## Corning Incorporated Life Sciences

Registered ISO 9001

-

6.40 in.

# **Product Description**

Catalog Number:

431281

Product Description:

Corning® 2 Liter disposable Erlenmeyer flask, PETG, baffled bottom, 6/case

Virgin PETC, month	USP Class VI requirements for	plactic c	containare and	
	USF, Class VI requirements for	plastic c		
Virgin Polypropylene, closures. Heavy meta 0.2 µM microporous I containers and closu	al free (meets <i>CONEG</i> red.) colo PTFE membrane, meets <i>USP, C</i> res. Thermoplastic elastomer lin	or conce <i>Class VI</i>	ntrate. requirements	for plastic
- 11.33 in.	Diameter of cap	-	2.12 in.	
	closures. Virgin Polypropylene closures. Heavy meta 0.2 μM microporous containers and closu requirements for plas	<ul> <li>closures.</li> <li>Virgin Polypropylene, meets USP, Class VI requirem closures. Heavy metal free (meets CONEG req.) cold 0.2 μM microporous PTFE membrane, meets USP, C containers and closures. Thermoplastic elastomer lin requirements for plastic containers and closures.</li> <li>11.33 in.</li> </ul>	<ul> <li>closures.</li> <li>Virgin Polypropylene, meets USP, Class VI requirements for closures. Heavy metal free (meets CONEG req.) color conce 0.2 μM microporous PTFE membrane, meets USP, Class VI containers and closures. Thermoplastic elastomer liner, mee requirements for plastic containers and closures.</li> <li>11.33 in. Diameter of cap</li> </ul>	<ul> <li>Virgin Polypropylene, meets USP, Class VI requirements for plastic contain closures. Heavy metal free (meets CONEG req.) color concentrate.</li> <li>0.2 μM microporous PTFE membrane, meets USP, Class VI requirements containers and closures. Thermoplastic elastomer liner, meets USP, Class requirements for plastic containers and closures.</li> <li>11.33 in. Diameter of cap - 2.12 in.</li> </ul>

### widest point Sterilization:

The product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (TIR 33) Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization. Sterility Assurance Level: SAL 10<sup>-6</sup>

Tolerances

+/- 0.05 in.

#### Pyrogens:

The product has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72: Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing. Results: less than 0.1EU/mL.

#### **RNase/DNase Testing:**

Diameter of flask @

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

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy: This product has been deemed animal free by virtue of not containing materials of animal origin and/or complies with the latest revision of EMA/410/01 section 6.4.

#### **Performance Testing:**

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures. Inverted leak test with an alcohol based solution. Integrity Testing: Visual Attributes: Visual examination of the product. Packaging: Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

#### Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date, start of manufacturing; Next 2 digits - Year of manufacture; Last 3 digits - Run number for that year.

**Revision Date:** 04-14-20

Rev No: 2