

CERTIFICATE OF COMPLIANCE

PEOPLE > SCIENCE > SOLUTIONS

Test Facility 6750 Wales Road Northwood, OH 43619 419.666.9455

TEST ARTICLE NAME

TAIRIPRO K4650

TEST ARTICLE IDENTIFICATION

FCFC K4650

TEST ARTICLE PHYSICAL DESCRIPTION

semitransparent pellet

TEST ARTICLE RECEIVED

July 28, 2015

SPONSOR

Yung-hung Peng

Formosa Chemicals & Fibre Corporation

Plastics Division, Room 105

No. 201

Tung Hwa North Road

Taipei, Taiwan, 105

Republic of China

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

Theresa A. Ford-Wells, BA, RVT, LATG

Medical Research Manager

Date