



Excellence in Single-use Fluidics

www.tblplastics.com

About Us

Independence

As an independent company, TBL Performance Plastics LLC has established itself as a customer centric producer of single-use systems (SUS) and fluidic components in the life sciences, fine chemical, and FDA related markets.

Strength

Established in 2008, TBL has invested heavily in its manufacturing, infrastructure, R&D, and our people. Today, we operate four manufacturing units, which come together in creating a fully integrated systems approach, which benefits end users through a highly qualified global network of technical distributors and private-label OEMs.

Innovation Through Collaboration

We designed our Sparta, New Jersey headquarters to sustain a creative environment that openly fosters ideas and innovation. The facility was designed to utilize maximum flexible space for our team and customers to collaborate freely.



Contact

Tel 973.383.2834

Fax 973.383.4161

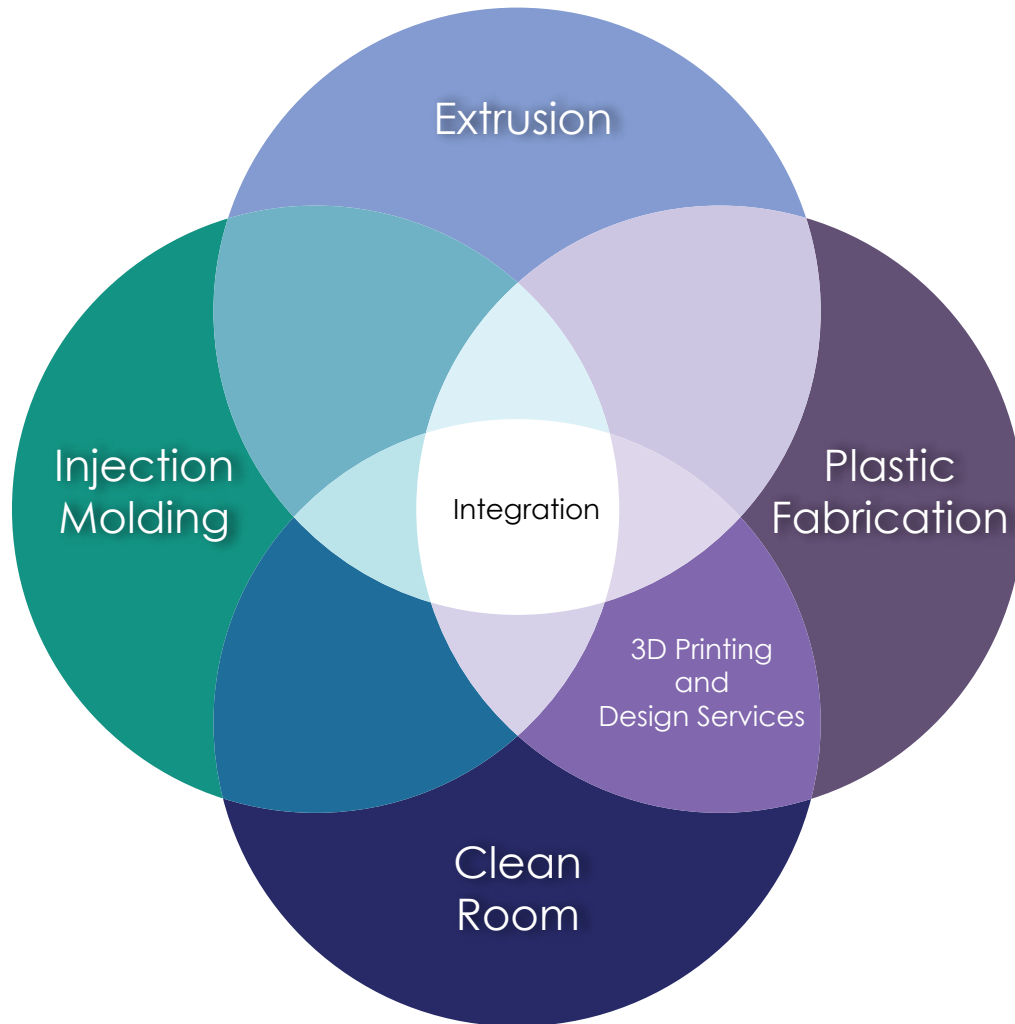
Location 18 White Lake Road, Sparta, NJ 07871

email sales@tblplastics.com

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The Power of Four!

True Integration Through Four Manufacturing Divisions



- Extrusion: Tubing
- Injection Molding: Fittings and Over-Molding
- Fully Accredited Plastic Fabrication
- Clean Room Services: Assembly, Design, Kitting, and Packaging (ISO Class 5,7,8)
- Design and Testing Services: 3D Rapid Prototyping, Product Characterization

Jane's idea



**Team
Collaboration**



**Computer Aided
Design**



**3D
Modeling**



**Prototype/ Characterization and
Performance Testing**



**Commercial
Part**

Clean Room

Clean-Room Assemblies, Custom Design, and Packaging

Our staff is well equipped to provide assembly and packaging services. TBL's design team commonly works with our customers to develop tailored solutions from the beginning stages through full-scale manufacturing processes in one of our ISO certified clean rooms.

Capabilities

- Designing, Engineering and Testing
- Validated ISO - Class 5 and 7 Environments
- Pressure Decay/ Leak Testing
- Medical-Grade Packaging (Fully Validated)
- Gamma-Irradiation and Sterilization Management
- Supply Chain Management
- Full Lot and Batch Traceability

Applications

- Bio-Pharmaceutical Manufacturing
- Up Stream Processes to Formulation/Fill
- Filtration
- Pilot Laboratories
- Peristaltic-Pump Tubing Assemblies
- Solid Oral Dosage



Fittings

Sanitary Fittings & Clamps

Standard Materials Available: ADIF Polypropylene and PVDF (Kynar®)

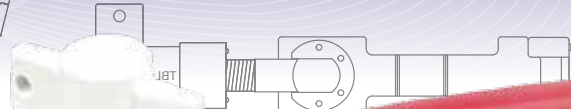
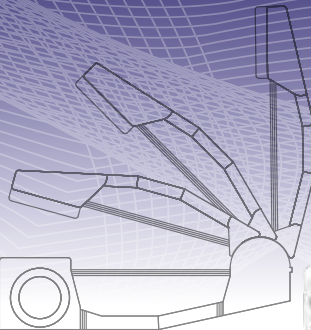
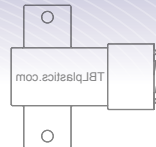
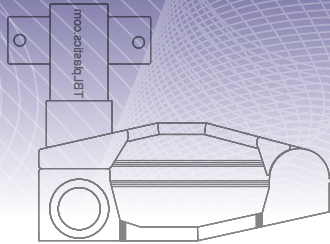
TBL offers a full line of sanitary fittings and clamps designed for critical-use applications where connective reliability, high purity, and chemical resistance are of concern. Contact your TBL representative or local distributor to discuss your specific needs.



EZ FittingTM Re-usable Tri-Clamp[®]

The EZ FittingTM is an excellent option for securely connecting tubing with a sanitary, Tri-Clamp[®] connection. The value in the EZ FittingTM is the ability to field fit and secure a hygienic Tri-Clamp[®] connection without special tooling or crimping devices. In addition, the fittings can be re-used with replacement tubing on a continuous basis.





Bio-Ease™ HD Hose Pinch Clamp

The Bio-Ease™ HD clamp is designed to satisfy the needs of the single-use disposable bio-pharm market. The quick swing-away lock nut grants a user-friendly operation that is compatible with a wide range of tubing sizes and materials making it ideal for single-use systems.

Tube Range: 3/16" ID to 1/2" OD

Wall: 0.085" to 0.200"



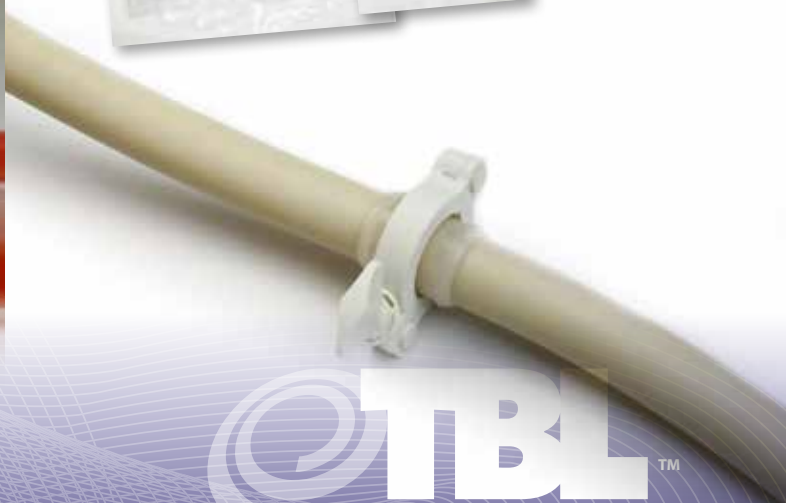
Cleanroom Packed Gaskets

TBL stocks a full line of cleanroom packed, Gamma Irradiated sanitary gaskets in both platinum-cured silicone and EPDM. Both comply with the highest regulatory standards for drug manufacturing. Gaskets are double bagged in an easy peel, low permeability, medical-grade pouch, and are available in single and ten packs.

Bio-Ease™ + Hinged Tri-Clamp®

Bio-Ease™ + hinged clamps are manufactured from an FDA grade, glass-reinforced, USP Class VI Nylon. The clamp is excellent for single-use transfer lines and other bio-process systems. The exclusive limited slip design and floating hinge self-adjusts for balanced contact pressure. It is a must for plastic-to-plastic connections, or plastic to metal.

Available Sizes: 3/4" (Mini) to 4"





aSURE™ Overmolded Connectors

- Eliminate Micro Contamination Sites
- Streamline Your Process
- Custom Design Capability

TBL has developed an internal manufacturing capability for over-molded Tri-Clamp® type end connection and junctions onto our various brands of tubing. We offer a wide range of size options and materials for your specific application. Our products are of exceptional quality with quick turnaround times, and our engineering team is available to provide application and design assistance where needed.

Over-Molded Sanitary Tri-Clamp®

Cellgyn™



HFB



Cleargreen®



Pharm-A-Line™ I



aSURE[™] Junction Connections (Patent Pending)

Making the seemingly impossible - possible!

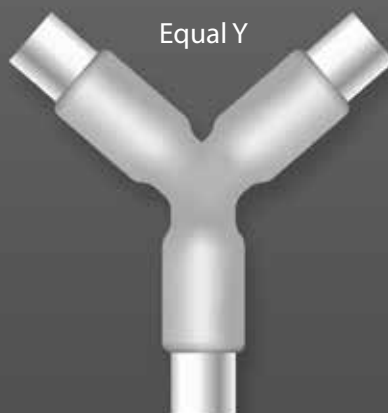
The platform is based on over-molding seemingly dissimilar materials together to achieve maximum seal integrity while creating customer-specific solutions.

Benefits

- Over-molded junctions typically exceed the pressure rating of the tube itself
- Eliminates bio egress to maintain sterility
- The broadest selection of materials, sizes, and connective options available



Equal Tee



Equal Y



90° Elbow



Reducer Tee



Reducer Y



Cross Tee



Reducer Coupling



Equal Coupling

aSURETM Pump-Tube Assemblies

As the drug development industry evolves, the need for optimum seal integrity, speed, and flexibility have become the key to the development and scaling of today's complex processes. TBL's over-molding system addresses media transfer applications using a novel approach.

Feature	Benefit
Innovative Over-Molding Process	Increases Pressure Rating/ Eliminates Leaks
Over-Sized Pump Insert Tube	Higher Flow Rates
Multiple Tubing Combinations in One Tube Set	Extended Pump Life/ Weldable Termination Points



Single-Channel Transfer Pump Segments

Double-Channel "Y" Segments



Available Materials Include

- Pharm-A-Line™ I (TPV)
- Cellgyn™ (TPE)
- ClearGreen® (PVC Med Grade)
- Customer Specified Tubing Available



Plugged Inlet and Outlet



Sterilizing Grade Hydrophilic
Filter Inlet/Outlet



Aseptic Connectors

aSURE™ Fittings

aSURE™ Fittings have been developed to address single- use connective applications where the most stringent hygienic practices are required.

Our novel design incorporates an elastomeric gasket with a rigid sanitary fitting, forming a one-piece composite design.

The functional benefit of this approach greatly reduces unintended contamination from bio-egress due to handling of a loose gasket while being installed.

The aSURE™ fittings are Autoclavable, Gamma Stable, certified animal ingredient free (ADIF), and medical grade.

aSURE™ WFI Sampler

The aSURE™ WFI Samplers are a simple solution for achieving a contaminant-free fluid sample from a WFI use point. The assemblies come double-bagged in an easy peel, low permeability, medical-grade pouch, and are available gamma irradiated. Demand the one piece aSURE™ design for the cleanest hassle-free connection.



For more information on this and other TBL products, visit TBL on-line.

tblplastics.com

Features

- Pharm-A-Clear™ Platinum-Cured Silicone Tubing
- aSure™ Fitting: Polypropylene / Cellgyn™ TPE (gasket area).
- Stainless Crimp: Ensures Safety and reliability.
- Tubing & Gasket: Platinum Cured Silicone.
- Gamma-Irradiated (25-40kGy)
- Double Bagged in Medical Peel Away Pouch
- Optional Bio-Ease™ Sanitary Clamp Available
- Materials: Certified USP Class VI, ISO 10993, 21 CFR 177.2600/1520, Animal Derived Ingredient Free (ADIF).



Tubing from TBL

Thermoplastic and Silicone Tubing for the Life Sciences

TBL manufactures and stocks a comprehensive line of high-performance tubing products in a broad range of materials and sizes.

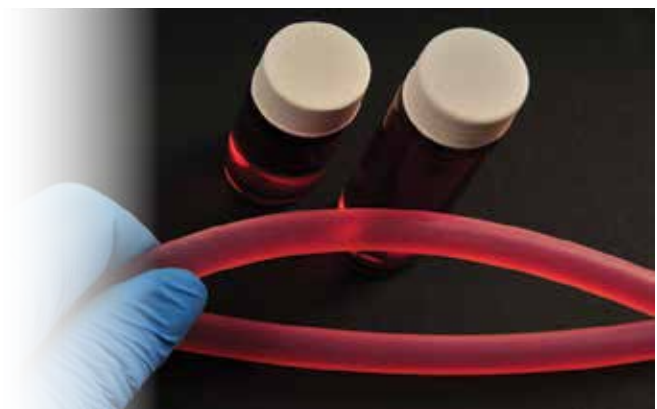
The company management has a deep heritage in the art of extruded tubing that dates back to the late 1940s. Today our modern cleanroom extrusion facility maintains the latest in technologies which ensures industry-leading tubing for the most critical applications.



Tubing

Pharm-A-ClearTM C Medical-Grade Platinum-Cured Silicone (Transfer) Tubing

Pharm-A-ClearTM C Platinum-Cured Silicone Tubing was developed to meet the most stringent requirements of the life sciences industries. Our medical grade Pharm-A-ClearTM C is manufactured in a state of the art ISO Class 7 Clean Room. Vertical extrusion techniques are employed in conjunction with continuous laser measurement to ensure exacting tolerances.



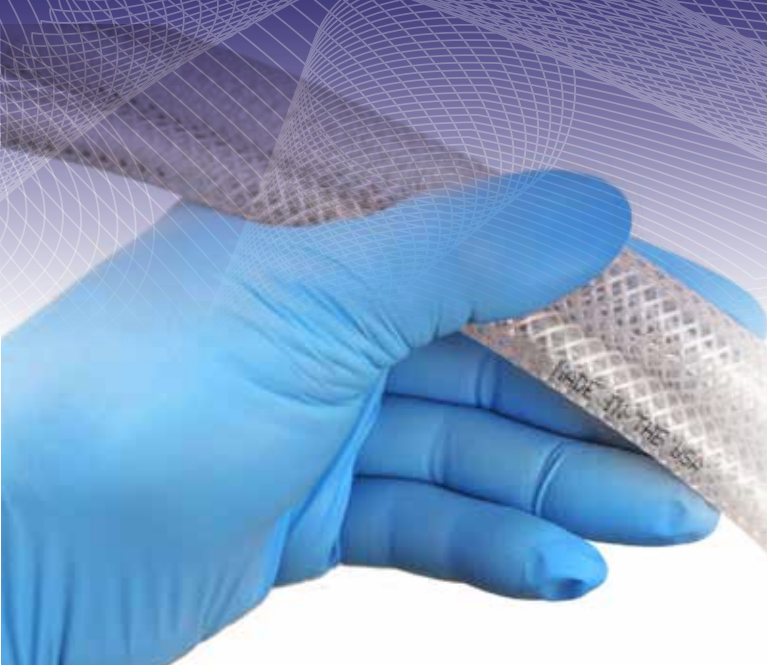
Pharm-A-ClearTM LH Low Hysteresis Platinum-Cured Silicone (Premium Pump Tubing)

Pharm-A-ClearTM LH Platinum-Cured Silicone Tubing was developed for the most critical and exacting meter dose **peristaltic-pump** applications. The LH series tubing is manufactured from a specific platinum-cured silicone compound that exhibits many unique characteristics which are not typical of other platinum compounds. LH exhibits the mechanical properties of peroxide-cured with the purity levels that only platinum-cured silicone compounds can assure.

Pharm-A-ClearTM R Platinum- Cured Braided Silicone Hose

High Performance Hose for the Most Demanding Applications. For higher temperature and pressure applications or those with a need for improved kink resistance, TBL offers Pharm-A-ClearTM R, platinum-cured braided silicone tubing. Pharm-A-ClearTM R is constructed using an inner and outer platinum cured silicone shell with polyester inner braiding. The inner core is a softer (60 durometer, Shore A) material for flexibility, while the outer shell is slightly harder (70 durometer, Shore A) for strength.

Available Sizes: 1/8" ID to 1" ID



Pharm-A-Clear™ PXS-R

Braid Reinforced Peroxide-Cured Silicone Hose

Peroxide-cured silicone can be advantageous in some applications where the need for purity is less critical. As a peroxide-cured silicone material, it also exhibits many superior mechanical attributes when compared to platinum-cured silicone. PXS-R is a medical grade material.

Pharm-A-Clear™ PXS-C

Peroxide Cured Silicone

Because of its excellent mechanical properties, it is the highest performing silicone material for **peristaltic-pumping** applications. PXS-C series meets many of the required regulatory approvals for medical use.

Peristaltic-pumping applications



Pharm-A-Line™ I

Peristaltic-Pump Tubing

Pharm-A-Line™ I tubing was specifically developed to provide superior performance in **peristaltic-pump** applications, with up to 1200 hours of service life. It is manufactured from virgin, medical-grade TPV and is extruded to exacting dimensional tolerances to ensure consistent flow rates in meter dose applications.

Pharm-A-Line™ I provides an exceptional alternative to silicone tubing when chemical resistance is a concern.





CellGynTM **Weldable TPE Tubing**

CellGynTM TPE tubing is designed specifically for cell culture media transfer. It has excellent barrier properties, and low platelet/protein binding. It is ideal for use in aseptic welding and sealing, and can be welded to competitive TPE tubing brands. Cellgyn is compatible with most aseptic welding machines. Consult TBL for a full validation package.

Cleargreen[®] **Phthalate-Free PVC Tubing**

ClearGreen[®] is the highest purity PVC tubing with the most comprehensive validation package on the market today. It is "crystal" clear, odorless, tasteless, and exceeds all relevant state, federal and international guidelines for extractables and leachability.

Cleargreen[®] 60 **Phthalate (DEHP) Free Vinyl Tubing**

Cleargreen[®] 60 is compounded from the same ingredients as our well established original formulation with one difference, it is designed to be softer for use in **peristaltic-pumps**, laboratory equipment, and vacuum lines.

Pharm-A-LineTM **VI/XL** **Co-Extruded Polyethylene-Lined EVA**

Pharm-A-LineTM VI/XL tubing combines the best properties of two dissimilar materials, providing a clear, seamless, lightweight and flexible tube. The liner (or fluid-contact surface) is made of a medical grade, chemically inert, polyethylene material. The outer liner consists of a high purity, low permeability EVA. Both materials are plasticizer free.

The tubing is ideal in applications where the chemical resistance of PE is preferred, but flexibility, clarity and barrier properties prohibit the use of standard PE tubing. Pharm-A-LineTM VI & XL can also be used with barbed fittings.





Fluor-A-Pure™ **PFA Tubing**

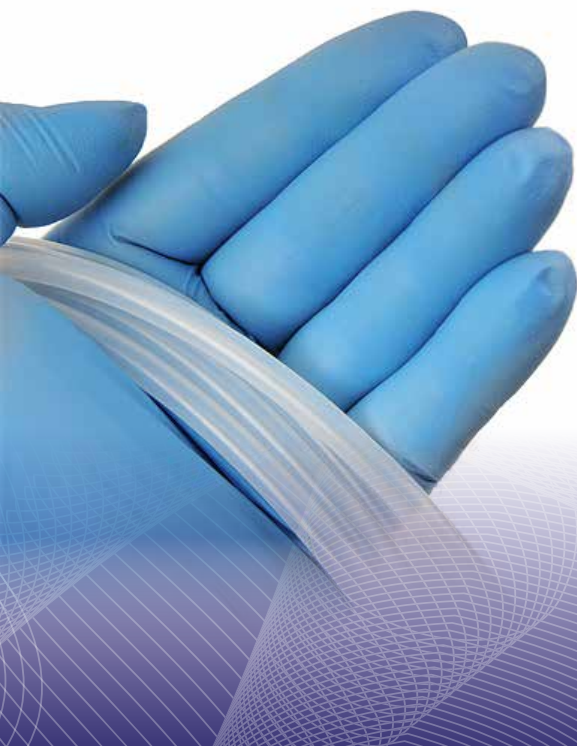
Fluor-A-Pure™ PFA tubing has been developed for the most extreme chemical and ultra high purity service conditions. Unlike typical high purity grades of PFA, Fluor-A-Pure™ is manufactured from 100% virgin PFA. The result is superior micro-porosity characteristics and internally smooth surface finishes.

Fluor-A-Pure™ **FEP Tubing**

Fluor-A-Pure™ FEP Tubing is an option where the chemical and thermal resistance of PTFE tubing is required at a lower cost. Unlike PTFE, FEP can be continuously manufactured to virtually any length, and is optically superior. Fluor-A-Pure™ FEP is made of 100% virgin grade FEP. It is resistant to a broad range of industrial solvents, bases and strong acids.

Fluor-A-Pure™ **PTFE Tubing**

PTFE (Polytetrafluoroethylene) is perhaps the most widely used fluoropolymer available because of its features which make it ideal for various applications. It is more flexible than all other tubing in its class, and can resist nearly all industrial chemicals. With a temperature range of approximately -200°C to 260°C, it offers the widest temperature range of the fluoropolymers. In addition, it has excellent electrical properties and low permeability.



KYNAR-FLEX® **PVDF Tubing**

KYNAR-FLEX® PVDF is constructed exclusively with FDA compliant materials that meet USP Class VI, NSF 61, and NSF 14 requirements. It also has low TOC, excellent chemical resistance to most strong chemicals, is UV stable, and is rated for high temperatures.

Plastic Fabrication

TBL is a reliable source to take

High-Purity Plastic Fabrication

TBL prides itself on the ability to meet customer's unique product requirements. We take a total systems approach in providing turnkey solutions. This has driven us to develop world-class custom plastic fabrication and assembly capabilities. We possess a highly skilled staff equipped with state-of-the-art plastic-fabrication equipment, and practice a multitude of fabrication disciplines. TBL's fabrication department caters to bio-pharmaceutical, laboratory equipment, and other high-purity industries. TBL stocks sheet from 1/8" to 1" and rod from 1" to 6" diameter. Some materials used are **Polypropylene, PVDF (Kynar®), PTFE, PVC, Udel® Polysulfone**, and various **engineering polymers**.



Purity Assured

- Full DVS Accreditation
- Dedicated exclusively to non-metallic fabrication and machining
- No Metals
- No Oils
- Corrugate Free
- Full Lot Traceability
- Medical Grade Materials



All materials are stocked in-house and available upon request.

For more information on Plastic Fabrication and other TBL services, visit TBL on-line.
www.tblplastics.com

your concept from an idea to an approved, finished design.



DVS GERMAN WELDING SOCIETY



Applications

- Multi-Port Media Tops/Carboy Caps
- Custom Tanks
- Dip Tubes
- Custom Adapters
- Funnells
- Filter Columns
- Laboratory Fixtures

Capabilities

- Heat Bending
- Solvent Bonding
- Heat Welding
- CNC Milling and Lathe
- Crevasse Free Fusion
- Post Forming
- Notching



Contact

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Regulatory Information

Tubing

Pharm-A-Clear™ Series – USP Class VI, ISO 10993 (Parts 6, 10 and 11), 21CFR 177.2600, Animal Derived Ingredient Free (ADIF) REACH and RoHS compliant

Cellgyn™ Series (TPE) – USP Class VI, ISO 10993 (Parts 4 and 5), 21CFR 177.2600, Animal Derived Ingredient Free (ADIF) REACH and RoHS compliant

Pharm-A-Line™ I (TPV) – USP Class VI, ISO 10993 (Parts 4 and 5), 21CFR 177.2600, BSE/TSE Compliant, Meets REACH and RoHS requirements

Pharm-A-Line™ VI - Non-contact loop- Ethylene Vinyl Acetate (EVA) USP Class VI, ISO 10993, DMF listed, REACH and RoHS compliance, Animal Ingredient Free (ADIF) food contact compliant (US and EU) Contact Liner- LDPE USP XXIII Class VI, Drug Master File Listed, Animal Ingredient Free (ADIF) , 21 CFR 177.1520 (c) 2.1, REACH and RoHS compliant

Cleargreen® Series - USP Class VI <88>. Has been tested to USP 661.1, REACH, RoHS, Consumer Product Safety Improvement Act (CPSIA) /Section 108 California Proposition 65 and BSE/TSE compliant.

PXS Series – Met the testing requirements for USP Class VI and ISO 10993 testing. PXS meets 21 CFR 177.2600 Please note extractive levels will vary with processing conditions

KYNAR-FLEX® (PVDF) passes USP Class VI <88>, CFR Title 21 Section 177.2600, meets or exceeds the requirements listed in ASTM D 3222, meets 94 VO, manufactured from NSF 51 and NSF 61 certified resin

Fluor-A-Pure™ PFA - passed USP Class VI <88>, CFR Title 21 Section 177.1520, meets or exceeds the requirements listed in ASTM D6867-03 and ASTM D3307, meets 94 VO

Fluor-A-Pure™ FEP passes USP Class VI <88>, CFR Title 21 Section 177.1520, meets or exceeds the requirements listed in ASTM D3296-03 and ASTM D2116, does not promote flame spread

Fluor-A-Pure™ PTFE - meets CFR Title 21 Sections 1550/2500 for food contact

Fittings

Polypropylene passes U.S. USP Class VI <88>, USP 661, ISO 10993-5, CFR Title 21 Section 177.1520, it is Drug Master File Listed, and meets the acceptable limits of Prop 65, REACH, and RoHS, Animal Derived Ingredient Free (ADIF)

PVDF (KYNAR®) passes U.S. USP Class VI <88>, USP 661, ISO 10993-5, CFR Title 21 Section 177.1520 and meets the acceptable limits of Prop 65, REACH, RoHS, Animal Derived Ingredient Free (ADIF)

HDPE passes USP XXIII, Class VI CFR Title 21 Section 1520 (C) 2.1, Drug Master File Listed and meets the acceptable limits of Prop 65, REACH and RoHS

Additional Declarations

TBL Performance Plastics, LLC certifies that the referenced products are manufactured free of defects, particulates, and/or impurities including Latex, Natural Rubber, Crape Rubber, BPA, and DEHP. TBL Plastics adheres to cGMP manufacturing guidelines.

Disclaimer

Regulatory statements provided on this page are guidelines to aid in the material selection process. Please consult your TBL representative for the most current regulatory certifications. Specifications are subject to change without notice.

Trademarks

Kynar® is a registered trademark of Arkema. Tri-Clamp® is a registered trademark of Ladish Company. Udel® is a registered trademark of Solvay Advanced Polymers.



Made in the USA

www.tblplastics.com