

Technical and Regulatory Information Overview

KryoSure®, VueLife® and LabPure® FEP Bags and Fluid Transfer Assemblies

Country of Origin

KryoSure®, VueLife® and LabPure® FEP bags and Fluid Transfer Assemblies are manufactured in the United States of America.

Manufacturing Location

Saint-Gobain Performance Plastics
50 W Watkins Mill Rd
Gaithersburg, MD 20878 USA
Telephone: (301) 990-1407

Materials of Construction

KryoSure®, VueLife® and LabPure® FEP bags are manufactured using 0.005" fluorinated ethylene propylene (FEP) film.

The materials of construction for the tubing and component materials that comprise the different FEP bag and fluid transfer assembly part numbers vary and can be made available upon customer request.

Manufacturing Environment

All FEP bags and Fluid Transfer Assemblies are manufactured and packaged in an ISO 7 cleanroom.

Medical Device Clearance

KryoSure® and VueLife® FEP bags are FDA 510(k) cleared. LabPure® FEP bags are intended for research and industrial applications only. LabPure products are not intended for use as a medical device or as part of a medical device, pharmaceutical, or biologics process.

Integrity Testing

The fittings and body of FEP bags manufactured with standard, untreated FEP film are pressure tested with medical grade, filtered N₂ gas at 5 PSI prior to release of the product. Pressure testing is performed on 100% of FEP bags.

Note: In special cases per customer request, only the fittings and not the body of the bag are tested during the pressure test for some bags manufactured using treated FEP film.

Shelf Life and Storage

Based on information provided by our suppliers, FEP bags and Fluid Transfer Assemblies are not considered to be temperature sensitive or have special storage conditions. Products awaiting shipment are stored in ambient lighting, temperature and humidity conditions. Ambient storage conditions consist of a cool dry environment away from direct sunlight at 70°F ± 20°F and a relative humidity range from 10% to 70% in original unopened packaging. Given all possible variables have not been examined as it is cost prohibitive, it is best practice to store product in its original packaging, protected from known sources of polymer degradation such as temperature, condensing or high humidity, sunlight/fluorescent light/UV, exhaust gases, chemical environment, mechanical stress, etc.

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NOTE: Users of the FEP bags and Fluid Transfer Assemblies are encouraged and recommended to periodically inspect the product in inventory for any visible signs of abnormality and accordingly test for properties suitable and specific to the end users' application and use.

In-House Steam Sterilization

Products sterilized in-house are sealed in autoclavable pouches and steam sterilized at 121°C and 16 PSI for pre-determined cycle time durations (60 or 120 minutes). Sterilization exposure is indicated by chemical indicators on each autoclave pouch. Saint-Gobain Gaithersburg uses the lot release method with *Geobacillus stearothermophilus* spore strips and ~24 hour incubation in nutrient media to assure a Sterility Assurance Level of 10^{-6} for product.

Conflict Minerals

There is no instance of conflict minerals, as defined by the Dodd-Frank Act, used in the FEP film.

Animal Derivative Content & Transmissible Spongiform Encephalitis (TSE/BSE) Risk

Based on information provided by our suppliers, bovine or other animal derived content materials are not used in the FEP film as defined in specification EMA/410/01 rev.3.

The animal derivative content and TSE/BSE risk for the tubing component materials that comprise the different FEP bag and fluid transfer assembly part numbers vary and can be made available upon customer request.

Plant Origin

The FEP film used in the manufacture of KryoSure®, VueLife® and LabPure® FEP bag does not contain raw materials that are derived from plants.

Bisphenol A (BPA)

BPA is not used in the formulation or manufacture of the FEP film used in the manufacture of KryoSure®, VueLife® and LabPure® FEP bags.

USP Class VI

The FEP film used in the manufacture of KryoSure®, VueLife® and LabPure® FEP bag meets the requirements of the current USP, Biological Test for Plastics, Class VI.

Slip Agents

Slips or slip agents are not used in the manufacturing or processing of FEP film used in the manufacture of KryoSure®, VueLife® and LabPure® FEP bags. Slips or slip agents are not used in the manufacturing or packaging process at Saint-Gobain Gaithersburg.

Latex, Gluten, and Allergens

FEP bag products and Fluid Transfer Assembly products do not come in contact with latex materials during the manufacturing or packaging process at Saint-Gobain Gaithersburg. FEP bag product and Fluid Transfer Assembly products do not come in contact with allergens as defined by the FDA (Milk, Eggs, Fish, Crustaceans, Soy, Wheat or other Gluten-containing sources, Peanuts and Tree Nuts) during the manufacturing or packaging process at Saint-Gobain Gaithersburg.

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Metals with Safety Concern (EMEA/CHMP/SWP/4446/2000)

End users must assess the suitability of FEP bag products and Fluid Transfer Assembly products for their individual applications in the context of the relevant Exposure Limits established by EMEA/CHMP/SWP/4446/2000

RESPONSIBILITY

This overview document is intended to provide users of Saint-Gobain KryoSure®, VueLife® and LabPure® FEP bags and Fluid Transfer Assemblies with the information necessary to assess the suitability of these products for use in their intended application.

Saint-Gobain has not run any analysis for concentration levels for the regulatory compliances listed above but has relied on raw material suppliers for this information. It is the responsibility of the customer to determine whether their use of Saint-Gobain product is safe, lawful (except as provided in the above certifications) and technically suitable for their intended purpose.