Carolina Components Group FlowTainer HDPE Cap Regulatory Overview

Date	September 20, 2022
Subject	Regulatory Compliance Statement
Parts Affected	FlowTainer Caps
Resin Material Type	Purell GC 7260
Resin Manufacturer	LyondellBasell
Revision Date	September 20, 2022

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

MATERIALS OF CONSTRUCTION:

FlowLinX products are manufactured from Purell GC 7260 HDPE resin, a drug master file listed (#5654) resin.

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BIOCOMPATIBILITY:

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

The resin material used to manufacture FlowLinX products is non-cytotoxic in accordance with USP <87>, Biological Reactivity Tests, In Vitro.

TSE/BSE/ADCF STATEMENT:

FlowLinX products may contain a tallow derived substance. Tallow derived materials used in this product fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMA/410/01, and as amended.

FOOD CONTACT APPLICATIONS:

FlowLinX products which are intended for the application of food and beverage processes are compliant to the extractable limits specified in
FDA 21 CFR 177.1520

EUROPEAN PHARMACOPEIA:

FlowLinX products meet EP 3.1.3 and EP 3.1.5

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ALLERGENS:

The material used to manufacture FlowLinX products 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.

LATEX:

Latex is not intentionally added in the formulation or manufacture of FlowLinX products.

PHTHALATES:

Material used to manufacture FlowLinX products is Phthalate-free.

REACH/RoHS:

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

CONFLICT MINERALS:

Conflict minerals as defined by the Dodd-Frank Act, are not used in the manufacture of FlowLinX products.

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STERILIZATION/SANITIZATION:

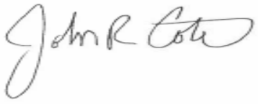
FlowLinX products may be sterilized/sanitized by gamma-irradiation.

GAMMA-IRRADIATION COMPATIBILITY:

FlowLinX products may be exposed to Gamma-Irradiation up to a total of **45kGy**.

SHELF-LIFE AND STORAGE CONDITIONS STATEMENT:

Non-Sterile and Non-Irradiated FlowLinX Product 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: 

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