



CONFIDENTIAL

CERTIFICATE OF COMPLIANCE

PEOPLE > SCIENCE > SOLUTIONS

Test Facility
6750 Wales Road
Northwood, OH 43619
419.666.9455

TEST ARTICLE NAME

PTFE Gasket

TEST ARTICLE IDENTIFICATION

Sigma 500

TEST ARTICLE PHYSICAL DESCRIPTION

1/16" thick, glass microsphere-filled, fully restructured, PTFE sheet gasketing

TEST ARTICLE RECEIVED

February 5, 2018

SPONSOR

Kathryn Worden
Flexitallic US, LLC
6915 Highway 225
Deer Park, TX 77536

USP Biological Reactivity Tests, *In Vivo* USP Plastic Class VI

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 1 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 70°C for 24 hours. The test article extracts met the requirements of a USP Plastic Class VI.

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| APPROVAL |  | 02-27-18 |
| | Arizona E. Carter, BS, ALAT Technical Reviewer | Date |