Medical Specialties
3M Health Care

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

PRODUCT CLINICAL DATA SUMMARY
NO. 1522
3M Double Coated Medical Tape
Effective: January 1996

No. 1522 3M Double Coated Medical Tape 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

In Vitro Hemolysis
Protocol reference: Autian, J. Toxicological Evaluation of Biomaterials, Artif. Organs 1, 53-60, 1977.
Results: Contains no components which are leachable in saline.

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: 1.0/8.0

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 Officials of the United States.
Results: No evidence of contact 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: Historically safe levels.

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In addition, the adhesive used in No. 1522 has been subjected to the following safety evaluations:

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 components.

Acute Systemic Toxicity in Albino Mice
Protocol reference: U.S. Pharmacopeia XXII, 1990, pg. 1499.
Results: No leachable components.

These tests are in accordance with the ISO 10993 Part-1 "Biological Evaluation of Medical Devices", as put forth by the FDA. No. 1522 has satisfied the requirements for devices in contact with intact skin for short term application (up to 29 days). The evaluation of the adhesive also satisfies the biological test requirements for USP Class V plastics.

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, 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.