Corning Incorporated Life Sciences

Registered ISO 9001:2008

Product Description

Catalog Number: 431533

Product Description: Corning® Storage Bottle, 1 L, Square, PET,

with HDPE Screw Cap

Component Materials:

Bottle - PET, clear, non-cytotoxic, meets USP, Class VI requirements for plastic containers and

closures.

Cap - HDPE, orange, non-cytotoxic, colorant is heavy metal free per CONEG requirements.

Attributes:

Capacity - 1000 mL; Tolerance: ± 50 mL

Product Dimensions - 214 mm Height (w/o cap); 92 mm Width;

37 mm Neck ID; 49 mm Cap OD

Autoclaving:

This product is not suitable for autoclaving.

Heating / Cooling:

This product is designed for use at temperatures ranging from -40°C to 50°C.

Vacuum / Pressure:

This product is not designed for and is not rated for vacuum or pressure applications.

Sterilization

This product is sterilized using an irradiation method compliant with the requirements of ANSI/AAMI/ISO 11137 to achieve a Sterility Assurance Level (SAL) of 10⁻⁶.

Pyrogens:

This product is tested to meet 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 0.1 EU/mL.

TSE/BSE:

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 and Veterinary Medicinal Product* by virtue that any component of the product which may include use of tallow derivatives has been processed per the specific conditions of section 6.4 of EMEA/410/01.

Lot Number Designation:

Each production lot is uniquely identified with an 8 digit lot number as follows: First 3 digits - Julian date, start of manufacturing; Next 2 digits - Year of manufacture; Last 3 digits - Batch identification.

Revision Date:

2 April 2013

Rev No: 1