



GIBRALTAR

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Report No.:

R-353612-R0

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1/15/2015

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e-FINAL REPORT

R-353612-R0

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PO #: 600399

GBL Sample #: 386266/1-6.436

Analyst#: 240

Date Received: 1/6/2015

Date Tested: 1/12/2015

Date Completed: 1/15/2015

ISO Cytotoxicity on Industrial Fabrics (PES or PA) coated with PVC or PU

Description

One clear plastic bag containing 6 various Industrial Fabrics (PES or PA) coated with PVC or PU.

Purpose

To determine the in vitro cytotoxicity of an extract of the test material. The experiment performed is an official ISO 10993-5.2009 test for screening test samples for cytotoxicity. The cells will be examined for general morphology, vacuolization, detachment, cell lysis, and membrane integrity.

Method

ISO 10993-5.2009. An extract was prepared in RPMI 1640 with 5 % bovine calf serum at 37 ± 2°C for 24 hours.

Amount of test material / extractant:

GBL# 386266/1 2.3 grams/11.5 mL

GBL# 386266/2 2.7 grams/13.5 mL

GBL# 386266/3 2.5 grams/12.5 mL

GBL# 386266/4 3.9 grams/19.5 mL

GBL# 386266/5 3.3 grams/16.5 mL

GBL# 386266/6 2.5 grams/12.5 mL

Assay Method: Elution Technique

Cell Line L-929

Cell Source ATCC # CCL1, NCTC Clone 929

Cell Culture Media RPMI 1640 with 5% Bovine Calf Serum, Penicillin 100U/mL, and Streptomycin 100µg/ML

Results

See attached table

Conclusion

The sample tested met the requirements of the ISO 10993-5 relativity test in vitro.

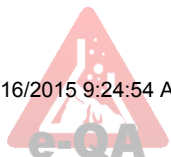
Respectfully Submitted,

GIBRALTAR LABORATORIES, INC.

Approved By: 1/16/2015 3:27:05 PM

Christopher Waskewich

1/16/2015 9:24:54 AM



Michael A Pannullo





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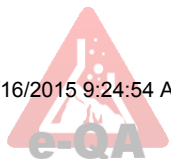
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GBL Ref.: 3532 - 6000 - 9443

Details for: 386266/1-6.436 ISO Cytotoxicity on Industrial Fabrics (PES or PA) coated with PVC or PU

Slash #	Sample Description	Lot #	Day 0	Day 2 Results (Score 0 to 4)
001	TPU 1009, PA fabric, One Side PU Coated	Z14166	0, 0, 0	0, 0, 0
002	TPU 2010, PA fabric, Two sides PU Coated	Z14273	0, 0, 0	0, 0, 0
003	TPU 2007, PA fabric, Two sides PU Coated	Z14253	0, 0, 0	0, 0, 0
004	TPU 2009, PA fabric, Two sides PU Coated	Z14425	0, 0, 0	0, 0, 0
005	TPU 2012, PA fabric, Two sides PU Coated	Z14478	0, 0, 0	0, 0, 0
006	TPU 1001L, PA fabric, One side PU Coated	Z10047	0, 0, 0	0, 0, 0
Positive Control			0, 0, 0	4, 4, 4
Negative Control			0, 0, 0	0, 0, 0

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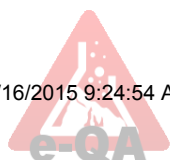
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Qualitative morphological grading of cytotoxicity of extracts

Grade	Reactivity	Condition of all Cultures
0	None	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth
1	Slight	Not more than 20 % of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasionally lysed cells are present, only light growth inhibition observable
2	Mild	Not more than 50 % of the cells are round, devoid of intracytoplasmic granules, no extensive cell lysis, not more than 50 % growth inhibition observable.
3	Moderate	Not more than 70% of the cell layers contain rounded cells are are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observable.
4	Severe	Nearly complete or complete destruction of the cell layers

Grades are based on microscopic changes in cell morphology.

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