



## Carolina Components Group FlowTainer PC Erlenmeyer Flask Overview

Date	August 3, 2023
Subject	Regulatory Compliance Statement
Parts Affected	FlowTainer Flask
Resin Material Type	Polycarbonate
Revision Date	January 30, 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 Erlenmeyer flasks are manufactured from polycarbonate.



## **Carolina Components Group FlowTainer PC Erlenmeyer Flask Overview**

### **BIOCOMPATIBILITY:**

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

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

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

The resin material used to manufacture FlowTainer Erlenmeyer flasks is non-cytotoxic in accordance with ISO 10993-5.

The resin material used to manufacture FlowTainer Erlenmeyer flasks does not cause a reaction after implantation in accordance with ISO 10993-6.

The resin material used to manufacture FlowTainer Erlenmeyer flasks does not cause irritation and skin sensitization in accordance with ISO 10993-10.

The resin material used to manufacture FlowTainer Erlenmeyer flasks does not cause adverse systemic reactions in accordance with ISO 10993-11.

### **USP <85> BACTERIAL ENDOTOXIN:**

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



## **Carolina Components Group FlowTainer PC Erlenmeyer Flask Overview**

### **USP <788> PARTICULATE MATTER IN INJECTIONS:**

FlowTainer Erlenmeyer flasks 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 Erlenmeyer flasks is certified to meet USP <661>, Plastic Packaging Systems and Their Materials of Construction

### **LATEX:**

Latex is not intentionally added in the formulation or manufacture of FlowTainer Erlenmeyer flasks.

### **PHTHALATES:**

Material used to manufacture FlowTainer Erlenmeyer flasks are Phthalate-free.

### **TSE/BSE/ADCF STATEMENT:**

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



## **Carolina Components Group FlowTainer PC Erlenmeyer Flask Overview**

### **NITROSAMINES**

Material used to manufacture FlowTainer Erlenmeyer flasks do not contain nitrosamines, and no nitrosamines are added or brought in during the production process.

### **MELAMINE**

Material used to manufacture FlowTainer Erlenmeyer flasks do not contain melamine, and no melamine is added or brought in during the production process.

### **ELEMENTAL IMPURITIES**

Material used to manufacture FlowTainer Erlenmeyer flasks do not contain elemental impurities, and no elemental impurities are added or brought in during the production process.

### **BISPHENOL-A**

Material used to manufacture FlowTainer Erlenmeyer flasks do not contain Bisphenol-A, and no Bisphenol-A is added or brought in during the production process.

### **REACH/RoHS:**

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



## Carolina Components Group FlowTainer PC Erlenmeyer Flask Overview

### **CONFLICT MINERALS:**

Conflict minerals as defined by the Dodd-Frank Act, are not used in the manufacture of FlowTainer Erlenmeyer flasks.

### **STERILIZATION/SANITIZATION:**

FlowTainer Erlenmeyer flasks may be sterilized/sanitized by autoclaving (121°C for 20 minutes) and gamma-irradiation.

### **GAMMA-IRRADIATION COMPATIBILITY:**

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

### **SHELF-LIFE AND STORAGE CONDITIONS STATEMENT:**

Non-Sterile and Non-Irradiated FlowTainer Erlenmeyer flask Shelf Life is 5 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:

Date: January 30, 2024