TOXIKON

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TEST RESULT CERTIFICATE

Project Number:	**TE 09090**	**Study Number:**	**09-B0224-N1**
Sponsor:	**Kraiburg TPE GmbH & Co.KG**	**Report Date:**	**20/02/2009**
Contact:	*Mr. Andreas Igerl*		
Address:	Friedrich-Schmidt Strasse 2 84478 Waldkraiburg, Germany	Date Sample Arrival: Technical Initiation:	10/02/2009 17/02/2009
PO.Number:	e-mail igerl 11-12-08	Technical Completion:	20/02/2009

Study	**Elution Test - ISO**	Temp/Time	37°C/24 hours
Test Item	TM 0 HET	Ratio	60 cm²/20 ml
Lot	N/A	Vehicle	MEM-Complete

REFERENCE: Based on "ISO 10993-5, 1999: Biological Evaluation of Medical Devices- Part 5:Tests for In Vitro Cytotoxicity." and "USP 31-NF 26, 2008: <87> Biological reactivity test, in vitro." Toxikon Reference: SOP 3.1.2.3, rev. 06

PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test item extract was determined. 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 pH of the extracts was measured and the extracts sterile filtered. The maintenance medium on the cell cultures is replaced by the extracts of the test item or control article in triplicate and the cultures are subsequently incubated for 48 hours, at 37±1°C, in a humidified atmosphere containing 5±1% carbon dioxide. Biological reactivity was rated on the following scale: Grade 0 (No reactivity); Grade 1 (Slight reactivity), Grade 2 (Mild reactivity), Grade 3 (Moderate reactivity) and Grade 4 (Severe reactivity). The test item is considered non-cytotoxic if none of the cultures exposed to the test item shows greater than mild reactivity (Grade 2).

RESULTS: No reactivity (Grade 0) was exhibited by the cell cultures exposed to the test item at the 48 hours observation. Severe reactivity (Grade 4) was observed for the positive control article. The negative control article showed no signs of reactivity (Grade 0).

CONCLUSION: 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

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