Corning Incorporated
Life Sciences

Registered
ISO 9001

Product Description

Catalog Number: **4616**

Product Description: **Corning ® Ultra Low Attachment, 25 cm² cell culture flask, canted neck, anti-tip skirt, vent cap**

Component Materials:

Flask	-	Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
Cap	-	Virgin High Density Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate. 0.2 μM microporous PTFE membrane, meets *USP, Class VI* requirements for plastic containers and closures.
Surface	-	Proprietary hydrogel.

Product Dimensions:

Length w/cap	-	3.78 in.	Height (depth)	-	1.03 in.
Width	-	2.06 in.	Tolerances	-	+/-0.05 in.

Sterilization:
This product is irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization.*
Sterility Assurance Level: SAL 10^{-3}

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: $\leq$ 0.1 EU/mL ($\leq$ 4EU/device)

Surface Characterization:
Surface is characterized to be hydrophilic and neutrally charged, composed of a covalently bound hydrogel layer that is biologically inert and non-degradable. This surface composition has been optimized for cell attachment inhibition.

Cell Attachment and Growth Characteristics:
The product has been tested for the attribute of cell attachment inhibition utilizing an attachment- dependent mammalian cell line in a serum supplemented media. Cell attachment inhibition must be $\geq$ 98% as compared to a standard tissue culture treated surface.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:
This product complies with the latest revision of EMEA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

Performance Testing:
Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Integrity Testing:	Forward pressurization of the product to 10 inches of water column.
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 - Batch identification.

Revision Date:
07-22-20

Rev No: 1