



DuraPure™ C93 Bioprocess container systems

- Single-use liquid handling systems
- Customized for your requirements

Parker domnick hunter has expanded its DuraPure™ C93 single ply bioprocess container line into an integrated fluid-handling system designed for durability and purity.

Each system is designed to seamlessly integrate with the rest of your process, whether it is going from media prep to cell culture, or ultrafiltration to final fill.

DuraPure™ C93 film is a high clarity medical film designed to provide the best combination of strength, flexibility, gas barrier and low extractables. The product contact layer of this 5-layer film is ultra low density polyethylene (ULDPE). The gas barrier layer is ethylene vinyl alcohol (EVOH). The recommended working temperature range of DuraPure™ C93 film is 0 °C to 60 °C, but it has been used in applications for short term exposures at temperatures less than -45 °C and up to 80 °C.

Features and Benefits

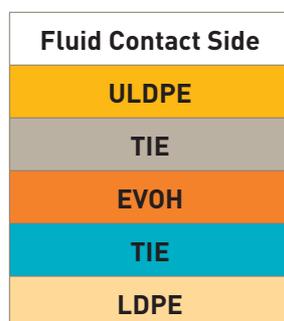
- 2D & 3D DuraPure™ C93 containers are available in 50ml to 2000L sizes
- A range of ports is available from 1/8" to 1"
- mitos-P platinum-cured silicone tubing with molded junctions and sanitary fittings, or TPE tubing and fittings
- DuraPure™ C93 bioprocessing containers are manufactured free from known animal derived components
- All materials used in the manufacture of the DuraPure™ C93 BPCs are fully traceable
- DuraPure™ C93 BPCs can be gamma irradiated
- Storing at room temperature [-65-70 °F] is recommended for DuraPure™ C93 BPCs. Shelf-life: physical property test data is available for product stored after irradiation
- Manufactured in a Class 7 (10,000) cleanroom



Note: DuraPure™ is a trademark of Parker Hannifin Corporation.

DuraPure™ C93 film is a 5-layer co-extruded film

The 5 co-extruded layers of the 13 mil, (0.325 mm) thick DuraPure™ C93 film are shown at right. Ultra low density polyethylene is the fluid contact layer, ethylene vinyl alcohol is the gas barrier layer, and low density polyethylene is the outer layer. Together, these layers offer the best combination of strength, flexibility, gas barrier and low extractables.



Purity

USP Class VI
LAL testing
Systemic toxicity testing
Intracutaneous reactivity testing
Muscle implantation testing
Extremely good extractables profile
Clean room manufacturing

System Integration

Peristaltic pumps
Filters
Sampling systems
Sensors

Specifications

Mechanical properties of DuraPure™ C93 BPC film

Mechanical properties:

- Film thickness: 0.325mm
- Specific gravity: ASTM D-792 0.9 g/cm³
- Film strength:
 - Tensile strength: ASTM D-882 13.5 MPa
 - Elongation: ASTM D-882 290%
 - Elastic modulus: ASTM D-882 360 MPa
- Optical properties:
 - Haze: ASTM D-1003 7%
 - Clarity: ASTM D-1003 97%
 - Transmittance: ASTM D-1003 93%
- Barrier:
 - Water vapor transmission rate: ASTM F-1249 0.33 g / (m²*day)
 - Oxygen permeability: ASTM D-3985 <0.05 cm³ / (m²*day*atm)
 - Carbon dioxide permeability: ASTM F-2476 <0.02 cm³ / (m²*day*atm)

Biocompatibility and physicochemical test results

Test Description	Test Reference	Results for Gamma-Irradiated DuraPure C93 Film
Biocompatibility tests		
USP VI for plastic	USP <88>	Pass
Hemolysis test	ISO 10993-4	Pass
Cytotoxicity	USP <87>	Pass
Implantation test	ISO 10993-6	Pass
Irritation & sensitization	ISO 10993-10	Pass
Acute systemic toxicity test	ISO 10993-11	Pass
Physicochemical tests		
Physicochemical test for plastics	USP <661>	Pass
European Pharmacopoeia 3.1.5	EP 5, 2005 chapter 3.1.5	Pass
LAL bacterial endotoxins assay	USP <85>	Report

Summary of extractables results for DuraPure™ C93 BPC*

	Volatile Extractables	Semi-Volatile & Non-Volatile Extractables	Acetate & Formate
Water	None detected	• Stabilizer: 0.5 ppm	Formate: None detected Acetate: 0.7 ppm
PBS, pH 3	Acetaldehyde: 0.15 ppm	• Fatty acid slip agents: 15 ppm e.g. Hexanoic acid at 8 ppm • Polyethylene constituents: 0.8 ppm e.g. 2-Octanone at 0.5 ppm • Stabilizers: 0.3 ppm	Formate: 1.4 ppm Acetate: 7.6 ppm
PBS, pH 10	None detected	• Fatty acid slip agents: 1.1 ppm • Polyethylene constituents: 0.3 ppm • Stabilizers: 1ppm e.g. Irgafos at 0.7 ppm	Formate: 1.8 ppm Acetate: 8.0 ppm
10% Ethanol	Acetaldehyde: 3.0 ppm	• Fatty acid slip agents: 20.5 ppm • Polyethylene constituents: 1.4 ppm • Stabilizers: 1ppm	Formate: 0.2 ppm Acetate: 0.2 ppm

* The data shown is derived from a gamma irradiated, complete bioprocessing system, including representative tubing, connectors and elastomers. Extraction volume: 500 mL. Surface area: 1150 cm². Extractions were conducted under accelerated conditions for 91 days at 40 °C, with water: PBS, pH3; PBS, pH 10; or 10% ethanol, to simulate 2 year exposure. Please note, although values are quantitative, they are meant to be qualitative as a starting point for customer leachables studies.

Detailed data and test reports are available upon request. Please contact your local Parker domnick hunter representative.

Services

Samples and prototypes of BPCs to fit your application are available upon request.

Open Architecture allows us to work with existing specifications or upgrade to fit your application needs.

Regulatory statements

Statement Available	Result
REACH Compliant	Yes
RoHS Compliant	Yes
Drug Master File (Listing numbers available)	Yes
Latex	No
Phthalates	No
PVC	No
Animal Derived Components	No

Parker domnick hunter technologies can be combined to produce integrated solutions that will speed up development times, increase efficiency and safety, and guarantee reproducible product quality. Visit www.parker.com/dhsingleuse



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