



Test Report

Toxicity testing of a material extract, Cytotoxicity Test

Test report number: ISO 202111-03295D_engl

commissioned by:

PerformCoat Europe AG
Widenstrasse 7

CH-9464 Rüthi / SG, Switzerland

CYTOX
biological testing of medical devices
Gottlieb-Keim-Straße 60
D-95448 Bayreuth, Germany
tel. +49-921-1511-254
fax +49-921-1511-255
mobile +49-179-5102577
info@cytox.de
www.cyttox.de

Test materials:

Dec 06th 2021

Stainless steel test specimens coated with chromium carbide (CrC) by PVD process

Test material received: Nov 19th 2021

Test performed: Dec 03rd 2021

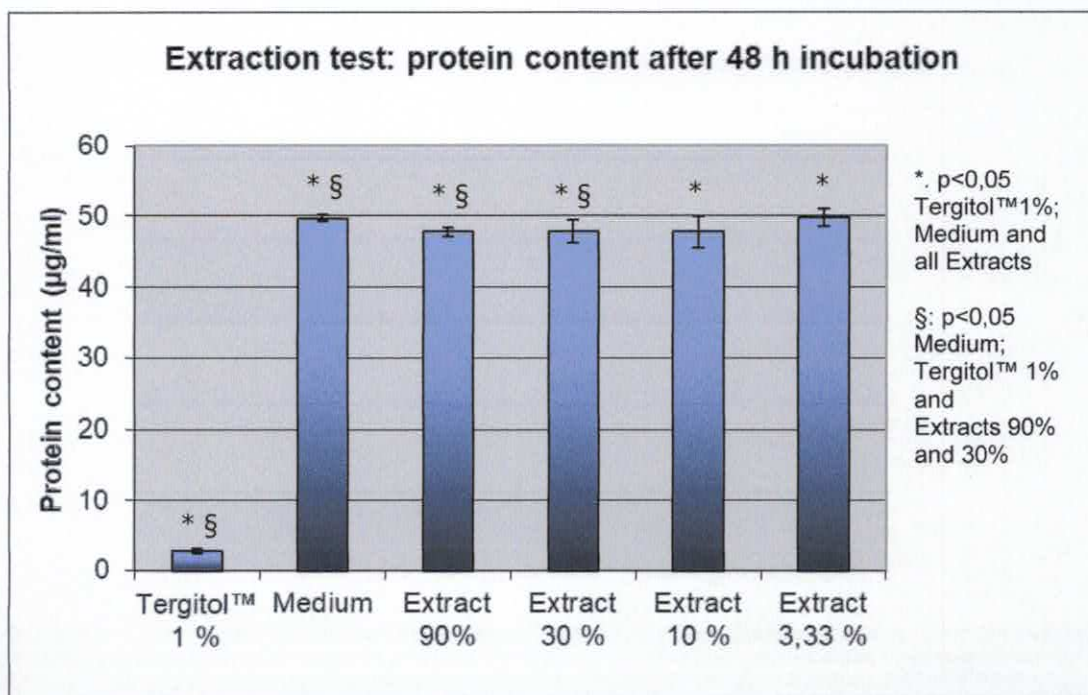
Result: The stainless steel test specimens coated with chromium carbide (CrC) by PVD process did not cause a cytotoxic effect.

Description of the test procedure:

Normative References: ISO 10993-5 (2009); ISO 10993-1 (2018); ISO 10993-12 (2021)

The materials were 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.

Tergitol™ 1 % 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					
	Tergitol™ 1 %	Culture medium	Extract 90 %	Extract 30 %	Extract 10 %	Extract 3,3 %
µg/ml						
Mean	2,80	49,68	47,81	47,77	47,76	49,82
Standarddev.	0,39	0,47	0,64	1,61	2,19	1,24

In the presence of Tergitol™ 1% in the cell culture medium 5,6 % 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 evaluated as 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 stainless steel test specimens coated with chromium carbide (CrC) by PVD process 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.