



PRODUCT CLINICAL DATA SUMMARY

3M No. 9907T

3M Tan Breathable Elastic Nonwoven Tape

Effective: May 2000

3M No. 9907T, Tan Breathable Elastic Nonwoven Tape, has been subjected to the following safety evaluations:

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. (LIMS 8350)

Results: Cumulative Score "CI" 847/693 Grand average irritation score = 1.22

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. (LIMS 8349)

Results: No evidence of induced contact sensitization.

These tests are in accordance with the ISO 10933 Part-1 "Biological Evaluation of Medical Devices", as put forth by the FDA. 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.