



PRODUCT CLINICAL DATA SUMMARY

NO. 9776

3M Foam Medical Tape

Effective: March 2002

The adhesive on No. 9776 3M Tan Foam Medical Tape, used with a similar foam 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).

Results: 0.0/0.0

Repeat 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: 0.0/8.0

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 allergic contact dermatitis or untoward effects observed.

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: Results were consistent with responses characteristic of adhesive materials; no untoward effects.

In addition, the foam alone has been subjected to the following tests:

Primary Skin Irritation Test (FHSA) – non-irritating

Ocular Irritation Study (USP/NF) – no evidence of significant eye irritation

Cytotoxicity- Agarose Overlay, Solid – non-cytotoxic

These tests are in accordance with the ISO 10993 Part-1 "Biological Evaluation of Medical Devices", as put forth by the FDA. The adhesive used with No. 9776 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.

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