Subject: Request for Exemption of Granular PTFE Resins in the Seal Industry from PFAS Restriction

Dear ECHA Scientific Committees,

I am writing on behalf of Bal Seal Engineering, a subsidiary of Kaman Corporation, a company specializing in the manufacture of custom seals, springs, and electrical contacts. Our products play a vital role in enhancing the performance and reliability of critical equipment across various industries, ranging from medical implantables and orthopedic instruments to diagnostic and analytical equipment, as well as aerospace applications. We greatly appreciate the opportunity to participate in the public consultation on the PFAS restriction, and we would like to request the exemption of granular PTFE (polytetrafluoroethylene) resins in the engineered seal industry from this restriction.

Granular PTFE resins, which are used for molding and ram extrusion of sheets, rods, or billets, are a substantial component of our products and are integral to the functioning of numerous applications. We believe that exempting granular PTFE resins from the PFAS restriction is necessary due to the following scientifically supported reasons:

Diverse Nature of PFAS: Polytetrafluoroethylene (PTFE) is a type of fluoropolymer, and it is essential to recognize the diverse nature of PFAS (per- and polyfluoroalkyl substances). While it is true that some PFAS compounds have been identified as environmentally detrimental, it is inaccurate to assume that all PFAS materials share the same characteristics[1]. Granular PTFE is chemically inert and does not degrade under normal environmental conditions. It is resistant to chemical reactions, heat, and moisture, making it a highly stable material[2]. Perfluorooctanoic acid (PFOA) or perfluorooctanesulfonic acid (PFOS), which are two of the most well-recognized and problematic PFAS compounds[1], have been excluded in the manufacturing processes, i.e. suspension polymerization, of granular PTFE resins by U.S. manufacturers[3], and restricted in EU for more than 10 years. In addition, PTFE resins in their granular form are hydrophobic and will not accumulate in aquatic environments as their dispersion form does. Therefore, it is essential to differentiate granular PTFE resins from other PFAS materials when considering regulatory restrictions.

Unique Properties of PTFE: PTFE possesses exceptional properties that cannot be easily replicated by alternative materials in the seal industry. Its low coefficient of friction provides excellent lubricity, enabling smooth movement and reducing wear between sealing surfaces[4]. This property is crucial in applications where repeated cycles and continuous sliding motions occur, such as in medical devices, valves, pumps, and rotary shaft seals. PTFE's high chemical resistance ensures that it remains stable and does not degrade when exposed to a wide range of chemicals[5,6]. This property is particularly valuable in applications where seals come into contact with aggressive substances, such as in chemical processing, oil and gas extraction, and laboratory equipment. More importantly, PTFE is among the best-performance fluoropolymers for cryogenic applications. PTFE and its modified forms have a working temperature that extends down to -328 °F (-200 °C) displaying little or no increased brittleness[7,8], and it has a high melting point, excellent electrical insulation properties, and is non-reactive with most materials, making it ideal choice for cryogenic applications and pressure fluctuations.

Environmental Impact Considerations: It is essential to evaluate the environmental impact of PTFE in a comprehensive manner. While it is true that PTFE is considered a long-lasting material and its production involves high energy consumption, the durability and extended lifespan of PTFE-based seals mitigate the need for frequent replacements and contribute to overall sustainability. Additionally, the fluorine content in PTFE is chemically stable and not readily bioavailable, meaning it does not readily enter environmental or biological systems. Studies have shown that PTFE has a very low potential for bioaccumulation and doesn't release harmful compounds in the environment[9–11]. Instead, as shown in Figure 1, the most-detected bioaccumulation substance from the PFAS group is perfluorooctanesulfonic acid (PFOS)[12], which is considered as one of the factors that leads to cancers and diseases. Therefore, PTFE does not pose the same level of risk as certain PFAS compounds that have demonstrated environmental persistence and bioaccumulation.

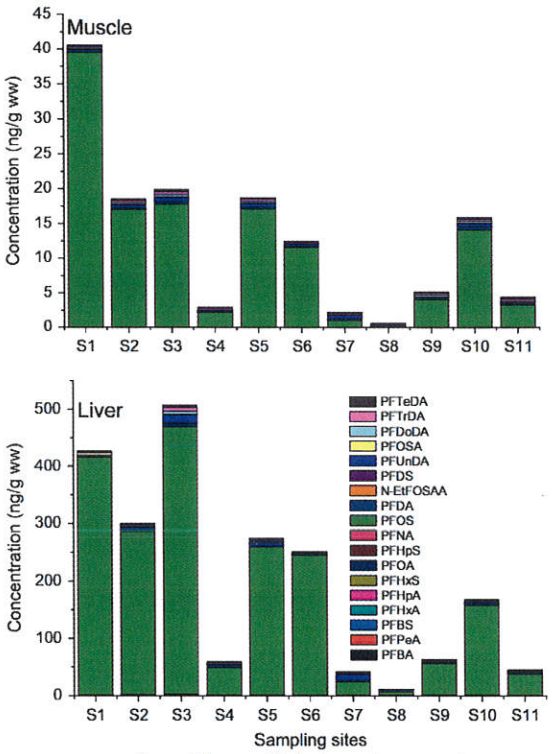

Figure 1 The PFASs concentrations in muscle and liver of fish from the sampling sites of the PRD rivers [12].

Negative Social and Economic Impact: Imposing a ban on PTFE in the seal industry would have severe social and economic consequences, not only for our company but also for the industries that rely on our products. Our PTFE-based seals are widely used in cutting-edge applications across various sectors, including medical, oil and gas, aerospace, and defense industries, where we have contributed hundreds of thousands of seals, partially shown in Table 1. Banning PTFE would necessitate the replacement of these seals with alternative materials, which may not provide the same level of performance and reliability. The resulting negative impacts would include compromised safety in medical devices, increased maintenance and downtime in industrial equipment, and potential failures in aerospace applications. These consequences would not only disrupt the affected industries but also have far-reaching effects on patient health, environmental sustainability, and technological progress.

Table 1 Partial seal applications at BSE in medical and aerospace industries

Seal Applications	Units sold
Atherectomy catheter	325k
Surgical Drill motor	7k
Surgical Drill/Reamer	130k/125k
Aircraft oxygen regulators	275k
Mine removal underwater vehicle	50k

Our spring-energized seals have exceptional properties that enable them to maintain performance in extreme conditions, and they are the key to innovation and excellence in these fields. The uniqueness of PTFE is one of the factors that made it happen. Hence, we respectfully urge you to exempt granular PTFE resins in the engineered seal industry from the PFAS restriction. Recognizing the specific characteristics and applications of individual materials within the PFAS group is vital to ensure that regulations are appropriately targeted and effective. By providing this exemption, you would not only safeguard the performance and reliability of essential equipment but also support the growth and sustainability of industries that rely on PTFE-based products.

Thank you for your attention to this matter, and we remain available to provide any further information or clarification as required. We appreciate your consideration of our request and trust that you will make a well-informed decision that benefits both the industry and the environment.

Sincerely,

3rd Aug 2023

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