

CONFIDENTIAL

CERTIFICATE OF COMPLIANCE

PEOPLE > SCIENCE > SOLUTIONS

Test Facility 6750 Wales Road Northwood, OH 43619 419.666.9455

TEST ARTICLE NAME

SSP2390-50D

TEST ARTICLE IDENTIFICATION

18-0612-1

TEST ARTICLE PHYSICAL DESCRIPTION

8 6" x 6" ASTM Test slabs - translucent

TEST ARTICLE RECEIVED

June 18, 2018

SPONSOR

Marty Migliori Specialty Silicone Products 3 McCrea Hill Road Ballston Spa, New York 12020

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 121°C for 1 hour. The test article extracts met the requirements of a USP Plastic Class VI.

APPROVAL

07-11-18

Arizona É. Carter, BS, MBA, ALAT Technical Reviewer