

CORNING GOSSELIN SAS  
123 Route de Caëstre  
59190 - Borre  
FRANCE  
[www.corning.com/lifesciences](http://www.corning.com/lifesciences)  
Refer to website for regional contact information

Date of certificate : 2024 - 10 - 11

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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

2022/10/01

### Lot number

836032

### Quality Management System

Complies with the current version of the ISO9001 standard.

### Sterility Assurance Level

Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, "Sterilization of health care products - Radiation". Products meet a minimum 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 ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing" and USP <85>, "Bacterial Endotoxins Test". The acceptance level for product is No More Than 0.10 EU/ml or No More Than 4 EU/device.

### 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."

**BSE/TSE** : Product complies with the latest revision of EMA/410/10 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

**Quality Control Testing** : Representative production samples are collected and inspected in accordance with current applicable product specifications. Key inspections and inline tests are listed below:

Visual Inspection - Pass  
Packaging Inspection - Pass  
Leak Test - Pass

### Expiration date

2025/10/01

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



Sandra Bianchi  
Plant Quality Manager, Borre  
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### Expiration statement

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

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



Sandra Bianchi

Plant Quality Manager, Borre

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