

Application for derogations from REACH PFAS restriction for fluoropolymer (PTFE)

Topic: Application of Forever Derogation for Fluorine-containing Polymers (PTFE)

Reasons: 1. The risk of polymers per se to environment and human is little; and 2. The processing aids used in the production of the polymers have been controlled or substituted by other laws or treaties; and 3. The raw material belt and reactor lining processed with polytetrafluoroethylene have sealing and high temperature resistance and corrosion resistance, and there is no substitute at present.

Applicant: JIANGYIN HUANYU RUBBER & PLASTIC CO., LTD

Submitted on August 15, 2023

From the fluoropolymers per se, such substances are a class of high molecular weight macromolecular polymers with a molecular weight well over 100000 Da, these fluoropolymers cannot cross the cell membrane, which to show that fluoropolymers satisfy widely accepted assessment criteria to be considered as "polymers of low concern" (PLC), and should be considered as distinctly different from other classes of PFAS (the grouping of all PFAS together is not supported by the scientific data). Data show that fluoropolymers have thermal, chemical, photochemical, hydrolytic, and biological stability, because of its strong chemical stability, it is difficult to pose a threat to the environment and human health. Fluoropolymers are not bioavailable or bioaccumulative, as evidenced by toxicology studies on polytetrafluoroethylene (PTFE): acute and subchronic systemic toxicity, irritation, sensitization, local toxicity on implantation, cytotoxicity, in vitro and in vivo genotoxicity, hemolysis, complement activation, and thrombogenicity. Clinical studies of patients receiving permanently implanted PTFE cardiovascular medical devices demonstrate no chronic toxicity or carcinogenicity and no reproductive, developmental, or endocrine toxicity. These fluoropolymers cannot be substances of very high concern (SVHCs) under REACH, do not meet the PM (persistent mobile) and PMT (persistent mobile toxic) criteria proposed by UBA, and do not meet the criteria for listing as a POP under the Stockholm Convention.

From the preparation process of fluoropolymers, the type and quantity of preparations used can be artificially controlled, and some countries have previously issued prohibition and replacement directives for preparations that may be PFAS in the production process, such as Canada's Prohibition of Certain Hazardous Substances Regulations (SOR/2012-285, and its amendments SOR/2016-252) in 2016. In 2019, the Ministry of Ecology and Environment of China issued the Announcement on the Prohibition of the Production, Circulation, Use, Import and Export of Persistent Organic Pollutants such as Lindane. And the 2019 EU POPs Regulation ((EU) 2019/1021) and its amendment Regulation (EU) 2020/784, etc. At present, there are no substances that may belong to PFAS in the preparation of fluoropolymers.

Polytetrafluoroethylene (PTFE) tubing is widely used in many industries and has some irreplaceable properties, the following are the main application industries and irreplaceability of PTFE tubing:

1. Chemical industry: Due to its excellent chemical and corrosion resistance, PTFE pipe is widely used in the chemical industry for piping systems, tanks, pumps and valves conveying a variety of corrosive media. It can withstand a wide range of acids, alkalis and solvents without corrosion or damage.
2. Pharmaceutical and food industry: PTFE tubing meets the hygienic requirements of the

pharmaceutical and food industries and is widely used in piping systems for the transportation of pharmaceuticals, food and beverages because of its excellent chemical purity. Its low coefficient of friction and smooth surface makes cleaning easier and does not contaminate materials.

3. Electronic and electrical industry: Because PTFE has good insulating properties, heat resistance and chemical resistance, it is widely used in cable insulation, electronic component housings, electrical insulation sleeves and other fields. It can provide reliable electrical insulation and protect electrical equipment from moisture, corrosion and chemicals.

4. Medical device industry: PTFE tubing has a wide range of applications in the medical device and biomedical fields, such as piping systems for the transportation of biological fluids, gases, and pharmaceuticals, as well as artificial cardiac vessels. Its low coefficient of friction, biocompatibility and chemical stability make PTFE tubing an ideal material choice.

5. Hydraulic and pneumatic systems: PTFE tubing is widely used for piping, fittings and seals in hydraulic and pneumatic systems due to its chemical resistance, temperature resistance, low coefficient of friction and good elasticity. It can withstand high pressures and temperatures while maintaining good sealing and fluid transfer properties.

In conclusion, PTFE tubing has many irreplaceable properties in the chemical, pharmaceutical, food, electronics, and medical industries, including:

1. Good chemical resistance: PTFE tubing has excellent resistance to a variety of corrosive chemicals, including strong acids, alkalis and organic solvents. This makes it an irreplaceable choice in industrial fields requiring the transportation of corrosive media, such as chemical, petroleum, electroplating, etc.

2. Excellent temperature resistance: PTFE tubing has excellent resistance over a wide range of temperatures. It can withstand high temperatures up to 260°C, while also maintaining good toughness and elasticity at very low temperatures. This makes it indispensable for applications in high or low temperature environments, such as heat exchangers, refrigeration equipment and thermocouples.

3. Low coefficient of friction: PTFE tubing has an extremely low coefficient of friction and a non-adhesive surface. This allows it to transport fluids with reduced energy loss, reducing drag and power requirements. In addition, the low coefficient of friction makes PTFE tubing indispensable in applications that require high speeds and reduced frictional wear, such as gas transfer systems and motion control devices.

4. Biocompatibility: PTFE tubing has good biocompatibility and can be compatible with biological tissues and body fluids. This makes PTFE tubing widely used in medical devices and biomedical fields, such as artificial cardiac vessels, catheters and so on. Its biocompatibility reduces the rejection of the material by biological tissues and reduces the risk of infection and other complications.

5. Good electrical insulation: PTFE tubes have excellent electrical insulation properties, which can effectively isolate the current and voltage to avoid electrical equipment failure and electric shock. In the electronic and electrical industry, PTFE tubes are widely used in cable insulation, electrical insulation sleeves and so on, and their electrical insulation properties are irreplaceable.

6. High purity and chemical stability: PTFE tubing is highly pure and chemically stable, and can maintain stability and reliability in extreme chemical environments. In the pharmaceutical and food industry, it will not react with or release harmful substances when conveying drugs and food, ensuring the quality and safety of products.

To summarize, PTFE tubing is widely used in chemical, pharmaceutical, food, electronics, medical devices and other industries due to its chemical resistance, temperature resistance, low coefficient of friction, biocompatibility, electrical insulation and chemical stability, and exists in an irreplaceable position in these fields.

Based on the above points, it can be seen that fluoropolymers, in terms of their production process and use as well as their downstream applications, do not harm the environment and human beings, and there are no relevant alternatives, and they should be exempted and allowed to be produced and used.