



## **Solventum MedTech OEM**

### **Product clinical data summary**

Product Name: Solventum™ Medical Film 9832F

Effective: February 2010

Medical Film 9832F as part of a tape construction with adhesive, and a different liner, has 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). Study number MRFE 5956

**Results:** 0.0/0.0

#### **Acute Intracutaneous 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. MRFE 05956

**Results:** No leachable toxic substances.

#### **Acute Systemic Toxicity in Albino Mice**

Protocol reference: U.S. Pharmacopoeia XXII, 1990, pg. 1499. Study #MRFE 05956

**Results:** No toxic leachables.

#### **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 # MRFE 05952

**Results:** No subjects showed evidence of sensitization. Low potential for sensitization as demonstrated in this evaluation.

These tests are in accordance with the ISO 10993 -1 "Biological Evaluation of Medical Devices", as put forth by the FDA. Medical Film 9832F has satisfied the requirements for devices in contact with intact skin for short-term application (up to 29 days).

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

**Solventum MedTech OEM**

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