

CORNING GOSSSELIN SAS  
123 Rue de Caëstre - CS40019  
59529 HAZEBROUCK CEDEX  
BORRE - FRANCE  
[www.corning.com/lifesciences](http://www.corning.com/lifesciences)  
Refer to website for regional contact information

Date of certificate : 2022 - 11 - 16

Page 1

### Product description

Corning PET Bottle 500 mL Graduated 31mm Screw Cap validated against IATA, Sterile, Triple-bagged, Pre-assembled, 12/Tra

### Catalogue number

432233

### Manufacturing date

2022/05/01

### Lot number

820401

**Quality Management System** : Complies with the current version of the ISO9001 standard

### 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

2025/05/01

### 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 to internal or agreed specifications that determine Assurance Quality Level. We confirm that product is compliant with ISO993/USP31 : Non-cytotoxic, Endotoxin-free / non-pyrogenic.*

This product met Corning Incorporated - Life Sciences' high standards of quality at the time of batch/lot release



Hugues Vanderschelden  
Plant Quality Manager, Borre  
[vandersch2@corning.com](mailto:vandersch2@corning.com)