Corning Incorporated Life Sciences

Registered ISO 9001

**Catalog Number** ETAT-05 **PDS reference** PDS\_Cbor\_50223 Version \_ 2 Product description Corning® Gosselin™ T Shaped Spreader, Green PS, Sterile, 50/Bag, 900/Box, 4500/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 and 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 Green PS

Secondary body composition N/a Closure N/a **Special feature** N/a Packaging 50/Bag, 900/Box, 4500/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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