

MD ALLOYS LTD

NIMON EXTRA: NiCrMo

Cytotoxicity Evaluation
Fluid Extract/L929 Mouse Fibroblast
[(ANSI/AAMI/ISO 10993-5:2009(E))]
(GLP)

November 24, 2010

JN10K0641

D. Observations

Microscopic readings for cellular response were performed at 24 hours (± 1 hour) and 72 hours (± 1 hour) after exposure.

At least one (1) well was stained with Trypan Blue at the final reading to help determine "percent lysed".

See Table I below for grading guidelines.

TABLE I

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

E. Additional Methods

Any additional steps required to complete the test that were not described above are indicated here:

N/A

RESULTS: See table below for the cellular response to extracts from the controls and test sample.

	24 Hours			72 Hours			Trypan Blue % Lysed
Material Positive Control	4	4	4	4	4	4	100%
Material Negative Control	0	0	0	0	0	0	0%
Extract Negative Control	0	0	0	0	0	0	0%
Test Article Undiluted	0	0	0	0	0	0	0%
Test Article Diluted 1/2	0	0	0	0	0	0	0%
Test Article Diluted 1/4	0	0	0	0	0	0	0%
Test Article Diluted 1/8	0	0	0	0	0	0	0%

DATE READ: 11-17-10 11-19-10
READ BY: Svetlana Carls Svetlana Carls

INTERPRETATION OF RESULTS:

- A. Assay Controls must meet the acceptance criteria for a valid assay.

All negative control responses must be no greater than a Grade 0.

Positive control responses must be no less than a Grade 3.

- B. The responses observed from the test article are interpreted according to current USP guidance.

Grades of 0 (None), 1 (Slight) or 2 (Mild) indicate the article meets the assay acceptance requirements.

Grades of 3 (Moderate) or 4 (Severe) indicate the test article does not meet the assay acceptance requirements.

- C. No statistical analyses of the data are being made.

CONCLUSION: The Grade 0 response from the undiluted sample preparation (as well as the 1/2, 1/4 and 1/8 dilutions) meets assay acceptance requirements of no more than Grade 2 reactivity (ref. USP).