



PRODUCT CLINICAL DATA SUMMARY

NO. 1538

3M Woven Medical Tape

Effective: January 1996

No. 1538 3M Woven 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: 1.0/0.5

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: 0.7/8.0

Modified Buehler Sensitization in Guinea Pigs

Protocol reference: Buehler, E.V.; Delayed Contact Hypersensitivity in the Guinea Pig, Arch. Dermat. 91:171 (1965).

Results: Weak sensitizer.

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 induced 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: Consistent with responses characteristic of adhesive material; within historically acceptable levels for surgical tapes.

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These tests are in accordance with the ISO 10993 Part-1 "Biological Evaluation of Medical Devices", as put forth by the FDA. No. 1538 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.

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.