O SEE NEXCEL®

BI01250

Precision Crafted for Diverse Bioprocessing Container Needs

TECHNICAL DATA SHEET - PROVISIONAL

SEE[®] NEXCEL[®] brand BI01250 is a cutting-edge coextruded material designed to redefine bioprocessing container performance for biopharma companies, suppliers, and system integrators.

Designed with a profound understanding of bioprocessing fundamentals, this film champions process excellence across a spectrum of bioprocessing, storage, sampling, and harvest situations—whether with mammalian cells or within the precision-driven domain of cell and gene therapy.

Leveraging a 10-layer architecture, NEXCEL® brand BI01250 is designed to excel across a range of critical performance parameters. Its extreme inertness ensures nothing interferes with the purity of the cell structure and resulting protein harvest. Maximum control of extractables and leachables enables greater yields of protein during upstream bioprocessing.



The film's robust exterior resists stress whitening, scuffs, and scratches to reduce the risk of unnecessary rejection. Additional benefits of this film include:

- Optimal seal strength and a wide sealing window
- Compatibility across a large range of port, tube, and connector configurations
- Redundant barrier layers that fortify control of oxygen transmission
- High performance even at temperatures reaching -80°C

Ultra-clean interior film technology is available in double wound or collapsed tubing format for potential automation in bag making and bioprocess design. Single wound is also available.

With NEXCEL® brand BI01250, excellence becomes the standard.

TYPICAL APPLICATIONS	2D	3D
Buffer Filtration & Storage Bag	•	•
Buffer Preparation Bag	•	•
Bulk Storage Bag		•
Cell Expansion Bag	•	•
Collection Bag	•	
Cryopreservation Bag	•	
Media Bag	•	•
Powder Containment	•	
Rocker Bag	•	
Sampling Bag	•	
Storage/Shipping Bag	•	•

BAG FORMATS

CONSTRUCTION:

Clear, coextruded 10-layer polyethylene-based film with EVOH barrier and no animal derived ingredients. Designed with raw materials free of PFAS processing aids and Irgafos[®] 168.

QUALITY:

Manufactured in ISO Class 7 cleanroom under ISO 15378 Quality System: Primary Packaging Materials For Medicinal Products - Particular Requirements For The Application Of ISO 9001:2015, With Reference To Good Manufacturing Practice (GMP).

BIOCOMPATIBILITY

PROPERTY	TEST STANDARD	RESULT
Bacterial Endotoxin	Bacterial Endotoxin	Pass
In-Vitro Cytotoxicity	In-Vitro Cytotoxicity	Pass
In-Vivo Cytotoxicity (USP Class VI)	In-Vivo Cytotoxicity (USP Class VI)	In Progress
Extractables	Extractables	Upon Request
Cell Culture	Cell Culture	Pass
Manufacturing Environment	Manufacturing Environment	ISO Class 7

PHYSICAL PROPERTIES

PROPERTY	TEST STANDARD	UNIT	RESULT
Standard Thickness (Gauge)	ASTM D6988	μm	318
Tensile Strength (L)	ASTM D882	MPa	18
Tensile Strength (T)	ASTM D882	MPa	17
Elongation at Break (L)	ASTM D882	%	>350
Elongation at Break (T)	ASTM D882	%	>350
Modulus (L)	ASTM D882	MPa	340
Modulus (T)	ASTM D882	MPa	360
02 TR (at 23°C, 0% RH, Bar)*	ASTM D3985	cm3/m2/24 hr.	< 0.2
CO2 TR (at 23°C, 0% RH, Bar)*	ASTM D3985	cm3/m2/24 hr.	< 1.0
MVTR (at 38°C, 100% RH, Bar)	ASTM F1249	g/m2/24 hr.	2.0
Haze	ASTM D1003	%	30
Basis Weight	ASTM D646	g/m2	294
Density	-	g/cm2	0.95
Break at Cold Temperature	ISO 8570	°C	< -80
Sealing Range Hot Bar†	Internal	°C	130-170
Sealing Range Impulse†	Internal	°C	160-200
Permanent Seal Strength†	ASTM F88	N/25mm	125
Roll Width	-	mm	1380 Max‡
Roll Length	-	m	200 Max‡
Core Diameter (ID)	-	mm	153.8
Scratch Resistance	Internal	Internal	+++
Pinhole Resistance	Gelbo Flex	Cycles	>4000, Pass
Sterilization by Gamma Irradiation	-	50 kGy	Pass
Leak Testing	Custom	2000L, Supported	30 Days

*Lowest detection limit | †Sealing range and seal strength can be affected by individual sealing parameters | ‡Max value for single wound

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For more information, please visit www.sealedair.com

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