

## **Application for exemption from EU REACH PFAS control for fluoropolymer films**

Subject: Application for permanent exemption of fluoropolymer films

Based on: First, the low environmental and human threat posed by the polymer itself;

The second is that the processing AIDS used in the production of polymers have been controlled or promoted to use alternative substances;

Third, fluoropolymer films are high-performance films based on fluoroplastic polymers (such as polytetrafluoroethylene, etc.).

Applicant □ Pengfei Zhou

Email □ pengfei.zh@dongyuechem.com

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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.

Fluoropolymer films are high-performance films based on fluoroplastic polymers, such as polytetrafluoroethylene, and others. These films as a class exhibit low coefficient of friction, chemical inertness, exceptional dielectric properties, weather and UV resistance, excellent optical properties, negligible moisture absorption, and outstanding performance at very high temperatures.

Fluoropolymer films are used in many markets, although none of them is used in large quantities. Current market demand for specialty fluoropolymer films is approximately \$150

million and expected to rise 5.4% per year to \$177 million in 2023. The growth is expected to be among the fastest of any major specialty resin, driven largely by expanding use of fluoropolymers mainly in photovoltaic modules and also in other markets, including fuel cells, health care, and specialty packaging materials.

**Reference file**  **Applications of Fluoropolymer Films**