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TEST RESULT CERTIFICATE

Sponsor	Saint-Gobain Performance Plastics	**Technical Initiation**	03/10/03
Address	3910 Industrial Avenue, PO Box 481 Beaverton, MI 48612	**Technical Completion**	03/17/03
Contact	Jerry Theiss	**Report Date**	03/26/03
P.O. Number	BV18920	**Project Number**	03-0938-N1

Test Article	Tygon 3350	**Ratio**	60 cm² per 20 mL
Lot #	76469	**Vehicles**	0.9% USP Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1:20 Alcohol in NaCl (EtOH), Polyethylene Glycol 400 (PEG)
Study	Biological Test for Plastics Class VI (4 Extracts)	**Extraction Conditions**	121±2°C for 1 hour
Comments	Per Sponsor's specifications, a duplicate report was created with alternative test material name: Biosil 1050.		

REFERENCE: USP 26, NF 21, 2003, <88> Biological Reactivity tests, *In Vivo*.

GENERAL PROCEDURE: The extraction conditions were performed as stated above. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP 26; including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article was implanted into the paravertebral muscles of rabbits for 7 days and observed for signs of hemorrhage, inflammation, necrosis, discoloration, encapsulation, and infection.

RESULTS: None of the mice injected with the test article extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, edema or clinical toxicity. In both the Systemic and Intracutaneous Tests the controls were normal through 72 hours. Also, the implant sites exhibited no significant signs of hemorrhage, inflammation, necrosis, discoloration, encapsulation, or infection compared with the control sites.

CONCLUSION: The test article meets the requirements of USP 26, NF 21, 2003 for the Biological Test for Plastics, Class VI-121°C.

AUTHORIZED PERSONNEL:

Stacy Pritt, DVM
Study Director

John Christensen, B.S.
Quality Assurance

Toxikon Corporation
15 Wiggins Avenue • Bedford, Massachusetts 01730
800.458.4141 • Main 781.275.3330 • Fax 781.271.1136
www.toxikon.com