

Standard Materials (Injection Molding)

The performance of your system depends on using the right material. For stopcocks, we offer our injection molded parts in two standard, high-performance plastics to ensure chemical compatibility and physical durability.

Kynar (DF#)

Kynar® PVDF is a high-performance fluoropolymer renowned for its exceptional chemical resistance, high purity, and robustness in demanding environments. This material meets numerous global food contact and regulatory standards, making it a premier choice for sensitive applications in the medical, pharmaceutical, food processing, and semiconductor industries.

Biocompatibility and Medical Use

This grade of Kynar® has successfully passed key biocompatibility tests, making it suitable for evaluation in medical device applications.

- **USP Class VI:** The material has passed the United States Pharmacopeia (USP) Class VI tests for plastics. This includes:
 - Acute Systemic Injection Test.
 - Intracutaneous Irritation Test.
 - Intramuscular Implantation Test.
- **ISO 10993:** The material has also passed the following ISO 10993 tests for biological evaluation of medical devices:
 - ISO 10993-4: Hemolysis (Direct Contact and Extract Methods).
 - ISO 10993-5: Cytotoxicity.

Medical Use: While specific Kynar® grades are designated as "Medical grades," products not designated as such are not authorized for use in applications involving contact with the body or circulating fluids. Furthermore, Arkema strictly prohibits the use of any of its products in medical devices that are implanted in the body or are in contact with bodily fluids or tissues for more than 30 days. It is the sole responsibility of the medical device manufacturer to determine the suitability and biocompatibility of all raw materials for the final application.

Food Contact Compliance

This Kynar® grade is suitable for food contact applications under multiple international regulations.

- **US FDA:** Complies with 21 CFR § 177.2510 for polyvinylidene fluoride resins intended for repeated use in contact with food. The finished article manufacturer is responsible for extraction testing and ensuring the article is thoroughly cleansed prior to first use.

- **EU:** The product contains only substances authorized by Regulation (EU) No 10/2011 for plastic materials intended for food contact. It meets Good Manufacturing Practice (GMP) requirements as defined in Regulation (EC) No 1935/2004.
 - Vinylidene fluoride has a Specific Migration Limit (SML) of 5 mg/kg.
- **MERCOSUR:** The material is formulated with substances authorized for use in food contact articles, including vinylidene fluoride [SML = 5 mg/kg].

Compliance and Certification Highlights

- **RoHS:** Compliant with EU and China RoHS directives for use in electrical and electronic equipment.
- **REACH:** Does not contain any Substances of Very High Concern (SVHC) above the 0.1% reporting threshold.
- **TSCA:** All components are on the Active TSCA Inventory.
- **Proposition 65:** Not known to contain any chemicals listed under California's Proposition 65.
- **PFAS Surfactants:** Arkema has reformulated its polymer recipes to be produced without the use of any PFAS surfactants.
- **Animal-Derived Substances:** No animal-derived substances are used in or around the manufacturing of this product, making it free from BSE/TSE concerns.
- **Allergens & Dietary Concerns:** Free from the eight major FDA food allergens, as well as gluten and lactose.
- **Other Substances:** Not known or expected to contain Bisphenol A (BPA), phthalates, natural rubber latex, GMOs, Persistent Organic Pollutants (POPs), or Volatile Organic Compounds (VOCs).

Thermal Stability and Handling

- **Thermal Decomposition:** To avoid thermal decomposition, do not overheat. At temperatures above 662°F (350°C), the material will thermally decompose and can release toxic and corrosive hydrogen fluoride (HF) gas. This decomposition can be promoted at lower temperatures (>536°F / >280°C) if the material is in contact with silica (glass fiber) or TiO₂.
- **Storage:** Store in a cool, dry place.

Gamma Stable Polycarbonate (GP#)

This transparent, medical-grade polycarbonate resin (CALIBRE™ MEGARAD™ 2081-15) is a high-performance thermoplastic specifically engineered for applications requiring biocompatibility and stability to gamma radiation sterilization. Its robust compliance profile and purity make it an ideal material for demanding medical and pharmaceutical devices.

Biocompatibility Evaluation

All of Trinseo's commercial medical-grade products have been evaluated to pass a standard battery of biocompatibility tests. These evaluations are conducted by NAMSA, a third-party lab, based on the guidelines of ISO 10993 and in accordance with FDA Good Laboratory Practice (GLP) Regulations.

The standard test battery for medical-grade qualification includes:

- **Hemolysis:** In Vitro Extraction and Direct Contact Methods (ISO 10993-4).
- **Cytotoxicity:** Elution Method (ISO 10993-5).
- **Implantation:** Muscle Implantation - 1 week (ISO 10993-6).
- **Sensitization & Irritation:** Guinea Pig Maximization Sensitization and Intracutaneous tests (ISO 10993-10).
- **Systemic Toxicity:** (ISO 10993-11).
- **Physicochemical Test:** (USP <661>).

Manufacturer's Responsibility: This testing is performed on the resin pellets and serves as a preliminary qualification step. The medical device manufacturer is responsible for evaluating their final product based on their specific manufacturing processes and conditions of use to ensure it is safe and effective.

Compliance and Certification Highlights

- **RoHS Compliant:** The product complies with the requirements of the EU RoHS Directive (2011/65/EU and its amendments), confirming it is not intentionally formulated with restricted substances like lead, mercury, cadmium, hexavalent chromium, and specified phthalates.
- **REACH Compliant:** Does not contain any Substances of Very High Concern (SVHC) from the candidate list above the 0.1% wt reporting limit. It also does not contain substances listed in Annex XIV.
- **SCIP Notification:** Because the resin does not contain SVHCs at or above 0.1%, a SCIP notification is not required for an article produced from it.
- **California Prop. 65:** This product contains a chemical that is at or below the "safe harbor level" as determined by a risk assessment and therefore does not require a warning label under the statute.
- **TSCA Compliant:** All components are in compliance with the U.S. TSCA Chemical Substance Inventory listing requirements.
- **Animal-Derived Components:** Free from ingredients of animal origin.

- **PFAS:** Not known to contain Perfluoroalkyl and Polyfluoroalkyl Substances. We do not routinely analyze our materials for these substances.
- **Substances of Concern:** Not intentionally formulated with Medium-chain chlorinated paraffins (MCCP).

Handling and Safety

- **Thermal Stability:** The material is stable, but exposure to elevated temperatures above 425°C should be avoided to prevent product decomposition.
- **Storage:** It is recommended to store this product in a cool, dry area.