June 22, 2023

European Chemicals Agency
P.O. Box 400, FI-00121 Helsinki, Finland

Sumitomo Electric Fine Polymer, Inc.

Comments on Annex XV Restriction Report (PFAS Restriction Proposal)

Sumitomo Electric Fine Polymer, Inc. is a wholly-owned subsidiary of Sumitomo Electric Industries, Ltd., specializing in electron beam irradiation technology and fluororesin processing technology. We supply unique products to a wide range of industries including automobiles, information and communications, home electronics and infrastructure. One of our novel products expected to be used in a wide variety of applications, especially for carbon neutral objectives, is FEX™, which is based on a unique electron beam cross-linking technology for fluoropolymers.

We welcome this public consultation opportunity, as we fully understand your tireless effort to protect EU citizens from harmful chemical substances. While we are in total agreement with the Dossier submitters' concerns per PFAS on human health and environment, we have different opinions on what and how PFAS should be regulated. We would like to take this opportunity to provide our comments based on scientific grounds. Our views outlined below are also being submitted by our parent company, Sumitomo Electric Industries, Ltd., whose activities also cover basic research and development of FEX™ technology. During the public consultation period, we plan to submit comments on several occasions to complete our views. This is our initial submission.

1) Request for exemption

We strongly request that perfluoropolymers (e.g., PTFE, PFA, FEP) and those cross-linked by electron beam irradiation be exempt from the scope of PFAS in the proposal for the following reasons.

Perfluoropolymers and those cross-linked by electron beam irradiation are materials that are neither bioaccumulative nor biotoxic. Their unique and outstanding properties have made them indispensable to society, especially in solving environmental problems, as they provide solutions unmatched by other materials.

Perfluoropolymers have totally different properties and hazardous levels compared to other harmful PFAS substances, such as PFOA or PFOS. If perfluoropolymers are collectively banned with those other PFAS simply because their chemical formulas are similar, without closely reviewing and classifying their properties, we may encounter serious consequences in terms of social economic impact. The reasons are detailed in sections 2) and 3) below.

2) Perfluoropolymers are neither bioaccumulative nor biotoxic

Because perfluoropolymers are chemically and biologically persistent and inert, elution of these materials is known to be very limited (Olabisi et al., 2016). Complying with EU regulations on PFOA and PFOS, we have seen a drastic improvement in the production process of perfluoropolymers. According to our analysis performed by a third party testing laboratory, PFOA was not detected from PTFE and PFA (see "PTFE_PFA_ analysis.pdf" as attached in Section Ⅳ). Therefore, no hazardous materials are expected to be leaching from perfluoropolymers, which indicates that animals or plants will not be absorbing PFOA nor perfluoropolymers themselves. If there is nothing being absorbed, then bioaccumulation and biotoxicity do not occur (Henry et al., 2009; OECD, 1993; Beyer EC.1993; Korzeniowski, S. H, et al., 2023; FCJ, 2023, see "FCJ.pdf" as attached in Section IV).

Since perfluoropolymers are chemically and biologically persistent and inert, they have been used as material for implantable artificial organs such as pericardial patches and artificial blood vessels (Henry et al., 2009; Olabisi, 2015; Gangal & Brothers, 2000).

It is also documented in the literature that perfluoropolymers are substances with distinctly different properties from potentially toxic low molecular weight compounds such as PFOA and PFOS, which were the starting point for this proposed restriction (Henry et al., 2009; OECD 1993; Olabisi, 2019; FCJ, 2023, see "FCJ.pdf" as attached in Section IV).

3) Perfluoropolymers are irreplaceable materials that can contribute significantly to solving environmental concerns

Perfluoropolymers have unique and excellent properties including persistency, inertness, non-adhesiveness, sliding capability, heat resistance and a low dielectric constant. Such properties have made the substances essential to society. In addition, products that are coated with cross-linked perfluoropolymers have excellent sliding durability (several hundreds to thousands of times higher durability) while maintaining an unparaleled level of low friction coefficient (Ikeda, 2020, See "Ikeda.pdf" as attached in Section Ⅳ). Moreover, the cross-linking occurs between the perfluoropolymer and the substrate material enhancing adhesive strength. This novel cross-linking technology has opened up new potential in areas where perfluoropolymers were once believed to be inapplicable due to the lack of durability. Its applications are expected to further expand and contribute to carbon neutrality in terms of energy saving and promotion of adhesive-free/solvent-free processes.

We would like to present some examples as follows, however please note that these are just a few of the many potential uses for these materials. Applications and sectors where perfluoropolymers contribute to solving environmental issues are not limited to those presented here. We are currently conducting R&D on a wide variety of applications that can contribute highly to carbon neutrality, including energy saving and low environmental load with adhesive-free/solvent-free processes.

Example 1: Reduce environmental load by solvent-free bonding with electron beam cross-linking

By forming perfluoropolymer coating on metal surface (e.g., Al, Cu, and SUS) and cross-linking it with electron beam irradiation, the perfluoropolymer is bonded to the surface of the substrate in a solvent-free condition where no adhesive or no solution with organic solvent is applied. We developed this coating technology and put it into practical use. Since a perfluoropolymer layer is formed by aqueous dispersion coating or extrusion method, this is a 100%-solvent-free process(Ikeda, 2020, See "Ikeda.pdf" as attached in Section Ⅳ). This technology has made it possible for perfluoropolymers to not only adhere to metal in a solvent-free manner, but also to bring about benefits described in examples 2 to 6.

Example 2: Reduce material waste and energy consumption by realizing higher durability with excellent sliding and non-adhesive capabilities on the coating

Using the technology to coat devices such as extrusion dies for common polymer materials such as polyethylene, a substantial reduction in the material waste and product waste is realized. Therefore, cross-linked perfluoropolymers contribute not only to reduction of environmental load but achieves this task with a solvent-free process. We will provide more details and reference(s) on this example in our subsequent public consultation submission.

Example 3: Improve energy conversion rate by enhancing the sliding property

Using the technology to coat sliding parts with perfluoropolymers, the energy conversion rate improves so that energy saving and reduction of environmental load are achieved. We will provide more details and reference(s) for this example in our subsequent public consultation submissions.

Example 4: Improve the energy conversion rate of specific electric wires by achieving a low dielectric constant and adhesive-free/solvent-free bonding

Since this coating technology does not require primer or adhesive materials, specific-purpose electric wires with this coating can maintain almost the same low dielectric constant of 2.1 as that of a fluoropolymer-only coating. Therefore, it improves the energy conversion rate while reducing environmental load. We will provide more details and reference(s) for this example in our subsequent public consultation submissions.

Example 5: Unique method for producing a specific medical product

This coating technology is the only coating technology used for producing a specific medical product. We will provide more details and reference(s) for this in our subsequent public consultation submissions.

Example 6: Reduction of load on production equipment and wear debris by applying FEX™ tape

FEX™ tape allows users to easily utilize the high wear resistance of FEX™ just by attaching it to an object. The use of FEX™ tape for equipment eliminates the need for frequent replacement of parts and tape due to wear and peeling, thus the product is expected to bring various advantages over conventional fluororesin tapes, such as extended service life and less frequent maintenance of equipment, improved workability, and the prevention of scratches on equipment. In addition, the product is environmentally friendly because its excellent slipperiness and wear resistance contribute to the reduction of load on equipment and wear debris, respectively. We will provide further information in separate submission(s) to complete our comments on the restriction proposal. In the meantime, please feel free to contact us if any questions arise.

Sincerely yours,

June 22, 2023

Yoshimasa Suzuki

Yoshimasa Suzuki
President
Sumitomo Electric Fine Polymer, Inc.

References

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