



MedTech OEM

Product clinical data summary

Product Name: Solventum™ Medical Tape 9877

Effective: January 1996

Medical Tape 9877 on Liner have been subjected to the following safety evaluations:

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).

Results: 0.0/0.0

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.

Results: 0.5/8.0

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 Official of the United States.

Results: No potential for the induction of allergic contact dermatitis.

These tests are in accordance with the ISO 10993 Part-1, "Biological Evaluation of Medical Devices", as put forth by the FDA. No. 9877 has satisfied the requirements for devices in contact with intact skin for short term application (up to 29 days). All laboratory testing was conducted in accordance with the FDA Good Laboratory Practices Regulations of 1978.

The use of the term "hypoallergenic" has come to indicate a product which is non-sensitizing to the general public. The hypoallergenic claim for this product is supported by clinical evaluation using the repeated insult patch test in humans, commonly known as the Draize test. This protocol involves repeated application of samples on 200 healthy volunteers for a 2- to 3- week induction period, followed by a 2-week rest period and a challenge application. To be termed hypoallergenic, Solventum Medical Specialties products are required to show no evidence of sensitization potential under these test conditions.

It is the responsibility of our customers to determine final suitability of our products for their application.