

Corning Incorporated  
Life Sciences

Registered ISO 9001

**Catalog Number** FC1000-52  
**PDS reference** PDS\_Cbor\_40256 Version \_ 2  
**Product description** Corning® Gosselin™ Square HDPE Bottle, 1 L, Graduated, 28 mm Red Tamper-evident Cap with Shaped Seal, Assembled, Sterile,

**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**

HDPE

**Secondary body composition**

HDPE/LDPE

**Closure**

28 mm Red Tamper-evident Cap with

**Special feature**

Assembled

**Packaging**

77/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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