Benefits of Fluoropolymers for Bioprocessing

APPLICATION NOTE

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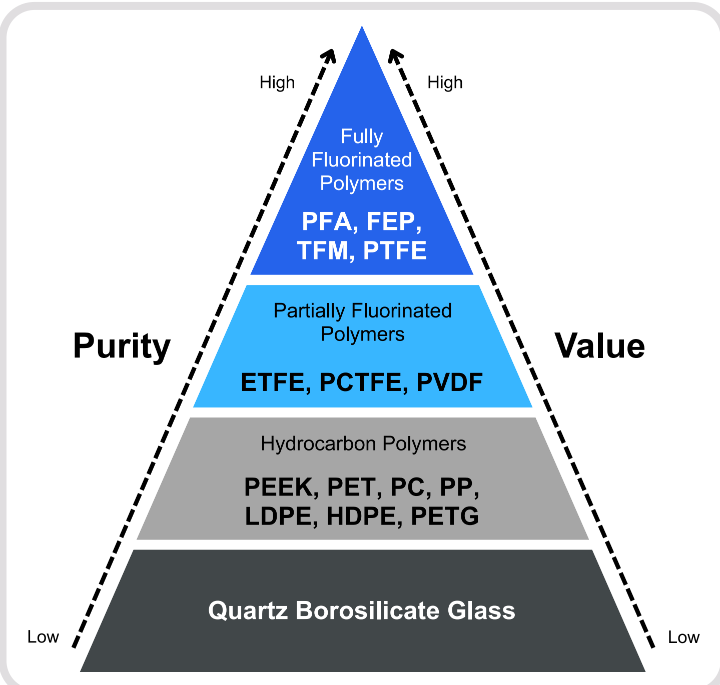
ABSTRACT



There is a considerable amount of confusion regarding the use of fluoropolymer plastics in bioprocessing. Where are they commonly used? Which material is suitable for which application? What are the relative benefits & risks of each?

There is also confusion about the compatibility of fluoropolymers with conventional sterilization methods. The suitability of fluoropolymers for bioprocessing is sometimes questioned due to the lack of application data.

The purpose of this application note is to provide a clear and concise overview of fluoropolymers, including where they are currently being used in bioprocessing and which materials are best suited for which applications. It will also provide a glimpse of potential future developments in fluoropolymers for single-use systems.

MOST COMMON FLUOROPOLYMER MATERIALS

Although there are many different materials within the fluoropolymer family, this application note covers the five most common in the life sciences industry - three of which are fully fluorinated (**PFA, PTFE,** and **FEP**), and two of which are partially fluorinated (**ETFE** and **PVDF**). As can be seen in the graphic above, fluoropolymers are innately higher in purity, and, due to improved performance characteristics, higher in value than conventional hydrocarbon plastics like PE and PP. Key commonalities that fluoropolmers share include:

- Extremely high purity compared to other plastics used in bioprocessing, including very low or no measurable leachables or extractables
- Inert and non-reactive with virtually every chemical used in life science applications
- Relatively low coefficients of friction (meaning no adhesion to biological materials), inherent resistance to bioburden and biofilm and ease of cleaning
- Very high thermal stability leading to an extensive service temperature range, to temperatures as high at 200°C and as low as liquid nitrogen (-196°C)
- Unmatched durability and are virtually unbreakable during use - even at blast freeze temperatures

FULLY FLUORINATED MATERIALS

Common fluoropolymer uses in bioprocessing include:

- Gaskets and diaphragms used in pure steam and pure water systems
- Coatings for stir bars
- Parts used in impeller systems
- Coatings and matrix for filter membranes
- Coatings on final product vial stoppers

PFA

Along with PTFE, PFA has the widest working temperature range of any fluoropolymer. It is translucent to the point of being almost transparent, making PFA ideally suited for contents that need inspection, such as the final product. Like FEP, PFA is melt processable, allowing it to be injection or blow molded, but it is also strong enough to allow precision machining of critical parts. It has the lowest trace metals content of any fluoropolymer, and very high purity resins are available. PFA has a smooth surface finish and a remarkably low coefficient of friction.

PTFE

PTFE was the original fluoropolymer discovered by scientists in 1938 and is still used as a coating for bakeware and cookware. The grade PTFE used in life science is not white but opaque, which is not ideal for labware; it is difficult if not impossible, to detect container contents in closed containers visually. PTFE has a higher level of trace metal contaminants than PFA and FEP, and resin quality varies widely. It must be machined or pressed into parts and is not injection moldable, limiting its use in precision applications. PTFE also tends to have high material creep, which can distort parts during and after manufacture. Along with PFA, it has the broadest working temperature range of any fluoropolymer. Parts made from PTFE tend to have a rough, porous surface finish which can be an issue for trace metal memory effects and general cleanliness.

FEP

FEP has a maximum working temperature lower than PFA and PTFE but is translucent, allowing easy inspection of contents. FEP melt processable, allowing it to be injection or blow molded. It has lower trace metal content than PTFE, and high purity resin is readily available. Parts made from FEP have a smoother surface finish, ensuring less risk of trace metal cross-contamination between samples. FEP is less expensive than PFA when the cost is an issue.

PARTIALLY FLUORINATED MATERIALS

ETFE

ETFE is as strong as fully fluorinated materials and has the same chemical resistance and temperature range. It is melt processable, allowing it to be injection or blow molded, but it is also strong enough to allow precision machining of critical parts. ETFE has lower gas barrier properties than PVDF, which can be a concern when used as a film (like in bags). Lower gas barrier properties are less of a concern when in a thicker format like bottles. However, what sets ETFE apart is its gamma stability, making it ideal for use in single-use systems.

PVDF

PVDF has superior chemical resistance, temperature range, and gas barrier properties, but is weaker than fully fluorinated materials or ETFE. It is also prone to chemical attack from strong bases and polar solvents and melt processable, allowing it to be injection or blow molded. Like ETFE, PVDF is gamma stable.

FLUOROPOLYMERS FOR CRITICAL MATERIALS STORAGE

Common issues with existing storage solutions for critical materials, like bulk final product, can almost always be traced back to container material selection. These can include:

- Product loss due to container failure
- Product adulteration due to chemical contamination, and lack of chemical stability, (particularly with acids, bases, and solvents)
- Critical materials can also adsorb to the container surfaces, reducing product recovery after storage

Fluoropolymers are inherently superior to conventional plastics. They are inert, non-reactive, and do not leach materials that can adulterate products. Fluoropolymers have unmatched durability, significantly reducing the incidence of container failures. They are also non-stick, ensuring product does not adsorb to surfaces.

Fluoropolymers are ideally suited to final product storage due to the following attributes:

- Low extractables/leachables
- Temperature stability (-200°C to 200°C
- Chemical stability
- Low particles
- Non-stick properties
- Gamma stability (ETFE/PVDF)

Final product storage and shipment methods are often limited due to container materials. For example, more products would be validated to lower storage and shipment temperatures, ensuring better product stability and improved product recovery, if the containers used could withstand temperatures below -70°C, (the limit for PE and other common single-use materials). The switch to fluoropolymers would extend the lower limit for freezing product and immediately improve process outcomes.

Furthermore and contrary to popular belief, all fluoropolymers are not incompatible with gamma irradiation. In fact, many of them, including ETFE and PVDF, are completely stable and even validated for gamma sterilization. Others, like PFA and FEP, can withstand doses of up to 40 kGy with little to no damage. Hydrofluoric acid release is also rare during gamma irradiation and only occurs during hot processing of

CONCLUSION

Fluoropolymers are materials with extremely high purity and are non-reactive with virtually every chemistry. Moreover, they are non-stick with no absorbance of biological materials, have very high thermal stability, and unmatched durability. They are ideal for storage, freezing, and shipment of critical bioprocess fluids, including bulk final product. Certain fluoropolymers, like ETFE, are even gamma stable, allowing them to be seamlessly integrated into single-use systems. Click here to learn more about the Savillex portfolio of fluoropolymer solutions designed specifically for the life sciences and bioprocessing.

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