TriForest Enterprises, Inc.
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Certificate of Quality

TriForest Labware certifies that this product meets the following criteria:

Description of Product:
Polycarbonate Erlenmeyer flask
125mL, 250mL, 500mL, 1000mL 2000ml sizes.
Catalog Numbers: FPC0125S, FBC0125S, FPC250S, FBC250S, FPC500S, FBC500S, FPC1000S, FBC1000S, FPC2000S, FBC2000S.
Pore Size: 0.22um PTFE membrane on the cap.
Lot Number:
Country of Origin: Taiwan

PRODUCT CRITERIA
Non-Toxin Leaching Resin: This product was manufactured using SABIC Lexan® 104-112 resin, FDA compliant.

Component Materials Toxicity
The materials pass the requirements of the MEM elution Cytotoxicity Procedure utilizing WI 38 or MRC5 cell lines. The base resin complies with all requirements of the US Food, Drug and Cosmetic Act and is produced in compliance with the conditions prescribed in Federal Food Additive Regulation 21 CFR 177.1580. The final formulated product complies with the extractive limitations set forth in the previously referenced Regulation 21 CFR 177.1580.

Heavy Metals
The resins used in the manufacture of TriForest Erlenmeyer flasks do not require reporting under the Superfund Amendment and Reauthorization Act (SARA) Title III Section 313. They would pass Toxicity Characteristic Leaching Procedure (TCLP) testing. Heavy metals such as lead (Pb), cadmium (Cd), mercury (Hg) and hexavalent chromium (Cr vi+) are not employed in the manufacture of Lexan® 104-112.

Membrane Gravimetric Extractable
The extractable level of the membrane was less than **1.00** weight percent of the membrane.

LOT CRITERIA
The manufacturing lot was sampled, tested and released by Quality Assurance for the following characteristics:

Sterilization
Product has been gamma irradiated and dosimetrically released based upon U.S. Association for the Advancement of Medical Instrumentation (AAMI) Recommended practices. Refer to the radiation certificate.

Pyrogens
An extract from the lot contained < **0.005** EU/ml per the Limulus Amebocyte Lysate (LAL) test method in the FDA *Guidelines on Validation Of The Limulus Amebocyte Lysate Test As an End Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, And Medical Devices*, December 1987.

AUDIT CRITERIA
Audit criteria tests are conducted on a routine basis as appropriate for each product configuration manufactured.

Bioburden
Samples were evaluated to determine the viable microbial bioburden of the product prior to sterilization.

Sterilization Validation
Gamma irradiation is validated on a quarterly basis utilizing the recommended practices of AAMI.

All TriForest Labware is for research use only, not for in vitro diagnosis or parenterals.

Quality Assurance Manager