

CORNING GOSSELIN SAS
123 Rue de Caëstre - CS40019
59529 HAZEBROUCK CEDEX
BORRE - FRANCE

Date of certificate : 2021 - 05 - 31

Page : 1/1

Product description

Octagonal bottle, 125 mL PET na graduated H115 Ø31 & tamper-evident screw cap na, 24/filmed pack, STERILE R

Catalogue number

431731

Manufacturing date

2021/02/17

Lot number

777272

Raw material statement

The Substances Bisphenol A, BSE / TSE, latex, and phthalates are not used or intentionally incorporated in the manufacture of the raw materials or final product.

Sterility Assurance Level

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

Non-Pyrogenic -

Tested and met the criteria established in the current version of United States Pharmacopeia (USP) Chapter <85> "Bacterial Endotoxins Test." The acceptance level for product is less than 0.1 EU/ml.

USP Class VI Testing -

All material resin is tested, qualified and shown to be non-toxic as established in the standards USP Class VI Chapter <87>, "Biological reactivity Tests, in Vitro" and Chapter <88>, "Biological Reactivity Tests, in Vivo."

Expiration date

2024/02/01

Expiration statement

This product is designed to have an expiration date of 3 years from the date of manufacture regarding sterility.

Performance testing (AQL)

Inspection based on a statistically significant number of samples towards internal or agreed specifications that determine Assurance Quality Level.



Cédric MAES
Plant Quality Manager, Borre
maesc@corning.com