

Corning Incorporated
Life Sciences

Registered ISO 9001

Catalog Number FV500-04
PDS reference PDS_Cbor_1517 Version _ 2
Product description Corning® Gosselin™ Rectangular HDPE Bottle, 500 mL, Graduated, 20 mm Red Tamper-evident Cap with Shaped Seal, Assembled

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

HDPE

Secondary body composition

LDPE

Closure

20 mm Red Tamper-evident Cap with

Special feature

Assembled

Packaging

170/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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