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

213C0320R-X01

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

4/25/13
Date

:hc

NAMSA

PEOPLE > SCIENCE > SOLUTIONS

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 cm^2:20 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