

Confidential
TCLAS_VI7

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Lab No. 07C_41356_01
P.O. No. CREDIT CARD - 5005
Test Facility: NAMSA
9 Morgan
Irvine, CA 92618

CERTIFICATE OF COMPLIANCE
USP BIOLOGICAL REACTIVITY TESTS, *IN VIVO*

USP PLASTIC CLASS VI

Test Article: INERTEX® SQ-S Expanded PTFE Gasket Sheet
ID No. Lot #: 882538072414

USP Systemic Toxicity Study in the Mouse: The test article was prepared as indicated below and injected into mice. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extractants.

USP Intracutaneous Toxicity Study in the Rabbit: The test article was prepared as indicated below and injected intracutaneously into rabbits. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater tissue reaction than the blank extractants.

USP Muscle Implantation Study in the Rabbit: The macroscopic reaction of the test article, implanted in rabbit muscle for one week, was not significant when compared to the USP negative control plastic.

The test article was prepared at a ratio of 60 cm²:20 ml and extracted at 121°C for 1 hour. The test article extracts met the requirements of a USP Plastic Class VI.

mlm Date Completed 07-20-07

Approved By R. Villani
Robert Villani, AALAS Certified
Supervisor, Toxicology