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	June 10, 2024

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.

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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 ≥ 5um, 10um and 25um 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

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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.

ALLERGENS:

The material used to manufacture does not contain allergens - as defined by FDA as Milk, Eggs, Fish, Crustaceans, Wheat, Soy, Peanuts, Tree Nuts - in the manufacture or formulation of this product.

NITROSAMINES

Nitrosamines are not intentionally added in the formulation or manufacture of FlowLinX products.

BPA / MELAMINE STATUS:

Neither BPA nor Melamine are used in the formulation or manufacture of the resin product used to manufacture FlowLinX products.

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ELEMENTAL IMPURITIES

Class 1, Class 2, and Class 3 elements highlighted in the ICH Q3D Guideline for elemental impurities were not detected for FlowTainer bottle products.

REACH/RoHS:

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

STERILIZATION/SANITIZATION:

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

GAMMA-IRRADIATION COMPATIBILITY:

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

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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.

Prepared By: Andrea Gijé Date: 06/10/2024

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