

Test Report
Toxicity testing of a material extract,
Cytotoxicity Test

Test report number: ISO 201910-02732A_engl

commissioned by:

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Test material:

Dec01 2019

Amparo DirectFitplastic, LOT 10001, colour black, used for US prosthetic sockets

Test material received: Nov 11th 2019

Test performed: Nov 15th 2019

Result: The amparo DirectFit plastic, LOT 10001, colour black, used for US prosthetic sockets did not cause a cytotoxic effect.

Description of the test procedure: Normative References: ISO 10993-5 (2009); ISO 10993-1

(2018); ISO 10993-12 (2012) The material was extracted for 24 h at 37°C and a partial

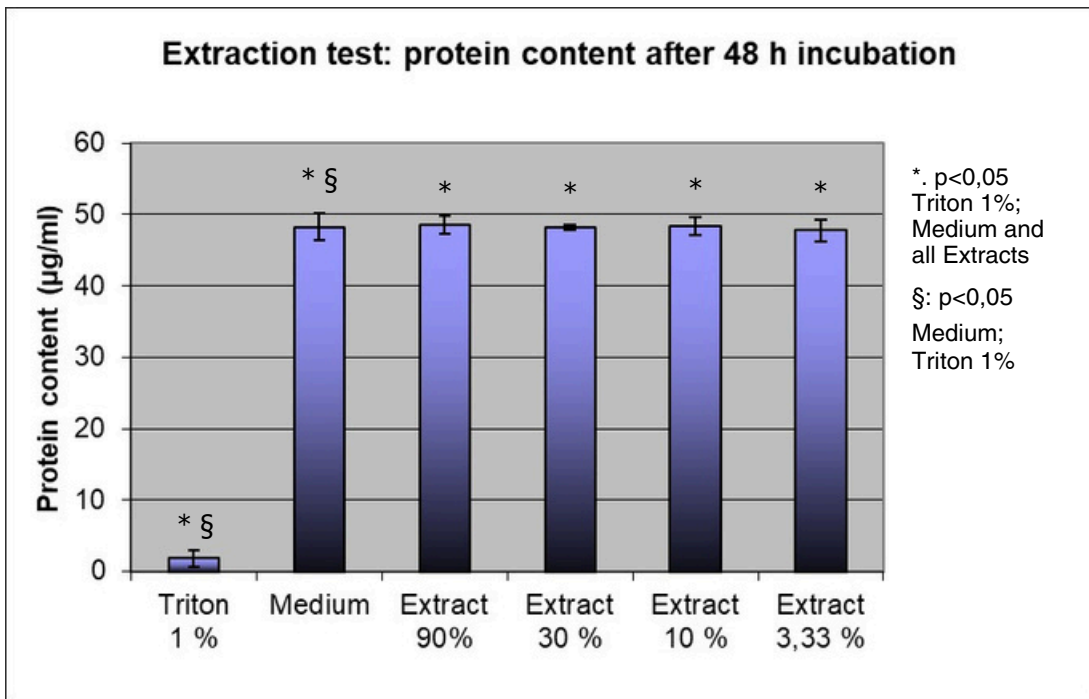
pressure of 5 % carbon

dioxide in extraction medium (DMEM medium with antibiotics, without fetal calf serum [FCS]). The material surface/ extraction volume ratio was 3 cm² material surface 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	Extract90%	Extract30%	Extract10%	Extract3,3 %
Mean	1,82	48,27	48,57	48,20	48,41	47,78
Standarddev.	1,22	1,91	1,33	0,37	1,28	1,46

In the presence of Triton X 100 in the cell culture medium 3,8 % 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 the case in this test. The material extract did not show a cytotoxic effect.

Result: The amparo DirectFit plastic, LOT 10001, colour black, used for US prosthetic sockets did not cause a cytotoxic effect.