



PEOPLE > SCIENCE > SOLUTIONS

Test Facility  
6750 Wales Road  
Northwood, OH 43619  
419.666.9455

**TEST ARTICLE NAME**

SSP2390-10D

**TEST ARTICLE IDENTIFICATION**

AB-08-066

**TEST ARTICLE PHYSICAL DESCRIPTION**

Clear, 10 durometer, cured silicone 6"X6"  
ASTM Sheets

**TEST ARTICLE RECEIVED**

January 7, 2022

**SPONSOR**

Amelia Berry  
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 cm<sup>2</sup>:20 mL and extracted at 121°C for 1 hour. The test article extracts met the requirements of a USP Plastic Class VI.

APPROVAL

*Sharayah M. Bonner*  
Sharayah M. Bonner, MS  
Senior Technical Reviewer

*03 Mar 2022*  
Date