

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

Topic: Application for Permanent Exemption for Fluoropolymers (PTFE)

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 PTFE is the fluoropolymer of choice for many medical device coating applications, and the human body has no rejection phenomenon.

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Requests for exemptions

We request that products such as the above be exempted from the draft PFAS.

Grounds for exemptions

PTFE, CAS NO.: 9002-84-0, can be identified as a polymer of low concern and requires a full exemption from the PFAS ban.

Perfluoroalkyl and polyfluoroalkyl (PFAS) is a harmful "permanent chemical". The substance is very resistant to both chemical and biodegradation and is often used as a lubricant in the production process, some of which perfluoroalkyl and polyfluoroalkyl are usually left on or in consumer products, but they do not break down naturally, so they are called "permanent chemicals". They have been linked to cancer, fetal complications, liver disease, kidney disease, autoimmune diseases, and other serious health problems.

Polytetrafluoroethylene (PTFE) is a synthetic tetrafluoroethylene fluoropolymer with a variety of applications. PTFE is a fluorocarbon solid because it is a high molecular weight polymer composed entirely of carbon and fluorine. PTFE is hydrophobic: neither water nor water-containing substances will wet PTFE because fluorocarbons exhibit only a small London dispersive force due to the low electrode polarization of fluorine. PTFE has one of the lowest coefficients of friction of any solid.

Polytetrahydroethylene is used as a non-stick coating for pans and other cookware. It is non-reactive, in part due to the strength of the fluorocarbon bonds, so it is commonly used in containers and piping systems for reactive and corrosive chemicals. When used as a lubricant, PTFE reduces friction, wear and energy consumption in machinery. It is used as a grafting material in surgery and as a coating for catheters.

Based on the toxicity data, human clinical data and physicochemical properties of PTFE, it is shown that PTFE meets widely accepted regulatory evaluation criteria and should be considered a low concern polymer PLC. PTFE has a high molecular weight, a narrow molecular weight distribution, and negligible oligomer content as well as organic and inorganic leachables. The data show that PTFE is thermally, chemically, photochemically, hydrolytically and biologically stable. PTFE has been extensively tested for compliance with U.S. and EU food contact and global medical device regulations (e.g., FDA, CFDA, MFDS Korea, PMDA Japan), including ISO 10993 biocompatibility testing and preclinical animal testing. Toxicological studies of PTFE have shown that PTFE has no acute or subchronic systemic toxicity, irritation, sensitization, implantation local toxicity, in vitro and in vivo genotoxicity, hemolysis, complement activation, or thrombosis. The data presented indicate that the PFAS for PTFE is well defined, meets the PLC criteria, and should be considered significantly different from the other categories of PFAS. Scientific data does not support combining all PFAS together.

PTFE should be exempted and allowed to be produced and used as it is not harmful to the environment and human beings in terms of its production process and use and its downstream applications, and for which there are no relevant alternatives.