

CONFIDENTIAL

CERTIFICATE OF COMPLIANCE

PEOPLE > SCIENCE > SOLUTIONS

Test Facility 6750 Wales Road Northwood, OH 43619 419.666.9455

TEST ARTICLE NAME

Polypropylene Pellets, YUNGSOX 1250D

TEST ARTICLE IDENTIFICATION YUNGSOX 1250D

TEST ARTICLE PHYSICAL DESCRIPTION Polypropylene

TEST ARTICLE RECEIVED December 23, 2015 SPONSOR

PEI-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

01-29-16

Arizona E. Čarter, BS, ALAT Technical Reviewer