Registered ISO 9001

#### **Catalog Number** HLC500-11 **PDS reference** PDS\_Cbor\_50580 Version \_ 3 **Product description** Corning® Gosselin™ Water Sampling Square HDPE Bottle, 500 mL, 20 mg/L Sodium Thiosulfate, Tamper-evident label, 55 mm Red Cap with Wad, Sterile, 175/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 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 Na2S2O3.5H2: minimum dose 20mg/L

## Primary body composition HDPE

# Secondary body composition

## Closure

Tamper-evident label, 55 mm Red Cap

## **Special feature**

20 mg/L Sodium Thiosulfate

Packaging 175/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.

**Hugues Vanderschelden** Plant Quality Manager, Borre vandersch2@corning.com