



Mechanical & Hardgoods Lab

## TEST REPORT

Report No.: HL10359/2009  
Page: 1 of 4  
Date: Mar. 13, 2009

**SPAZIO CONCEPTS PTE LTD.**

32 Sungei Kadut Way, #03-03 Teambuild Industrial Building  
Singapore 728787.

The following merchandise was submitted and identified by the applicant as:

**Product Description:** Handrail  
**Style/Item No.:** GB 400-70cm  
**Manufacturer/Vendor:** SPAZIO CONCEPTS PTE LTD.

We have tested the submitted sample(s) as requested and the following results were obtained:

**Test Requested:**  
ISO 10993-5 Cytotoxicity Test

**Purpose:**

This test applies cell culture to determine the lysis of cells (cell death), the inhibition of cell growth, and other effects on cells caused by medical devices, materials and/or their extracts.

**Materials:**

Test Article: Handrail

Other Materials:

Medium: DMEM (Dulbecco's modified Eagle medium)  
Cell Line: L-929 mouse fiberglass (NCTC Clone 929, Strain L)  
Enzyme: Trypsin-EDTA  
Dimethylsulfoxide: (DMSO)

**Received Date:** Jan, 24, 2009

**Testing Period:** Jan, 24, 2009 ~ Mar. 13, 2009

Signed for and on behalf of  
SGS Taiwan Ltd.

Benson Liao  
Supervisor

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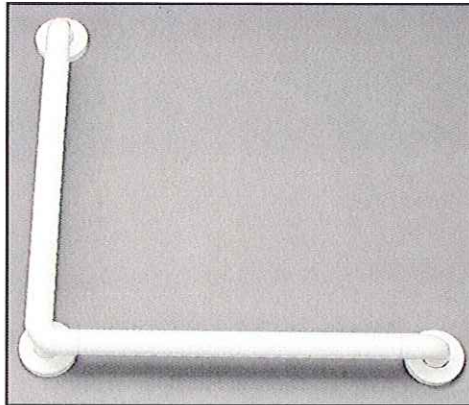


Figure 1 Appearance of the sample

**References:**

The test was conducted based upon the following references:

ISO 10993-1:2003(E) Biological evaluation of medical devices --- Part 1: Evaluation and testing

ISO 10993-5 Biological Evaluation of medical Devices Test for in vitro cytotoxicity

ISO 10993-12:20(E) Biological evaluation of medical devices--- Part 12: Sample preparation and reference material

ISO/IEC 17025:2005 General Requirements for the Competence of Testing Calibration Laboratories

USP 30 Biological Reactivity Tests, in vitro

**Methods:****Extraction method:**

4g of test article was extracted in 20ml of DMEM (Dulhcco's modified Eagle medium) at 37°C  
For 24 hours.

**Test Method:**

The Cells:

L-929 mouse fibroblasts were cultured in DMEM with 10% fetal bovine serum. The cell suspension was made at density of  $7.0 \times 10^3 \sim 1.0 \times 10^3$  cells/ml. 1 ml of this cell suspension were pipette in each well. The 24-well cell culture plate was then incubated at 37°C with 5% CO<sub>2</sub>.

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**The Controls:**

1. Negative Control: DMEM 10% FBS.
2. Positive Control: Dimethylsulfoxide (DMSO) final concentration 5% in DMEM 10% FBS.

**Test Article:** Test article extract with 10% FBS

**Test Procedure:**

A monolayer of L-929 mouse fibroblasts was grown to near confluency, in each well of a 24 well cell culture plate. The culture medium was removed from 24-well cell culture plate and replaced it with 1 ml of the test article extract or the controls medium. The cultures were incubated for 24hours at 37°C with 5% CO<sup>2</sup>. Then the monolayer was examined microscopically for cell malformation or degeneration. The cell layer was trypsinized and the cell number was counted. All the cultures were performed triplicate.

**Assessment Method:**

1. Microscopic Examination

Grade	Reactivity	Conditions of all cultures
0	None	Discrete intracytoplasmic granules; no cell lysis.
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granulas; occasional lysed cells are present.
2	Mild	Not more than 50% of the cells are round and devoid of intracytoplasmic granulas; extensive cell lysis and emtry areas between cells.
3	Moderate	Not more than 70% the cell layers contain rounded cells and / or are lysed.
4	Severe	Nearly complete destruction of the cell layers.

2. The Cell Number

The cell layer was trypsinized and the cell number was counted. If the cell number of the test Article extract was over 50% less than negative control, the test article was cytotoxic for L-929 mouse fibroblasts.

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**Results:**

- (1) Microscopic Examination  
None of the cultures showed sign of cell malformation (reactivity grading=0 or “none”).  
Except for the positive control, where the cells became round in shape and were detached  
From the culture plate surface (reactivity grading=4 or “severe”).
- (2) The Cell Number  
The cell number within the monolayer was listed in Table 1.  
The cell number of the test article extract was not over 50% less than negative control.

Table 1 The average cells number for each culture

	Total Number of cells within monolayer (x10 <sup>3</sup> )			
	#1	#2	#3	Average
Negative control	3.35	4.04	3.53	3.64 +/- 0.36
Positive control	1.30	1.43	1.36	1.36 +/- 0.07
Test article extract	3.18	3.99	3.69	3.62 +/- 0.41

**Conclusion:**

In our opinion, the submitted sample which the cell number for the test article extract was not over 50% less than the negative control and cell reactivity grading was equal to 0 (none). Therefore, the test article showed “negative” cytotoxicity.

**Figure Index:**

Figure 1: Appearance of the sample

**Table Index:**

Table 1 : The average cells number for each culture

This test was performed by Europe America Biotechnology Co., Ltd.  
TAF No.: 1828

--- End of Report ---

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