



## **PRODUCT CLINICAL DATA SUMMARY**

**Number 1527**

**3M Plastic Medical Tape**

**Effective: October 2009**

Product 1527 has been subjected to the following studies:

### **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. 3M Study # LIMS 09525

**Results:** No evidence of induced contact hypersensitization.

### **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). 3M Study # I2MS 05-010216

Results: Not toxic

### **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. 3M Study # LIMS 09525

**Results:** No experimental irritation

These tests are in accordance with the ISO 10993 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.

It is the responsibility of our customers to determine the final suitability of our products for their application.