



PRODUCT CLINICAL DATA SUMMARY

NO. 9956

3M Polyester Medical Release Liner

Effective: January 1996

No. 9956 3M Polyester Medical Release 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).

Results: 0.0/0.0

Primary 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: 0.2/8.0

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.

Results: Does not contain components leachable and irritating when injected intracutaneously.

Acute Systemic Toxicity in Albino Mice

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

Results: Does not contain any components leachable in saline, cottonseed oil, 1:20 ethanol:saline, or PEG 400 which are toxic when injected systemically into mice.

This evaluation satisfies the USP Class V biological test requirements for plastics. 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.