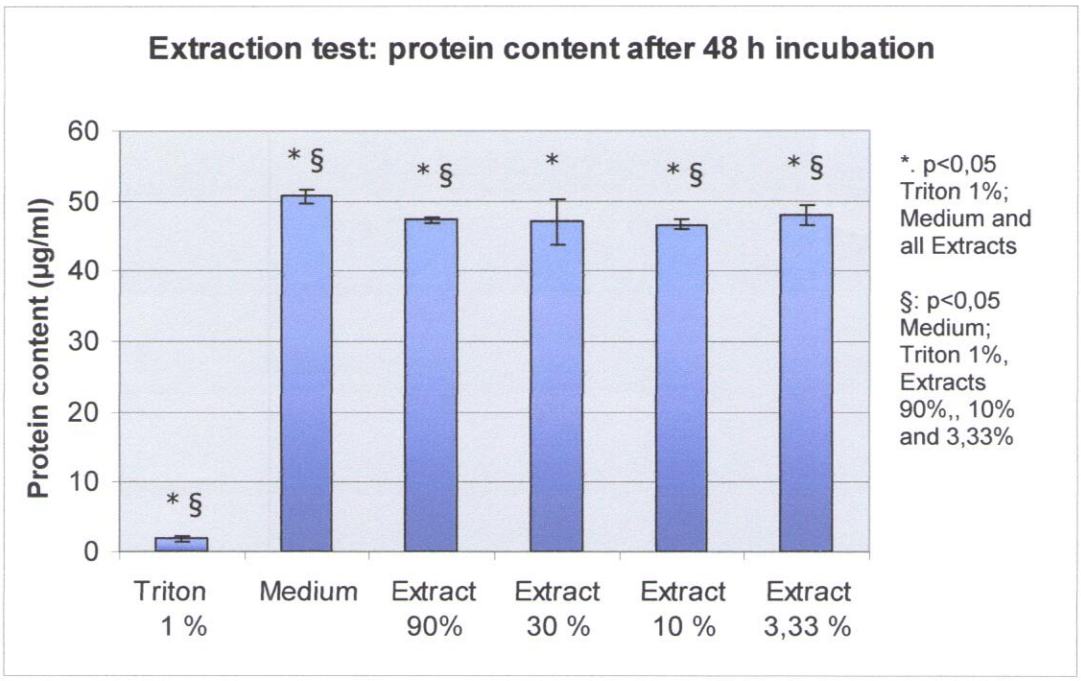
Result:	**The pure synthetic resin test specimen consisting of epoxy resin "L" and hardening agent "EPH 500" didn´t cause a cytotoxic effect.**

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 cm^2 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					
µg/ml	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: _____

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

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Test Report

Toxicity testing of a material extract, Cytotoxicity test

Test report number: ISO 201302-01259A_engl

commissioned by:

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D-71107 Waldenbuch, Germany

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Test material: May 21st 13

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

Test material received: May 13th 13 Test performed: May 20th 13

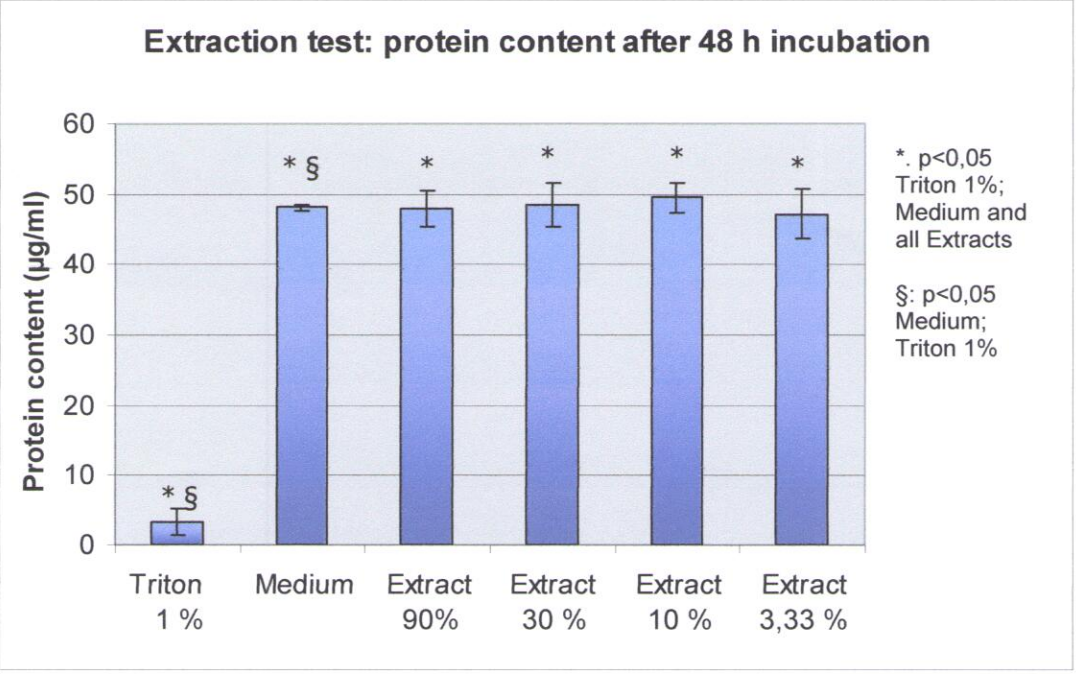
Result:	**The pure synthetic resin test specimen consisting of epoxy resin "L" and hardening agent "S" didn´t cause a cytotoxic effect.**

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 cm^2 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					
µg/ml	Triton 1 %	Culture medium	Extract 90 %	Extract 30 %	Extract 10 %	Extract 3,3 %
Mean	3,28	48,10	48,02	48,47	49,53	47,22
Standarddev.	1,97	0,48	2,54	3,17	2,06	3,40

In the presence of Triton X 100 in the cell culture medium 6,8 % 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 "S" didn´t cause a cytotoxic effect.**

Explanatory notes:

none

Test performed by: _____

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

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