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TEST RESULT REPORT: 14-B5539-N1

Project Number:	**TE141761**	**Report Date:**	**20/11/2014**
Sponsor:	**Kraiburg TPE GmbH & Co. KG**		
Contact Person:	*Oliver Lippert*		
Address:	Friedrich-Schmidt-Strasse 2	Date Sample Arrival:	14/11/2014
City, State, Zip:	84478 Waldkraiburg	Technical Initiation:	17/11/2014
Country:	Germany	Technical Completion:	20/11/2014

Study:	**Quantitative MEM-elution: XTT**	Temp/Time	37°C/24 hours
Test article name:	**THERMOLAST® M TM4LFT**	Ratio	25cm²/20mL
Lot number:	**N/A**	Vehicle	MEM-Complete

REFERENCE: According to "ISO 10993-5, 2009: Biological Evaluation of Medical Devices- Part 5:Tests for In Vitro Cytotoxicity." Toxikon Reference: SOP 3.1.2.3, rev. 09

PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test item extract was determined. The control articles were autoclaved prior to the preparation of the extracts. Extracts were prepared at 37±1°C for 24 hours in a humidified atmosphere containing 5±1% carbon dioxide (static). Positive (natural rubber) and negative (silicone) control articles were prepared to verify the proper functioning of the test system. The extracts were sterile filtered .The maintenance medium on the cell cultures is replaced by the extracts of the test item or control article in quadruplicate and the cultures are subsequently incubated for approximately 48 hours, at 37±1°C, in a humidified atmosphere containing 5±1% carbon dioxide. Subsequently XTT-reagent was added to the wells and the cultures incubated for another 3-5 hours. Biological reactivity was evaluated by a photo spectrometer at 450 nm wavelength. A test item is considered to be cytotoxic if viability is less than 70% of the blank (only culture medium).

RESULTS: 102 % viability was observed for the cell cultures exposed to the test item at the 48 hours observation. 3 % viability was observed for the positive control article. The negative control article showed a viability of 96 %.

OPINION AND INTERPRETATION: Based on the evaluation criteria mentioned above, the test item is considered non-cytotoxic.

RECORD STORAGE: All raw data generated in this study will be archived at Toxikon Europe, according to SOP 4.2.8.

AUTHORIZED PERSONNEL

Ir Peter Cornelis
Study Director

Petra Beltman
Quality Assurance