Corning Incorporated Life Sciences

Registered ISO 9001

Catalog Number

BBAG-04 **PDS reference** PDS_Cbor_43347 Version _ 1 **Product description** Corning® Gosselin™ Blender Bag, 400 mL, Lateral Filter, PE, Sterile, 50/Bag, 500/Box, 1500/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 PE

Secondary body composition $N\!\!\!/a$ Closure N/a **Special feature** Lateral Filter Packaging

50/Bag, 500/Box

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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