



PRODUCT CLINICAL DATA SUMMARY

Product Number 9832F

3M Polyurethane Film on White Carrier

Effective: February 2010

The film as part of a tape construction with adhesive, and a different liner, 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). 3M Study number MRFE 5956

Results: 0.0/0.0

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. MRFE 05956

Results: No leachable toxic substances.

Acute Systemic Toxicity in Albino Mice

Protocol reference: U.S. Pharmacopoeia XXII, 1990, pg. 1499. 3M Study number MRFE 05956

Results: No toxic leachables.

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 # MRFE 05952

Results: No subjects showed evidence of sensitization.

Low potential for sensitization as demonstrated in this evaluation.

These tests are in accordance with the ISO 10993 -1 "Biological Evaluation of Medical Devices", as put forth by the FDA. Product Number 9832 has satisfied the requirements for devices in contact with intact skin for short-term application (up to 29 days).

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