



PRODUCT CLINICAL DATA SUMMARY

Product Number 9945

3M Hydrocolloid Adhesive Tape

Effective: February 2005

A structurally similar product, using a different backing, 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 # : MRFE 05798)

Results: 1.0/1.0

Acute Primary Skin Irritation on 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. (3M Study # MRFE 05798)

Results: 1.5/8.0.

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. (3M Study # MRFE 05798)

Results: No irritating leachables in test mediums, irritating when injected intracutaneously`

Acute Systemic Toxicity in Albino Mice

Protocol reference: U.S. Pharmacopoeia XXII, 1990, pg. 1499.

<88> Biological Reactivity Tests, In Vivo, Fifth Supplement, USP XXII-NF XVII, 1990. (3M Study # MRFE 05798)

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 05794)

Results: No subjects showed evidence of sensitization.

These tests are in accordance with the ISO 10993 Part-1 "Biological Evaluation of Medical Devices", which is recognized by the FDA as a consensus standard, to demonstrate biocompatibility.

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