Medical Materials & Technologies
3M Health Care

3M Center
St. Paul, MN 55144-1000
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3M PRODUCT CLINICAL DATA SUMMARY
Product Number 9841
3M Polyurethane Tape on Liner
Effective: June 1997

3M Medical Materials and Technologies Product 9841 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).
Results: 0.0/0.0

Acute Primary Skin Irritation on 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: 1.2/8.0.

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.
Results: No leachable toxic substances.

Acute Systemic Toxicity in Albino Mice
Protocol reference: U.S. Pharmacopoeia XXII, 1990, pg. 1499.
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.
Results: No subjects showed evidence of sensitization.
Low potential for sensitization as demonstrated in this evaluation.

21 Day Cumulative Irritation Test 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 untoward effects were observed with any of the subjects entered in this study.

These tests are in accordance with the ISO 10933 Part-1 "Biological Evaluation of Medical Devices", as put forth by the FDA. Product Number 9841 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 the final suitability of our products for their application.