Medical Specialties
3M Health Care

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PRODUCT CLINICAL DATA SUMMARY
NO. 9776
3M Foam Medical Tape
Effective: March 2002

The adhesive on No. 9776 3M 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
Cytotocicity- 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.

The use of the term "hypoallergenic" has come to indicate a product that 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.