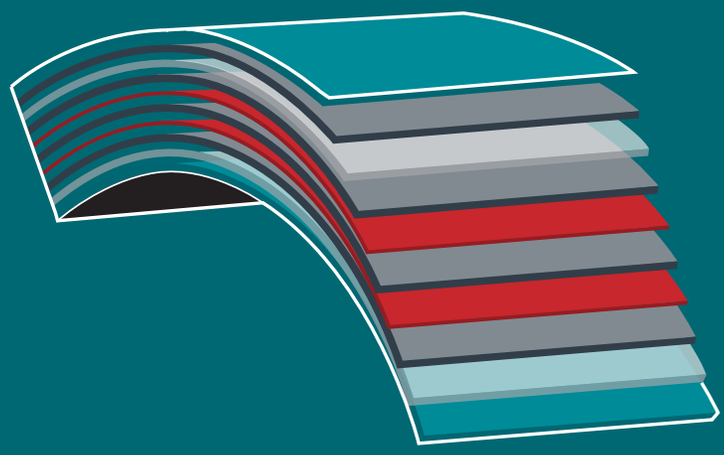
SEE® | NEXCEL®

# BIO1250

## Precision Crafted for Diverse Bioprocessing Container Needs



### TECHNICAL DATA SHEET – PROVISIONAL

SEE® NEXCEL® brand BIO1250 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 BIO1250 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 BIO1250, excellence becomes the standard.

**BAG FORMATS**

| 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 | • | • |

**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 |
| O2 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



For more information, please visit **www.sealedair.com**