TOXIKON

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TEST RESULT CERTIFICATE

Sponsor	KRAIBURG TPE GmbH & Co. KG	**Technical Initiation**	11/20/2014
Address	Friedrich-Schmidt-Str. 2 84478 Waldkraiburg, Germany	**Technical Completion**	11/28/2014
Contact	Oliver Lippert	**Report Date**	12/8/2014
P.O. Number	Not Supplied by Sponsor (N/S)	**Final Non-GLP Report**	14-04156-N4

Test Article	THERMOLAST ® M TM7ADT	**Ratio**	3 cm^2/1 mL
Lot/Batch #	Not Supplied by Sponsor (N/S)	**Vehicle**	USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO)
Study	Systemic Injection Test – ISO	**Extraction Conditions**	70 ± 2 °C for 24 ± 2 hours
Comments	Storage Condition: Room Temperature Physical State: Solid Density: 0.89 Color: translucent		

REFERENCES: The study was conducted based upon the following references: ISO 10993–11, 2006, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity. ISO 10993–12, 2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The Systemic Injection Study is designed to screen test article extracts for potential toxic effects as a result of a single–dose systemic injection in mice. The extraction conditions were performed as stated above. The test article extracts were injected intravenously at 50 mL per kg (NaCl) and intraperitoneally at 50 mL per kg (CSO) in groups of five mice. Similarly, groups of mice were injected with the control articles (vehicles). Body weight measurements were made prior to dose administration, and then daily for 3 days. The animals were observed for signs of biological reactivity for 72 hours post inoculation.

RESULTS: Two test animals and four control animals lost an insignificant amount of weight (less than 4%). All other test and control animals maintained or gained in body weight. None of the animals injected with the test article extracts or the control articles exhibited any signs of toxicity throughout the observation period.

CONCLUSION: The animals treated with the test article extracts did not exhibit biological reactions greater than the controls. Therefore, the test article meets the requirements of the ISO 10993–11 guidelines for the Systemic Injection Test.

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