The feedback on PFAS restriction— Fluoropolymers

On behalf of Zhejiang Jusheng Fluorochemical Co., Ltd., we would like to extend our greetings to your honored countries that proposing the draft of PFAS restriction . Our company has always made unremitting efforts to comply with domestic and international regulations and continuously conducts strict self review of the compliance of products exported to the European Union. For a long time, we have supported the EU's various regulations and policies aimed at reducing the risks of toxic and harmful substances to human health and the environment. We do our best to take effective measures on reducing the harmful polymers to human health and the environment. But regarding the REACH restriction proposed on March 22nd, we have different understandings and concerns.

1. The REACH restriction proposal will seriously obstruct the social and economic development

PFASs are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–) is a PFAS. According to the definition,more than 10000 organic fluorides (PFAS) will be included.On page 16 of this restriction, PFAS substances are classified, while polymers (FPs) such as PTFE, PVDF, FEP, PFA, etc. are included in the control scope in other categories. In addition to polymers not fully listed in the definition, fluororubber (FKM) and ethylene tetrafluoroethylene copolymer (ETFE) are also included in the control scope according to the definition.

Since the discovery of polytetrafluoroethylene (PTFE) in 1938, fluoropolymers have gone through more than half a century of development and have developed into a complete range of fluororesins and fluoroplastics. PTFE, PVDF, and FEP are the main products of fluororesin materials, accounting for over 90% of the global fluororesin material market[1]. The petrochemical industry is the largest consumer sector of fluororesins, followed by the fields of machinery, electronics and electrical, coatings, textiles, cookware, and medical devices; Automotive components are the largest consumer area of fluororubber.

More than 87% of the production and manufacturing of fluoropolymers in foreign countries are mainly concentrated in developed countries such as Europe, the United States, and Japan, driving the development of downstream healthcare, electrical, textile, automotive, and other livelihood industries, and promoting the construction progress of new infrastructure, including the construction of 5G base stations, ultra-high voltage, intercity high-speed railways and urban rail transit, new energy vehicle charging stations, big data centers, artificial intelligence, industrial internet, and other fields. The downstream application of fluorinated polymer materials is closely related, providing millions of jobs.

The excellent performance of fluoropolymers is closely related to downstream applications: on the one hand, the corrosion resistance, strong acid and alkali resistance, and the vast majority of solvent properties of fluoropolymers make them the main corrosion resistant materials in industries such as petroleum, chemical, and automotive, used for corrosive gas pipeline transportation, garbage incineration, valve sealing, heat exchanger, etc. On the other hand, fluoropolymers with low friction coefficient, self-lubrication, and non stickiness can be used as bearings for chemical equipment, papermaking machinery, agricultural machinery, and as piston rings, machine tool guides, guide rings, etc. Widely used as a support slider for bridges, tunnels, steel roof trusses, large chemical pipelines, storage tanks, as well as a bridge support and bridge swivel in civil and construction engineering. In addition, fluoropolymers have weather resistance, low loss, and low dielectric constant properties, which can be made into enameled wires for use in micro motors, thermocouples, and control devices.

With the continuous development of artificial intelligence, computer vision, and big data, the demand for PFA materials used in contact baskets, containers, and other fields in chip manufacturing is constantly increasing. According to the statistical data released by WSTS in June 2022 on the semiconductor market size of major regions worldwide from 2016 to 2022, the semiconductor market size in the United States in 2022 was approximately 149 billion US dollars, accounting for 23% of the global market size. The largest market size in the Asia Pacific region was approximately 390.6 billion US dollars, accounting for 60.4% of the global market size.

Fluoropolymers have penetrated into various industries due to their excellent performance. And it promotes the development of emerging fields such as semiconductors, 5G communication, and new energy, which is crucial for the development of human society and economy.

2. Long development and cost uncertainty of fluoropolymer substitutes

The restriction proposal in Table 8 "Summary of Alternative Solutions and Cost Impact of Comprehensive Prohibition of PFASs on PFAS Production and Main PFAS Usage Fields" (pages 81-115) lists the substitutes situations of fluoropolymers.

For example, in the field of wires and cables, EPDM, silicon materials, PEEK, etc. can replace polymers such as PTFE, FEP, PFA, etc. In film and coating applications, polyolefins, PET, EVA can replace substances such as PVDF, ETFE, etc. However, there are still many uncertainties with this substitutes , such as whether the processing technology of the substitute is mature, whether its performance can reach or even surpass the current level of fluoropolymers, and whether the cost of the substitution process is economical.

In addition, Table 8 of the restriction proposal also lists products that are currently irreplaceable. For packaging of medical device, PCTFE-based packing for medicinal preparations ,medical devices and molecular diagnostics and PTFE-based in ophthalmic solution packaging are irreplaceable for time being. In the semiconductor manufacturing process, PFA used for chip manufacturing has excellent low ion precipitation and low permeability, making it an irreplaceable product. The development of alternatives is a lengthy process, and if the development of alternatives is not achieved within the exemption period, it will have catastrophic consequences for fields such as medical devices and semiconductors.

3. Fluoropolymers are harmless to the environment and humans

Article 68 of the European REACH regulation defines "restriction" as a means of protecting human health and the environment from unacceptable risks posed by chemical substances. It is classified according to its manufacturing process and molecular structure, and points out that PFAS and its degradation products may exist in the environment for a longer period of time than any other artificial chemical.

Fluoropolymers such as PTFE, PFA, FEP, and ETFE are classified as PFAS substances based on their molecular structure, but their toxicological data is significantly different from other PFAS substances. Fluorinated polymers have chemical stability, biological stability/inertness, negligible solubility in water, no bio-accumulation, non-bioavailable,and no toxicity, and have no impact on human and environmental health[2].

Linear perfluoropolyether polymers (with>24 (CF2CF2CF2O) monomer repeat units in their main chain) are very stable under hydrolysis, photolysis, and microbial degradation test conditions, and the total degradation amount is negligible compared to the total polymer amount of 2ppm[3].

Clinical studies have shown that medical devices such as artificial blood vessels, interventional devices, intravascular stents, mesh patches for hernia repair, and sutures used for surgery made of fluoropolymers have no chronic toxicity or carcinogenicity, reproductive, developmental, or endocrine toxicity after implantation in the human body , and do not have bioavailability or bioaccumulation.

4. Strong durability does not equate to risk

The restriction illustrates that PFAS and their degradation products may persist in the environment longer than any other man-made chemical. However,persistence is not equal to human risk. The key element of risk is molecular entering the human body through cell membranes. Research has shown that the molecular size which can enter the human cell membrane is below 100000 Da, but the molecular weight of fluoropolymers far exceeds this value [4]. Due to the high molecular weight and the largevmolecular volume , the fluoropolymers cannot pass through the human cell membrane.

Although fluorinated polymers degrade very slowly and have strong "persistence", they cannot enter the human body and cause harm. In Anderson's published paper, perfluorocarbonic acids can transform organic fluorine into inorganic fluorine under low-temperature mineralization conditions, exhibiting non-toxic properties[4]. And in this chemical reaction mode, there is hope that it can be extended to other PFAS substances. Evaluating fluoropolymers as having an impact on human health solely based on their "durability" is insufficient [5].

It is an excessive preventive measure that European countries incorporate fluoropolymers into PFAS restrictions.we should treat fluoropolymers differently from other PFAS substances because of its unique properties. Incorporating fluoropolymers into PFAS substances is unreasonable and it should be excluded.

Reference

[1]《□□□□ ·□□□□□□□□□□□》,□□□□□□□□□2022

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