

Corning Incorporated  
Life Sciences

Registered ISO 9001

## Product description

**Catalog Number**

P500B-12

**PDS reference**

PDS\_Cbor\_32907 Version \_ 1

**Product description**

Corning® Gosselin™ Octagonal PET Bottle, 500 mL, Graduated, 31 mm Tamper-evident Cap, Sterile, Pre-assembled, 12/Tray,

**Sanitary 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>-3</sup>

**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.

**Primary body composition**

PET

**Secondary body composition**

HDPE PHARMA

**Closure**

31 mm Tamper evident Cap

**Special feature**

Pre-assembled

**Packaging**

12/Tray, 120/Case

### **Regulation Statement**

We hereby confirm that we do not intentionally use the following substances in the manufacturing of the product :

- LATEX
- BISPHENOL A (CAS No 80-05-7)
- PHTHALATES as per Regulation 1907/2006/EC (SVHC) .

Raw material suppliers also guarantee the following requirements through certificates of compliance :

- EU Food Contact 1935/2010/EC and 10/2011/EC.

We hereby confirm that we do not intentionally use the following substances in the manufacturing of the product :

pongiform 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.

- Compliance to REACH SVHC candidate list (Regulation 1907/2006/EC). They certify that the here above mentioned products do not contain ore than 0.1% (w/w) of any substance of very high concern listed in the ECHA candidate list in accordance with Article 33 of the Reach egulation, as updated on January 12, 2017.
- Heavy Metals Free as per directive 94/62/EC. The chemical composition of this product meets the relevant requirements of Directive 92/62/EC as amended) on packaging and packaging waste. The sum of the concentration Cd, Cr (VI), Hg and Pb in this product does not exceed 100 ppm

Raw material suppliers also confirm through certificates of compliance that they do not intentionally use the following substances :

- LATEX
- BISPHENOL A (CAS No 80-05-7)
- PHTHALATES as per Regulation 1907/2006/EC (SVHC) .



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