

CERTIFICATE OF COMPLIANCE

PEOPLE > SCIENCE > SOLUTIONS

Test Facility 6750 Wales Road Northwood, OH 43619 419.666.9455

TEST	ART	ICI F	NA	MF

Polypropylene pellets, Yungsox 5050S

TEST ARTICLE IDENTIFICATION

Not Provided

TEST ARTICLE PHYSICAL DESCRIPTION

Polypropylene

TEST ARTICLE RECEIVED

September 16, 2013

SPONSOR

Yao-Tsung Hsieh
Formosa Plastics Corporation
No. 1 Hsin-Hwa 1st Road Lin-Yuan District
Kaohsiung City,
Taiwan

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

Date

P.O. No.: 75708007 Prepaid 100813 Lab Number: 13T_48552_11

TCLAS_VI7

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