Corning Incorporated
Life Sciences

Registered ISO 9001

Catalog Number	P1000B-50
PDS reference	PDS_Cbor_47090 Version _ 1
Product description	Corning® Gosselin™ Octagonal PET Bottle, 1 L, Graduated, 31 mm Tamper-evident Cap, Sterile, Assembled, 12/Pack, 48/Case

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 10-3

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
Assembled

Packaging
12/Pack, 48/Case

Regulation Statement

We hereby confirm that we and/or our raw materials suppliers 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 1935/2004/EC and 10/2011/EU.
However, our finished products have not been validated for food contact applications. They are designed for laboratory applications only.

- BSE/TSE compliant: the animal origin materials and/ or derived materials were not intentionally used during manufacturing process.
As such, our finished products do not contain substances considered at risk for transmitting BSE/TSE.

- Complies to REACH SVHC candidate list (Regulation 1907/2006/EC). Do not contain more 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 Regulation.

- Heavy Metals as per directive 94/62/EC: meets the relevant requirements on packaging and packaging waste.
The sum of the concentration Cd, Cr (VI), Hg and Pb does not exceed 100 ppm.



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