

**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Product Description

Catalog Number: 3345

Product Description: Breathable Sealing Film for Tissue Culture Plates

Component Materials:

Sealing Film - White Rayon non-woven

Sterilization:

The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization*.

Sterility Assurance Level: SAL 10⁻⁶

Endotoxin (pyrogen) Testing:

The product has been tested according to ANSI/AAMI ST 72:2002[(R)2010] *Bacterial endotoxins test methodologies, routine monitoring and alternatives to batch testing*. No pyrogens were detected.

Results: Test sample extraction had an undetectable level of endotoxin at 0.05 EU/mL

RNase/DNase Testing:

This product has been tested and is free of any detectable RNase/DNase contamination.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest revision of EMEA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Visual Attributes: Visual examination of the product.

Peel Test: Inspection for peel uniformity.

Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date, start of manufacturing; Next 2 digits - Year of manufacture; Last 3 digits - Batch identification.

Rev No: 1