Application for exemption from EU REACH PFAS control for fluoropolymers (PTFE)

Topic: Application for Permanent Exemption for Fluoropolymers (PTFE processed articles)

Reasons: The first polymer itself poses little threat to the environment and the human body; The second is that the processing AIDS used in the production of polymers have been controlled or promoted to use alternative substances;The third is that all kinds of products (plates, rods, tubes, gaskets, films, etc.) processed with PTFE have excellent properties such as high and low temperature resistance, corrosion resistance, non-stickiness, etc., for which there are no substitutes at present.

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Submitted on August 16, 2023

From the fluoropolymer itself, 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 chronicl 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.

All kinds of products processed by PTFE (plates, rods, tubes, gaskets, films, etc.) are widely used in many industries and have many irreplaceable properties in chemical, petroleum, construction, electronics and medical devices, such as:

1.Excellent temperature resistance:Various types of PTFE products can be used stably at temperatures from -180℃ to 260℃ under no-load conditions, and have excellent tolerance. It can withstand high temperatures up to 260℃, while also maintaining good toughness and elasticity at extremely low temperatures.This makes it indispensable for applications in high or

low temperature environments, such as heat exchangers, refrigeration equipment and thermocouples.

2.Excellent corrosion resistance:PTFE tubing and gaskets have excellent resistance to a wide range of corrosive chemicals, it can withstand a wide range of acids, alkalis and solvents without corrosion or damage.It can be used in more extreme working environments or working media, which makes it an irreplaceable choice in semiconductor, medical, oil and other industrial fields.

3.Low friction coefficient：PTFE is the material with the lowest coefficient of friction among known solids. Utilizing its properties to make PTFE staircase panels can effectively avoid thermal expansion and contraction as well as damage to buildings caused by seismic shockwaves, thus reducing casualties during earthquakes.The low coefficient of friction also makes PTFE plates indispensable in applications that require high-speed movement and reduce friction and wear.

4.Good electrical insulation:PTFE has excellent electrical insulation properties, which can effectively isolate currents and voltages to avoid malfunctions and electric shocks in electrical equipment.In the electronic and electrical industries, PTFE film and PTFE tubes are widely used in cable insulation, electrical insulation sleeves, etc. Their electrical insulation properties are irreplaceable.

5.Biocompatibility:PTFE has good biocompatibility and is compatible with biological tissues and body fluids.This makes PTFE tubing widely used in medical devices and biomedical fields,because of its physiological inertia, as artificial blood vessels, catheters and other long-term implantation in the body without adverse reactions.

To summarize, all kinds of products processed by PTFE are widely used in chemical, petroleum, construction, electronics, medical equipment and other industries due to its temperature resistance, corrosion resistance, low friction coefficient, electrical insulation and biocompatibility, and have an irreplaceable position in these fields.

Based on the above three 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 that there are no relevant alternatives, and that they should be exempted and allowed to be produced and used.