

Corning Incorporated
Life Sciences

Registered ISO 9001

Catalog Number HP500B-50
PDS reference PDS_Cbor_46609 Version _ 1
Product description Corning® Gosselin™ Water Sampling Octagonal PET Bottle, 500 mL, Graduated, 20 mg/L Sodium Thiosulfate, 31 mm Tamper-evident

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 2 years from the date of manufacture regarding sterility.

Performance testing (AQL)

Inspection based on a statistically significant number of samples towards to internal that determine Assurance Quality Level. Gravimetric dose of thiosulfate Na₂S₂O₃·5H₂O: minimum dose 20mg/L

Primary body composition

PET

Secondary body composition

HDPE PHARMA

Closure

31 mm Tamper-evident Cap

Special feature

20 mg/L Sodium Thiosulfate

Packaging

12/Pack, 120/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
- BISPHEENOL 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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