

Corning Incorporated  
Life Sciences

Registered ISO 9001

## Product description

**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-

### **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 that determine Assurance Quality Level. Gravimetric dose of thiosulfate  $\text{Na}_2\text{S}_2\text{O}_3 \cdot 5\text{H}_2\text{O}$ : 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 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 ore 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 egulation, 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

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- LATEX
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