



## **Solventum MedTech OEM**

### **Product clinical data summary**

Solventum™ Medical Foam Tape 9776

Effective: March 2002

The adhesive on Medical Foam Tape 9776, 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.**

## **Solventum MedTech OEM**

**Phone** 1-800-742-1994

**Web** [go.Solventum.com/MedTechOEM](https://go.Solventum.com/MedTechOEM)

© Solventum 2025. Solventum, the S logo and other trademarks are trademarks of Solventum or its affiliates.

791988