Medical Specialties
3M Health Care

3M Company
St. Paul, Minnesota 55144-1000

PRODUCT CLINICAL DATA SUMMARY
NO. 9962
3M Anti-fog Film
Effective: April 1996
Revised: November 2005 to add 3M study reference numbers.

No. 9962 3M Anti-fog Film 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 # 00571.
Results: 0.25/0.25

Acute Primary Skin Irritation in Albino Rabbits
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 # 00571.
Results: 0.3/8.0

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. 3M Study # 00571.
Results: Does not contain components which are leachable and are irritating when injected intracutaneously.

Acute Eye 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 # HRFE 00632.
Results: No irritation.

These tests are in accordance with the ISO 10993 Part-1 "Biological Evaluation of Medical Devices", as put forth by the FDA. No. 9962 has satisfied the requirements for devices in contact with intact skin for short term application. 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.