NxFlex™ F4000D1 Film

PRODUCT DESCRIPTION

NxFlex F4000D1 is a medical grade, 5-Layer film specifically designed for bioprocess applications such as large 2-D Pillow Bags (50L and larger) and for 3-D bioprocess containers. This film utilizes an extremely inert PE solution contact layer to minimize extractables. This film has been developed for clarity, high mechanical performance, puncture and tear resistance, and bio-compatibility.

FILM CONSTRUCTION

The Inner solution contact layer, is a highly inert, medical grade polyethylene (PE) custom formulated with the purpose of minimizing extractables. An additional thin tie layer is incorporated in this composite film during lamination.

To minimize gas diffusion, a layer of polyethylene vinyl alcohol copolymers (EVOH) is coextruded between a PA (Nylon) layer and a layer of medical grade polyethylene (PE) to provide excellent gas barrier properties.

The Outer, non-contact strength layer is the polyamide (Nylon) surface that is coextruded with the EVOH and medical grade polyethylene (PE) layers.

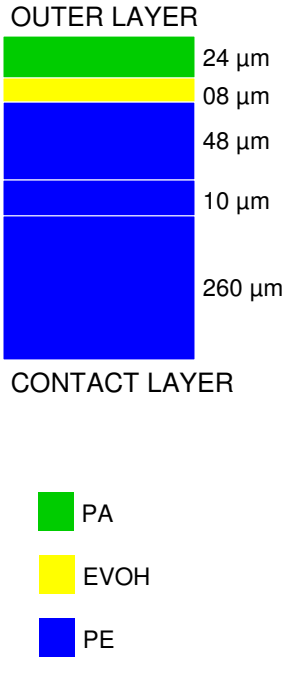
This 5-layer composite construction creates a visually clear and flexible film with very high mechanical strength and good impact and tear resistance. This film offers an excellent solution for large BPC's that require the most inert solution contact layer for the highest bio-compatibility requirements.

VALIDATION

All NxFlex™ films undergo extensive physical and biocompatibility testing before release. We supply a Certificate of Conformance with each shipment to ensure adherence to specifications and for lot traceability.

ANIMAL DERIVED COMPONENT FREE

In the production of NxFlex™ films, no animal derived components or materials are used in the manufacturing process. The films are considered safe for use in food and bio-pharmaceutical applications.



Physical Data Characteristics		
PROPERTY	**TEST PROTOCOL**	**AVERAGE VALUES**
Film Gauge		350 µm
Tensile Strength (MD) (N/15mm)	ASTM D882	80.4 N/15mm
Tensile Strength (TD) (N/15mm)	ASTM D882	76.9 N/15mm
Ultimate Elongation (MD)(%)	ASTM D882	406%
Ultimate Elongation (TD)(%)	ASTM D882	481%
Oxygen Transmission Rate	ASTM D3985	1.46 cc/m^2/day
Moisture Vapor Transmission Rate	ASTM F1249	1.06 g/m^2 /day
Solution Contact Material		PE
Temperature Range		0ºC to 60ºC
Sterilizable Range		25kGy to 50kGy

Biocompatibility Data (Post Gamma Irradiation @ min. 25kGy)*		
PROPERTY	**TEST PROTOCOL**	**AVERAGE VALUES**
USP Class VI	USP 26 <88>	Pass
Cytotoxicity	USP 26 <87>	Pass
Non Volatile Residue	USP 26 <661>	<2 mg
Heavy Metals	USP 26 <661>	<1 ppm
Buffering Capacity	USP 26 <661>	<1 mL

* All biocompatibility testing performed by Toxikon Corporation, Bedford, MA.

RIM Bio, Inc.

Single Use BioProcess Containers

Phone: 206-362-3992
Email: info@rimbio.com
Web: www.rimbio.com