

TEST ARTICLE NAME

PEOPLE > SCIENCE > SOLUTIONS

Test Facility 6750 Wales Road Northwood, OH 43619 419.666.9455

Polypropylene pellets, Yungsox 5050M

TEST ARTICLE IDENTIFICATION

not supplied

TEST ARTICLE PHYSICAL DESCRIPTION

Polypropylene

TEST ARTICLE RECEIVED

June 1, 2012

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

APPROVAL

Technical Reviewer

P.O. No.: 75708007 Lab Number: 12T_37488_11 TCLAS_VI7

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