



Carolina Components Group FlowTainer PC Bottle Regulatory Overview

Date	September 20, 2022
Subject	Regulatory Compliance Statement
Parts Affected	FlowTainer
Resin Material Type	PC
Revision Date	October 6, 2023

USE OF THIS REGULATORY INFORMATION

The information provided as requested is intended to be used for informational purposes only. Carolina Components Group relies on information provided by its suppliers. Carolina Components Group makes no representation or warranty as to the completeness or accuracy of the information contained herein. It is intended for use by persons having technical skill, at their own discretion and risk, who will make their own determination as to its suitability for their purposes prior to use. As with any material, evaluation of compound under end-use conditions prior to specification is essential. Customers must make their own determination that use of this product is safe, lawful, and technically suitable for the intended use.

MANUFACTURING ENVIRONMENT:

ISO 7 Clean room facility (certified operational) in accordance with ISO 14644 principles.

MATERIALS OF CONSTRUCTION:

FlowTainer bottles are manufactured from polycarbonate resin.



Carolina Components Group FlowTainer PC Bottle Regulatory Overview

BIOCOMPATIBILITY:

The resin material used to manufacture FlowTainer bottles is certified to meet USP <88>, Biological Reactivity Tests, Class VI, In Vivo.

The resin material used to manufacture FlowTainer bottles is certified to meet USP <87>, Biological Reactivity Tests, In Vitro

The resin material used to manufacture FlowTainer bottles is non-hemolytic in accordance with ISO 10993-4.

USP <85> BACTERIAL ENDOTOXIN:

The resin material used to manufacture FlowTainer bottles is certified to meet USP <85>, Bacterial Endotoxin.

USP <788> PARTICULATE MATTER IN INJECTIONS:

FlowTainer bottles meet specifications per USP <788>, Particulate Matter In Injections. The number of particles $\geq 5\mu\text{m}$, $10\mu\text{m}$ and $25\mu\text{m}$ in each milliliter of the product shall not exceed 100, 25 and 3, respectively.

PHYSIOCHEMICAL:

The resin material used to manufacture FlowTainer bottles is certified to meet USP <661>, Plastic Packaging Systems and Their Materials of Construction



Carolina Components Group FlowTainer PC Bottle Regulatory Overview

TSE/BSE/ADCF STATEMENT:

No animal products, or by-products, are used in the manufacture of, nor intentionally added to FlowTainer bottle products.

FOOD CONTACT APPLICATIONS:

FlowTainer bottles which are intended for the application of food and beverage processes are compliant to the extractable limits specified in FDA 21 CFR 177.1520 (c) 3.1a. and FDA 21 CFR 177.1580.

REACH/RoHS:

Material used to manufacture FlowTainer bottle products are compliant with REACH/RoHS requirements as indicated in the SVHC Table update 08JUL2021.

LEACHABLES/EXTRACTABLE (L/E) PROFILE:

The polycarbonate resin used to manufacture FlowLinX products as been tested for extractables per the recommended guidelines of the BioPhorum Operations Group (BPOG). Results of the testing are available upon request.

STERILIZATION/SANITIZATION:

FlowTainer bottles may be sterilized/sanitized by Gamma-Irradiation.



Carolina Components Group FlowTainer PC Bottle Regulatory Overview

GAMMA-IRRADIATION COMPATIBILITY:

FlowTainer bottles may be exposed to Gamma-Irradiation up to a total of **45kGy**.

SHELF-LIFE AND STORAGE CONDITIONS STATEMENT:

Non-Sterile and Non-Irradiated FlowTainer bottle Shelf Life is 3 Years from Date of Manufacture when stored away from exposure to direct sunlight within its original product packaging under ambient temperature and humidity conditions. Gamma irradiated product, when stored under the same conditions, will have a 2 Year Shelf Life.

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