Medical Specialties
3M Health Care

3M Center
St. Paul, MN 55144-1000
651 733 1110

PRODUCT CLINICAL DATA SUMMARY
Product Number 9943
3M brand Hydrocolloid Adhesive Tape
Effective: September 2002

3M Product Number 9943, without the backing, 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: .5/0.5

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: 1.3/8.0.

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 irritating leachables.

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

In Vitro Hemolysis
Protocol reference: Autian, J. Toxicological Evaluation of Biomaterials, Artif. Organs. 1, 53-60, 1970.
Results: Slightly hemolytic.

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.

21-day Cumulative Irritation 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: Consistent with responses characteristic of this type of test. Now untoward effects were observed with any of the subjects entered into this study.

These tests are in accordance with the ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, as put forth by the FDA. Product Number 9943 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 Regulation of 1978 and in accordance with OECD guidelines.

The use of the term "hypoallergenic" has come to indicate a product that 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, 3M 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 the final suitability of our products for their application.