

CORNING GOSSELIN SAS  
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59529 HAZEBROUCK CEDEX  
BORRE - FRANCE

Date of certificate : 2020 - 03 - 19

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### Product description

*Corning Octagonal PET Bottle, 125mL Graduated, 31mm IATA-Validated Screw Cap Sterile, Pre-assembled, 24/Tray, 48/Case*

### Catalogue number

432331

### Manufacturing date

2019/11/05

### Lot number

728343

### 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<sup>-6</sup>

**Leakproof -** With a torque value of 2,5N.m (22lb.in), this product meets IATA Packaging Instruction 650 requirements to ensure leakproof performance during air transport conditions; however, this is not designed for packaging and transport of UN3373 Biological and Infectious Substances.

**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

2022/11/01

### 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. We confirm that product is compliant with ISO993/USP31 : Non-cytotoxic, Endotoxin-free / non-pyrogenic.*



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