

# CERTIFICATE OF COMPLIANCE

PEOPLE > SCIENCE > SOLUTIONS

Test Facility 6750 Wales Road Northwood, OH 43619 419.666.9455

**TEST ARTICLE NAME** 

Polypropylene Pellets, YUNGSOX 1024

TEST ARTICLE IDENTIFICATION

YUNGSOX 1024

TEST ARTICLE PHYSICAL DESCRIPTION

Polypropylene

**TEST ARTICLE RECEIVED** 

June 30, 2016

SPONSOR

PEI-I PAO

FORMOSA PLASTICS CORPORATION, PP DIVISION NO. 1 SHIH-HWA 1ST ROAD.LIN-YUAN DISTRICT,

KAOHSIUNG.

KAOHSIUNG, TAIWAN, 832

R.O.C.

# 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 4 g:20 mL and extracted at 70°C for 24 hours. The test article extracts met the requirements of a USP Plastic Class VI.

**APPROVAL** 

Arizona E. Carter, BS, ALAT

Technical Reviewer

0 9-19-16 Date