

PBL Pacific BioLabs

The Service Leader in Bioscience Testing

SPONSOR 12993

Chett Norton
Triangle Fluid Controls
399 College Street E.
Belleville, ON K8N 5S7
Canada

REPORT DATE: 4/15/13



MSP NUMBER: 13C0320R

P.O. NUMBER: CHETT-080313

PAGE: 1 of 1

CERTIFICATE

CLASS VI – 121°C PLASTIC TESTS (USP 35 <88>, REV. 5/2012)

Name: Durlon 9000

Physical Description: PTFE Gasket Material

Total Quantity Received for Testing: 8 50mm x 60mm pieces, 8 1mm x 10mm pieces

Storage Condition: Room Temperature

Date Received: 3/19/13

Class VI - Intracutaneous Test

PBL Report No.: 13C0320R-X02

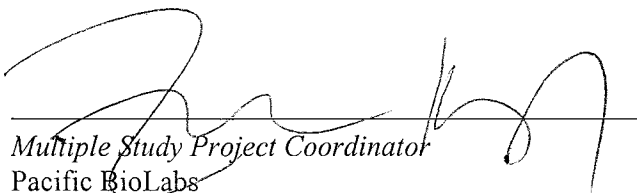
Class VI - Systemic Injection Test

PBL Report No.: 13C0320R-X03

Class VI - Implantation Test

PBL Report No.: 13C0320R-X04


The test article met the requirements for Plastic Class VI – 121°C testing per USP <88>.



Multiple Study Project Coordinator
Pacific BioLabs

4/25/13

Date



QAU Review
:hc

4/25/13

Date

Confidential
TCLAS_VI7

Walter Lee
Inertech, Inc.
641 Monterey Pass Road
Monterey Park, CA 91754

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