**Solventum MedTech OEM**
**Product clinical data summary**
Product Name: Solventum Medical Tape 9832W
Effective: August 2005

A similar composition to Solventum Medical Tape 9832W, with a different carrier, has been subjected to the following safety evaluations:

***In Vitro* Cytotoxicity (Agar Overlay)**
The 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

*Study number MRFE 5956*

**Acute Intracutaneous Irritation in Albino Rabbits**
An 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: No leachable toxic substances.

*Study number MRFE 05956*

**Acute Systemic Toxicity in Albino Mice**
Protocol reference: U.S. Pharmacopoeia XXII, 1990, pg. 1499.
Results: No toxic leachables.

*Study number MRFE 05956*

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

*Study number MRFE 05952*

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

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, 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.**

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