

TEST RESULT REPORT N°: 11-B0887-N1

Project Number:	TE 11307	Study Number:	11-B0887-N1
Sponsor:	Kraiburg TPE GmbH & Co. KG	Report Date:	11/04/2011
Contact:	<i>Mr. O. Lippert</i>		
Address:	Friedrich-Schmidt-Str. 2 84478 Waldkraiburg Germany	Date Sample Arrival:	30/03/2011
		Technical Initiation:	04/04/2011
PO.Number:	N/A	Technical Completion:	08/04/2011

Study	Quantitative MEM-elution: XTT	Temp/Time	37°C/24 hours
Test Item	THERMOLAST®M TM9HET	Ratio	60cm ² /20mL
Lot	N/A	Vehicle	MEM-Complete

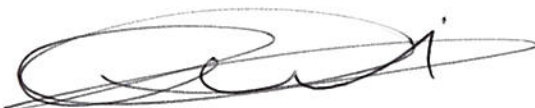
REFERENCE: According to "ISO 10993-5, 2009: Biological Evaluation of Medical Devices- Part 5: Tests for In Vitro Cytotoxicity." Toxikon Reference: SOP 3.1.2.3, rev. 09

PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test item extract was determined. The samples and 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 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 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: 93.76% viability was observed for the cell cultures exposed to the test item at the 48 hours observation. 2.67% viability was observed for the positive control article. The negative control article showed a viability of 94.05%.

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



Gaby Boonen
Quality Assurance

The test results on the enclosed report are only referring to the tested articles. Partly reproduction of this report can only be allowed after written permission of Toxikon. Toxikon guarantees that all results are acquired by testing according to officially accepted scientific methodology.