

Corning Incorporated
Life Sciences

Registered ISO 9001

Product description

Catalog Number

LR500-04

PDS reference

PDS_Cbor_1569 Version _ 1

Product description

Corning® Gosselin™ Round HDPE Bottle, 500 mL, 58 mm Red Cap with Wad, Assembled, Sterile, 140/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

HDPE

Secondary body composition

HDPE

Closure

58 mm Red Cap with Wad

Special feature

Assembled

Packaging

140/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 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, 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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