



Solvantum MedTech OEM

Product clinical data summary

Product Name: Solvantum™ Hi-Tack Medical Transfer Adhesive 1504XL

Effective: June 2017

Hi-Tack Medical Transfer Adhesive 1504XL has been subjected to the following safety evaluation:

Repeated Insult Patch Test (Draize) in Humans

Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States. (study number I2MS 05-010284 05-055)

Results: Material did not indicate potential for dermal irritation or allergic contact sensitization.

A compositionally similar product, MSX-6069 aka MSX-6082, was tested and produced the following results:

In Vitro Cytotoxicity (Agar Overlay)

Protocol reference: Guess, W. L. et al; "Agar Diffusion Method for Toxicity Screening of Plastics on Cultured Cell Monolayers" J. Pharm. Sci. 54:1545-1547 (1965). (study number TDID 2640 04-129 I2MS 05-010171)

Results: Not cytotoxic

Acute Primary Skin Irritation in Albino Rabbits

Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States. (study number TDID 2640 04-129 I2MS 05-010172)

Results: Primary Irritation Index = 0, not a dermal irritant

These tests are in accordance with the ISO 10993 Part-1 "Biological Evaluation of Medical Devices", as put forth by the FDA.

It is the responsibility of our customers to determine final suitability of our products for their application. Final testing of a converted device made with this material is the responsibility of the customer.