# Impact on SMEs of a restriction on fluoropolymers

**The European Small Business Alliance for Fluoropolymers comments on the ANNEX XV RESTRICTION REPORT on per- and polyfluoroalkyl substances (PFASs)**

September 2023


_Executive Summary:_

*The European Small Business Alliance for Fluoropolymers (ESBAF) is a newly formed ad-hoc coalition of European SMEs that safely utilize fluoropolymers across diverse, complex, and critical supply chains and for various standard chemical processes. ESBAF counts nine SMEs among its membership, covering various stages of the manufacturing supply chain, all of whom have only recently been alerted of the potential impacts of the PFAS restriction proposal. While recognizing the necessity of addressing risks from certain PFAS concerns, ESBAF emphasizes the distinctive nature of fluoropolymers compared to other PFAS, their demonstrated benign hazard profile, the lack of recognised alternatives in high-performance and strategic applications, and the severe consequences the restriction may have on SMEs. Ultimately, ESBAF calls for fluoropolymers to be excluded from the scope of the proposed restriction.*


SMEs play a vital role in driving economic growth, fostering innovation, and creating employment opportunities in Europe. They form the backbone of European society, contributing significantly to the development and prosperity of the EU. As the EU pursues its industrial goals and strategic autonomy, the delicate balance between independent industrial capabilities, innovation, and SME viability becomes paramount. In a recent report, the European Commission underscores the unprecedented challenges faced by SMEs amidst economic uncertainty.[1] In this context, the proposed REACH restriction on Per- and Polyfluoroalkyl Substances (PFAS) poses an existential threat to the many SMEs who safely utilize fluoropolymers (such as PTFE, FKM, FFKM, etc.) along various strategic supply chains.

These fluoropolymers, possessing unparalleled properties, serve as the foundation of supply chains in vital sectors such as hydrogen, semiconductors, the food industry, and medical devices, to name a few. While some strategic end uses are benefiting from time-bound derogations under the proposed restriction, the SMEs constituting the intricate and essential remainder of these supply chains have been left in a precarious position. In this paper, ESBAF outlines its key arguments in favour of an exclusion of fluoropolymers from the scope of the impending restriction, to safeguard the vibrancy and resilience of the SMEs that underpin Europe's economic fabric and society more generally.

ESBAF's key messages regarding the proposed restriction dossier are:

- **Fluoropolymers are distinct from other PFAS:** ESBAF recognizes the importance of addressing the risks associated with certain PFAS of concern, but stresses that it is crucial to differentiate between fluoropolymers and other polymeric and nonpolymeric PFAS.[2] Fluoropolymers are high molecular

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[1] Di Bella, L., Katsinis, A., & Lagüera-González, J. (2023). *SME Performance Review*. European Commission's Joint Research Centre. Link
[2] Henry, B. J., Carlin, J. P., Hammerschmidt, J. A., Buck, R. C., Buxton, L. W., Fiedler, H., Seed, J., & Hernandez, O. (2018). A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integrative Environmental Assessment and Management, 14*(3), 316-334. doi:10.1002/ieam.4035

weight (typically a number average molecular weight in a range of Da 30000 to 500000 g/mol)[3] polymers with unique properties attributable to the strong C–F bonds, the strongest single bond in organic chemistry[4], making them highly stable. Unlike certain PFAS of concern, fluoropolymers have been extensively studied and proven to be safe for use in their intended applications. In addition, 96% of commercially accessible fluoropolymers conform to the OECD Polymer of Low Concern (PLC) criteria.[5] Finally, given their intrinsic properties, fluoropolymers do not deteriorate during both intended use and exposure to environmental conditions.[6] It is crucial to adopt a differentiated approach to regulating fluoropolymers to ensure a balanced, proportional, and evidence-based regulatory approach.[7,8]

- **There are no viable alternatives for fluoropolymers in many high-performance applications:** Fluoropolymers demonstrate extraordinary qualities that include exceptional resistance to chemicals, heat (up to 325 degrees Celsius continuously), aging, and weathering, along with unique electrical performances.[9,10] These polymers maintain their stability when exposed to hydrocarbons, solvents, acids, bases, and their combinations, which underscores their strong compatibility with various chemicals. The strong C−F bond present in these polymers greatly enhances their remarkable ability to withstand the detrimental effects of both hydrolytic and oxidative factors. This inherent stability, combined with their unique characteristics, leads to exceptional and lasting performances in various critical and strategic applications. Restricting the use of fluoropolymers without viable alternatives would hinder technological advancements, limit product innovation, and compromise the overall competitiveness of European industries. Further, replacing fluoropolymer compounds with lower performing substances may potentially lead to regrettable substitutions from a hazard and sustainability point of view, since the structural properties of fluoropolymers ensure a safe and sustainable use of products / chemical processes.

- **The proposed restriction would have severe consequences for European industries, particularly SMEs:** While certain end-uses have been granted derogations in the proposed restriction dossier, there is a notable absence of consideration for the various comprehensive supply chain for these end-uses. Many SMEs, which are integral to advancing a range of EU objectives, are reliant on fluoropolymers for their operations. Consequently, a ban on fluoropolymers will likely lead to supply chain vulnerabilities impacting the EU's ability to access the fluoropolymers it needs to develop strategic technologies, potentially leading to the erosion of these industries as a whole. Given that SMEs are the backbone of our economy, the potential fallout could result in business closures, job losses, and hindered economic

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[3] Maccone P, Apostolo M, Ajroldi G. Molecular weight distribution of fluorinated polymers with long chain branching. Macromolecules 2000,33,1656-1663.
[4] Atkins. P, Paula. J, 2014, Atkins' Physical Chemistry 10th Edition, Oxford University Press, Oxford, Page 985-986, Table 10C.2a and 10C.2b.
[5] Organisation for Economic Co-operation and Development. (2009). *Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern*. Link
[6] Sales, J., & et al. (2022). Fluoropolymers: The Safe Science That Society Needs. *International Chemical Regulatory and Law Review, 5*(1), 13-17.
[7] OECD. (2009). Data analysis of polymer characteristics. Link
[8] UK Health and Safety Executive. (2023). *Regulatory management options for Poly- and perfluoroalkyl substances (PFAS)*. Link
[9] Zulfiqar, S., & et al. (1994). Study of the thermal degradation of polychlorotrifluoroethylene, poly (vinylidene fluoride) and copolymers of chlorotrifluoroethylene and vinylidene fluoride. *Polymer Degradation and Stability, 43*(3), 423-430. Link
[10] McKeen, L. W. (2014). *The Effect of Long-Term Thermal Exposure on Plastics and Elastomers*. Elsevier. Link

growth. In fact, among our member companies, the majority would be at risk of closure, while the remainder would face extensive restructuring.

- **The restriction as it stands would be impossible to implement for SMEs:** The current proposed restriction presents a significant challenge for SMEs due to the complex and interconnected nature of the supply chains utilizing fluoropolymers. This complexity arises from the involvement of various stakeholders, making it difficult for small businesses to accurately track and classify the diverse end-uses that these products serve. The lack of harmonized classification for PFAS under the CLP Regulation also results in the absence of information transmission along the supply chain (such as through safety data sheets), leading to a time-consuming and often unfeasible analysis of the extent of impact. This situation leaves SMEs struggling to identify specific applications and qualify for potential derogations. The lack of clarity regarding end-use purposes, coupled with uncertainty about derogation eligibility, greatly impedes SMEs' ability to navigate the intricate regulatory landscape.

ESBAF calls on EU regulators to exclude fluoropolymers from the scope of the proposed restriction on PFAS. While it is essential to address potential risks associated with certain PFAS of concern, it is equally important to consider the supply chain complexities and the indispensable role of SMEs in driving innovation and economic growth. By excluding fluoropolymers from the proposed restriction, European SMEs will be able to continue their contributions to the wealth of the society, economic growth, technological advancement, and job creation.

**About ESBAF:**
The European Small Business Alliance for Fluoropolymers (ESBAF) is a newly formed ad-hoc coalition of SMEs that utilize fluoropolymers across diverse and complex European supply chains and standard chemical processes. ESBAF counts nine SMEs among its membership, covering various stages of the manufacturing supply chain, all of whom have only recently been alerted of the potential impacts of the PFAS restriction proposal and who are underrepresented in Brussels.

# Case study: supply chain impacts of a ban on FFKM

## Introduction

The Netherlands, Germany, Denmark, Norway, and Sweden submitted a restriction dossier on per- and polyfluoroalkyl substances (PFAS) to the European Chemicals Agency (ECHA). The main objective of this effort is to restrict the manufacturing, selling, and importing of about 10,000 chemical compounds, including fluoropolymers. This case study investigates the scenario of a ban on a widely used fluoropolymer, Perfluoroelastomers (FFKM), aiming to explain the impact of such restriction on standard industrial processes found in various supply chains.

### What is FFKM?

FFKMs are advanced synthetic elastomers that consist of fully fluorinated compounds polymeric component. Monomers used within these polymers are: tetrafluoroethylene (TFE), a perfluoro alkyl vinyl ether (PAVE), and a fully fluorinated cure site monomer (such as 1-Iodo-trifluoro-ethene). FFKM elastomers are notable for their remarkable chemical and thermal resistance to both chemicals and high temperatures, their outstanding ability to repel resist gas and liquid permeation, and their capacity to withstand the effects of weather and ozone.[11,12,13] Operating effectively within a wide temperature range of -45 to 330 °C, FFKM elastomers offer versatile performance attributes and are widely used in industrial applications, such as critical sealing solutions for the aerospace, pharmaceutical, medical, chemical processing, and semiconductor sectors.[14,15]

## The Integrated Supply Chain for FFKM: Ensuring Quality and Performance

### Compounder:

Compounders buy FFKM polymers from major specialty chemical producers. They combine these base polymers together with additives, such as fillers, curatives, and pigments to produce a carefully engineered product that provides desired properties tailored for specific applications.

### Manufacturers of Seals and Gaskets:

FFKM compounds are used by manufacturers to produce a broad range of seals and gaskets, which are essential components for creating leak-proof and durable connections of mechanical parts across many industries. During the manufacturing process, the FFKM undergoes vulcanization, an irreversible chemical process that enhances its properties by crosslinking/vulcanizing the polymeric chains into a 3-dimensional structure with high molecular weight. This process determines some of the article's final chemical, physical, mechanical, and dimensional properties. The most common process to achieve this, uses a tool and press. By applying pressure and temperature the compound achieves the desired shape and necessary properties.

### Distributors:

Distributors purchase these FFKM seals and gaskets from manufacturers to place them on the market. They play a critical role in ensuring that the right products reach the right applications, based on specific requirements.

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[11] Drobny JG. 2006. Fluoroplastics. Shropshire (UK): Rapra Technology. p 12.
[12] Greene-Tweed. (2021a). FKM versus FFKM–A comparison of properties. https://live-greene-tweed.pantheonsite.io/wp-content/uploads/2020/04/FKM-vs-FFKM-Properties-Comparison-R3.pdf
[13] Green-Tweed. (2021b). FKM vs. FFKM. https://www.gtweed.com/materials/fkm-vs-ffkm/
[14] Atkinson, S. (2018). Essential high-purity sealing materials for semiconductormanufacturing. Sealing Technology,7,5–7. https://doi.org/10.1016/S1350-4789(18)30284-8
[15] Marshall, J. 2017. Kalrez®-type perfluoroelastomers—Synthesis, propertiesand applications. In J. Scheir (Ed.), Modernfluoropolymers(pp. 349–358). John Wiley and Sons.

**Applications in Pumps and Equipment:**
These FFKM seals and gaskets find their way into various industrial equipment, such as pumps, or are first integrated into mechanical seals which will then be used further in the supply chain. Pumps, which are used for fluid transport, require seals that can withstand aggressive chemicals and maintain their integrity over time. The properties of FFKMs ensure reliable performance in these harsh environments.

**Impact on End-Use Equipment:**
The pumps, equipped with FFKM seals are integrated into larger systems that produce specific end-use products. End-use applications may include pharmaceuticals, chemicals, medical devices, food and beverage, semiconductors, and green hydrogen. The integration into many different end-uses showcases the diverse role that FFKMs plays in supporting critical and strategic industries.

**Considerations:**
The above provides a simplified depiction of the fluoropolymer supply chain reduced to only its essential steps and exemplifies its complexity and deep level of integration within industrial processes. The diverse applications of FFKMs increase the number and complexity of supply chains. Often, stakeholders, especially those early in the supply chain, will not even know the final use of their FFKM product.

To shed more light on the impacts a ban on FFKMs would mean to modern day society, the following case study illustrates what would happen if FFKMs would be replaced by a non-fluorinated elastomer.

**<u>The example of the Centrifugal Pump and non-fluorinated O-Rings</u>**

A pump manufacturer receives a request for a centrifugal pump. Centrifugal pumps are used in a variety of industrial processes, such as for the production of semiconductors or the electrolysis of green hydrogen. All applications demand high-level precision engineering and require robust components to ensure safe and efficient production.

A centrifugal pump is a mechanical device that uses a rotating impeller to create a flow of fluid by converting rotational energy into kinetic energy, resulting in increased pressure and movement. A centrifugal pump needs seals to prevent fluid leakage at points where the rotating shaft meets the pump casing. These seals maintain fluid containment and contribute to efficient pump performance by reducing internal recirculation.

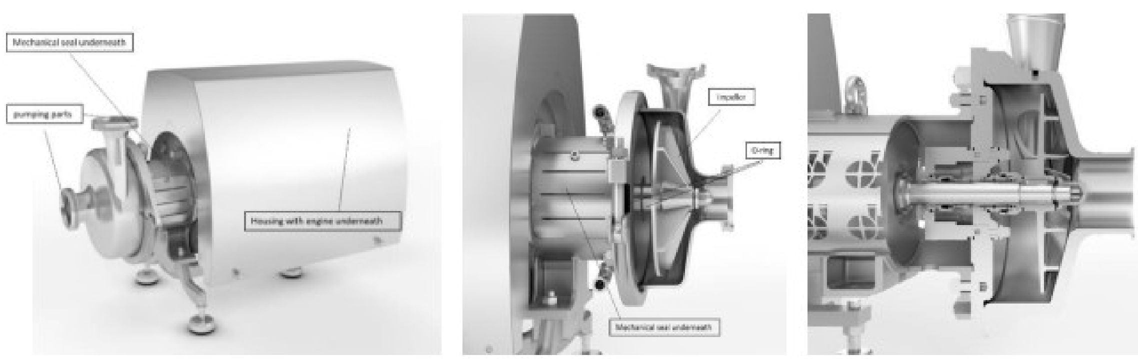

*Figure 1: Centrifugal pump*

In order to ensure that the seals provide the correct technical performance characteristics, the pumps manufacturer engages with a distributor and a mechanicals seals manufacturer. Mechanical seals consist of a stationary sealing face and a rotating sealing face, while incorporating an elastomer seal like an O-ring to create a secure barrier between stationary and rotating components. For this elastomeric part the mechanical seal manufacturer also engages with the distributor who recommends using FFKM seals. For all applications where a particularly aggressive medium is pumped at elevated temperature, the seals require a very high chemical and thermal resistance. (For the purpose of this case study, the example sheds light on FFKM parts, specifically O-rings. However, centrifugal pumps also require rubber-based form parts and integrate other fluoropolymers, such as polyvinylidene fluoride (PVDF) and Polytetrafluoroethylene (PTFE)).

FFKMs provide the required thermal and chemical characteristics. The excellent thermal resistance allows the material to seal for a significant period, this can be evidenced by the low compression set (see Figure 2 below). A compression set is the term used to describe the phenomenon wherein a material undergoes permanent deformation and loss of its ability to maintain a seal after being subjected to compression or maintained in a compressed state over an extended period. This metric serves as an indicator of the material's ability maintain a seal effectively, where a lower figure indicates a longer seal life. The below graph shows the compression set of an FFKM against the compression set of a "high temperature" silicone and HNBR. Figure 2 visualises that the compression set of an FFKM is significantly lower than that of a "high temperature" silicone or a HNBR. It indicates a minimum increase of life of 500 times when using an FFKM over non PFAS alternatives.

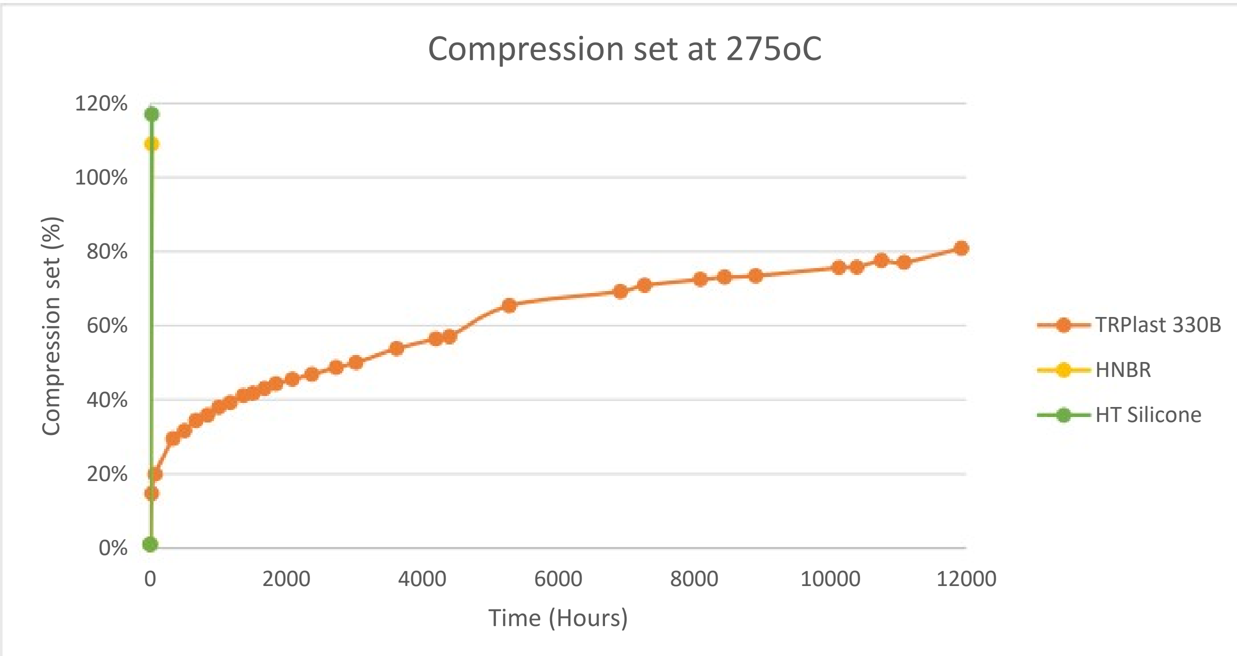


*Figure 2: Compression set of an FFKM against the compression set of a "high temperature" silicone and HNBR (data generated by one ESBAF member)*

In order to match the right compound for the application, the distributor uses a so-called 'chemical resistance guide. A chemical resistance guide is a compilation of materials and their corresponding reactions to different chemicals. It provides valuable information about the chemical resistance of compounds when exposed to specific chemical agents through a scale from A (suitable) to D (not suitable). Annex A provides an example of such a list showcasing that in most mediums FFKMs perform best (A).

The distributor requests the required FFKM parts at a seal manufacturer who uses the correct FFKM compound and produces O-rings with the desired dimension, hardness, and physical properties. These products are integrated into the centrifugal pump. The integrated efforts of stakeholders in the fluoropolymer supply chain culminate in a reliable, safe, and environmentally conscious production process.

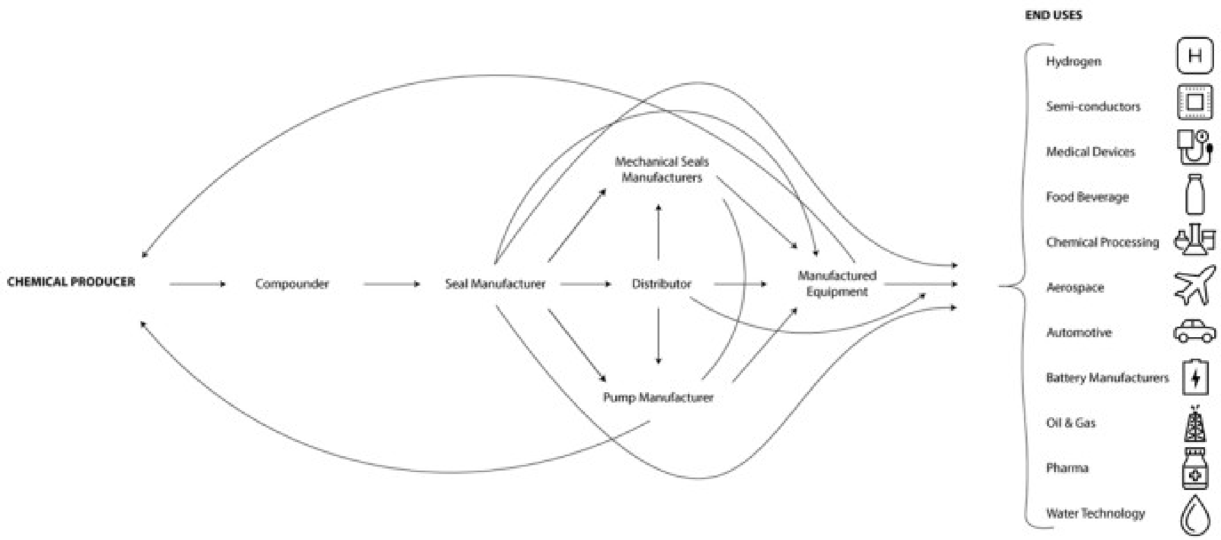


*Figure 3: Simplified visualisation of the fluoropolymer supply chain, including a selected number of end-uses*

**What would happen in the event of a ban on FFKMs?**

As explained previously, fluoropolymers display strong thermal and chemical resistance. If FFKMs were to be banned, the FFKM parts in the pump would have to be substituted by non-fluorinated elastomer parts. This substitution would have several important and detrimental impacts.

(Please note that this analysis focuses solely on the sealing parts of a pump and doesn't account for the main parts, which also require resistant materials such as FFKMs and/or other fluoropolymers.)

**Technical Performance would be compromised:**
Using a non-fluorinated O-ring in a medium that requires high chemical resistance would result in deterioration of the seal or a significantly reduced seal life. Using a non-fluorinated elastomer in an aggressive medium can typically cause 3 effects:

1. Seal swelling, this can cause several failures such as increased permeation of chemicals, seal breakdown which then combines with process fluid, splitting caused by excessive swelling which compromises the seal. the photo below shows a typical swollen elastomer, where a tear has formed that caused fluid leakage.

*Figure 4: Swelling of a seal with low chemical resistance (e.g. non-fluorinated) used in aggressive medium (Illustration from ESBAF members)*

2. Polymer degradation, this can cause cracking or softening and reduces the ability for a material to maintain a seal significantly, which in turn reduces service life. This can not only cause fluid leakage but can cause contaminants to pass into process fluids. The below photo shows a typical example of a degraded material.

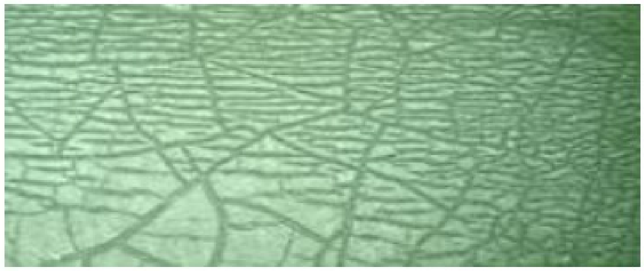

*Figure 5: Polymer degradation (Illustration from ESBAF members)*

3. Polymer dissolution, this can occur where the process fluid dissolves the polymer itself. This physically removes seal material, and quickly causes seal failure.

*Figure 6: Polymer dissolution (Illustration from ESBAF members)*

From a thermal resistance perspective, the non-fluorinated elastomer can only be used in processes that occur up to 200 degrees Celsius. Every process at higher temperatures also results in material failure up to degradation and therefore loss of sealing integrity. Processes at a higher temperature will lead to a significantly reduced service life and hence time until leakage for non PFAS materials.

**Risk to the environment would increase substantially:**
The decreased chemical and thermal resistance of O-rings due to using non-fluorinated materials can have significant environmental implications. The accelerated breakdown of O-rings necessitating immediate replacements not only undermines circularity goals by generating more waste and resource consumption but also leads to reduced operational efficiency with higher energy consumption for maintenance and replacement processes. Moreover, the heightened risk of leaks due to compromised O-ring durability can result in emissions of harmful substances, potentially posing severe environmental risks and contamination of ecosystems.

**Workers' Health and Safety would be at risk:**
The diminished thermal resistance and chemical resistance of using non-fluorinated elastomers pose significant hazards to worker safety. The heightened potential for leaks and the risk of swelling-induced pressure compromises the structural integrity of applications, potentially leading to total failures. Such failures severely jeopardise workers health and safety by e.g., exposing them to hazardous substances.

**Conclusion: Ensuring Resilience, Sustainability, and Safety in the Fluoropolymer Supply Chain**

The FFKM supply chain highlights the intricate interplay of various stakeholders, from chemical companies to end-users. In addition, the example of a centrifugal pump with and without FFKMs show that the fluoropolymer's unique properties are vital for maintaining performance, sustainability, and safety across the supply chain. Any restrictions on FFKM would disrupt this supply chain, potentially leading to negative impacts on equipment reliability, environmental protection, worker safety, and standard industrial processes.

## Annex A: Chemical resistance guide

| Medium | NR, IR | SBR, BR | IIR | EPDM, EPM | NBR | CR | SI, VMQ | FFKM |
|---|---|---|---|---|---|---|---|---|
| Acetic Anhydride | B | B | B | B | C | B | C | A |
| Acetyl Chloride | D | D | D | D | D | D | C | A |
| Acrlylonitrile | D | D | D | D | D | D | D | A |
| Alkazene (Dibromoethylbenzene) | D | D | D | D | D | D | D | A |
| Amyl Acetate (Banana Oil) | D | D | C | C | D | D | D | A |
| Amyl Chloronapthalene | D | D | D | D | D | D | D | A |
| Amyl Napthalene | D | D | D | D | D | D | D | A |
| Aniline Hydrochloride | B | D | B | B | B | D | D | A |
| Ansul Ether (Anesthetics) | D | D | C | C | C | D | D | A |
| Aqua Regia | D | D | D | C | D | D | D | A |
| Aroclor, 1248 | D | D | C | C | C | D | B | A |
| Aroclor, 1254 | D | D | D | C | D | D | C | A |
| Askarel | D | D | D | D | B | D | D | A |
| Asphalt | D | D | D | D | B | B | D | A |
| Banana Oil (Amyl Acetate) | D | D | C | C | D | D | D | A |
| Benzene | D | D | D | D | D | D | D | A |
| (Nitrobenzine) (Pet Ether) | D | D | D | C | D | B | D | A |
| Benzoic Acid | D | D | D | C | C | D | C | A |
| Benzoyl Chloride | D | D | D | D | D | D | * | A |
| Benzyl Benzoate | D | D | B | B | D | D | * | A |
| Benzyl Chloride | D | D | D | D | D | D | D | A |
| (Phenylbenzene) | D | D | D | D | D | D | D | A |
| Bromine-Anydrous | D | D | D | D | D | D | D | A |
| Bromine Trifluoride | D | D | D | D | D | D | D | A |
| Bromine Water | D | D | C | B | D | D | D | A |
| Bromobenzene | D | D | D | D | D | D | D | A |
| Butadiene | D | D | D | C | D | D | D | A |
| Butyl Acetate | D | D | C | C | D | D | D | A |
| Butyl Acrylate | D | D | D | D | D | D | * | A |
| Butyl Amine | D | D | C | B | C | D | D | A |
| Butyl Benzoate | C | B | B | B | D | D | * | A |
| Butyl Oleate | D | D | B | B | D | D | * | A |
| Butyl Stearate | D | D | C | C | B | D | * | A |
| Butylene | D | D | D | D | B | C | D | A |
| Butyraldehyde | D | D | B | B | D | C | D | A |
| Carbamate | D | D | B | B | C | B | * | A |
| Carbitol | B | B | B | B | B | B | B | A |
| Carbolic Acid (Phenol) | D | D | B | B | D | C | D | A |
| Carbon Bisulfide | D | D | D | D | C | D | D | A |
| Carbon Tetrachloride | D | D | D | D | C | D | D | A |
| Cellosolve | D | D | B | B | D | D | D | A |
| Cellosolve Acetate | D | D | B | B | D | D | D | A |
| Chlorine (Dry) | D | D | D | D | D | C | D | A |
| Chlorine (Wet) | D | D | C | C | D | C | D | A |
| Chlorine Dioxide | D | D | C | C | D | D | * | A |
| Chlorine Trifluoride | D | D | D | D | D | D | D | A |
| Cholorobenzene | D | D | D | D | D | D | D | A |
| Chlorobromomethane | D | D | B | B | D | D | D | A |
| Chlorobutadiene | D | D | D | D | D | D | D | A |
| Chlorododecane | D | D | D | D | D | D | D | A |
| Chloroform | D | D | D | D | D | D | D | A |
| O-Chloronapthalene | D | D | D | D | D | D | D | A |
| 1-Chloro-1-Nitro Ethane | D | D | D | D | D | D | D | A |
| Chlorosulfonic Acid | D | D | D | D | D | D | D | A |
| Chlorotoluene | D | D | D | D | D | D | D | A |
| Chrome Plating Solutions | D | D | B | B | D | D | B | A |
| Chromic Acid | D | D | C | C | D | C | C | A |
| Coke Oven Gas | D | D | D | D | D | D | B | A |
| Cresol | D | D | D | D | D | C | D | A |
| Cresylic Acid | D | D | D | D | D | C | D | A |
| Cumene | D | D | D | D | D | D | D | A |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Cyclohexanone | D | D | B | B | D | D | D | A |
| P-Cymene | D | D | D | D | D | D | D | A |
| Decalin | D | D | D | D | D | D | D | A |
| Dibenzyl Ether | D | D | B | B | D | C | * | A |
| Dibenzyl Sebecate | D | D | B | B | D | D | C | A |
| Dibromoethylbenzene | D | D | D | D | D | D | D | A |
| Dibutyl Amine | D | D | D | C | D | D | C | A |
| Dibutyl Ether | D | D | C | C | D | C | D | A |
| Dibutyl Phthalate | D | D | C | B | D | D | B | A |
| Dibutyl Sebecate | D | D | B | B | D | D | B | A |
| O-Dichlorobenzene | D | D | D | D | D | D | D | A |
| Dichloro-Isopropyl Ether | D | D | D | C | D | D | D | A |
| Dicyclohexylamine | D | D | D | D | C | D | | A |
| Diethylamine | B | B | B | B | B | B | B | A |
| Diethyl Benzene | D | D | D | D | D | D | D | A |
| Diethyl Ether | D | D | D | D | D | C | D | A |
| Diethyl Sebecate | D | D | B | B | B | D | B | A |
| Diisobutylene | D | D | D | D | B | D | D | A |
| Diisopropyl Benzene | D | D | D | D | D | D | * | A |
| Diisopropylidene Acetone (Phorone) | D | D | C | C | D | D | D | A |
| Dimethyl Aniline (Xylidine) | C | C | C | B | C | C | D | A |
| Dimethyl Formamide | D | D | B | B | B | C | B | A |
| Dimethyl Phthalate | D | D | B | B | D | D | * | A |
| Dinitrotoluene | D | D | D | D | D | D | D | A |
| Dioctyl Phtalate | D | D | B | B | C | D | C | A |
| Dioctyl Sebecate | D | D | B | B | D | D | C | A |
| Dioxane | D | D | B | B | D | D | D | A |
| Dioxolane | D | D | C | B | D | D | D | A |
| Dipentene | D | D | D | D | B | D | D | A |
| (Phenylbenzene) | D | D | D | D | D | D | D | A |
| Diphenyl Oxides | D | D | D | D | D | D | C | A |
| Dowtherm Oil | D | D | D | D | D | D | C | A |
| Dry Cleaning Fluids | D | D | D | D | C | D | D | A |
| Epichlorohydrin | D | D | B | B | D | D | D | A |
| Ethanolamine | B | B | B | B | B | B | B | A |
| Ethyl Acetate | D | D | B | B | D | C | B | A |
| Ethyl Acetoacetate | C | C | B | B | D | C | B | A |
| Ethyl Acrylate | D | D | B | B | D | D | B | A |
| Ethyl Benzene | D | D | D | D | D | D | D | A |
| Ethyl Cellosolve | D | D | D | D | D | D | D | A |
| Ethyl Cellulose | B | B | B | B | B | B | C | A |
| Ethyl Chlorocarbonate | D | D | C | B | D | D | D | A |
| Ethyl Chloroformate | D | D | C | B | D | D | D | A |
| Ethyl Ether | D | D | C | C | C | C | D | A |
| Ethyl Formate | D | D | B | B | D | B | * | A |
| Ethyl Mercaptan | D | D | D | C | D | C | C | A |
| Ethyl Pentachlorobenzene | D | D | D | D | D | D | D | A |
| Ethylene Chloride | D | D | C | C | D | D | D | A |
| Ethylene Chlorohydrin | B | B | B | B | D | B | C | A |
| Ethylene Dichloride | D | D | C | C | D | D | D | A |
| Ethylene Oxide | D | D | C | C | D | D | D | A |
| Ethylene Trichloride | D | D | C | C | D | D | D | A |
| Fatty Acids | D | D | C | C | B | B | C | A |
| Fluorobenzene | D | D | D | D | D | D | D | A |
| Freon 21 | D | D | D | D | D | D | D | A |
| Furan, Furfuran | D | D | D | C | D | D | * | A |
| Furfural | D | D | B | B | D | C | D | A |
| Gasoline | D | D | D | D | B | C | D | A |
| Glauber's Salt (Aqueous) | B | D | B | B | D | B | * | A |
| Halowax Oil | D | D | D | D | D | D | D | A |
| N-Hexene-1 | D | D | D | D | B | B | D | A |
| Hydrochloric Acid (Hot) 37% | D | D | C | C | D | D | D | A |
| Hydrofluoric Acid (Conc.) Cold | D | D | C | C | D | D | D | A |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Hydrofluoric Acid (Conc.) Hot | D | D | D | D | D | D | D | A |
| Hydrofluoric Acid- Anhydrous | D | D | C | C | D | D | D | A |
| Hydrogen Peroxide (90%) | D | D | C | B | D | D | B | A |
| Hydroquinone | B | D | B | B | C | D | * | A |
| Hypochlorous Acid | B | D | B | B | D | D | * | A |
| Iodine Pentafluoride | D | D | D | D | D | D | D | A |
| Iodoform | D | D | D | D | * | D | * | A |
| Isophorone | D | D | C | C | D | D | D | A |
| Isopropyl Acetate | D | D | B | B | D | D | D | A |
| Isopropyl Chloride | D | D | D | D | D | D | D | A |
| Isopropyl Ether | D | D | D | D | B | C | D | A |
| Lacquers | D | D | D | D | D | D | D | A |
| Lacquer Solvents | D | D | D | D | D | D | D | A |
| Lactic Acid (Hot) | D | D | D | D | D | D | B | A |
| Lavendar Oil | D | D | D | D | B | D | D | A |
| Linoleic Acid | D | D | D | D | B | D | B | A |
| Maleic Acid | C | C | B | B | D | C | * | A |
| Malic Acid | C | C | B | B | D | C | * | A |
| Mesityl Oxide | D | D | B | B | D | D | D | A |
| Methyl Acrylate | D | D | B | B | D | B | D | A |
| Methylacrylic Acid | D | D | B | B | D | B | D | A |
| Methyl Bromide | D | D | D | D | B | D | * | A |
| Methyl Cellosolve | D | D | B | B | C | C | D | A |
| Methyl Chloride | D | D | C | C | D | D | D | A |
| Methyl Cyclopentane | D | D | D | D | D | D | D | A |
| Methylene Chloride | D | D | D | C | D | D | D | A |
| Methyl Formate | D | D | B | B | D | B | * | A |
| Methyl Isobutyl Ketone | D | D | C | B | D | D | D | A |
| Methyl Methacrylate | D | D | D | C | D | D | D | A |
| Methyl Oleate | D | D | B | B | D | D | * | A |
| Methyl Salicylate | C | C | B | B | D | D | * | A |
| Monochlorobenzene | D | D | D | D | D | D | D | A |
| Monomethyl Aniline | D | D | B | B | D | D | * | A |
| Naphtha | D | D | D | D | B | C | D | A |
| Naphthalene | D | D | D | D | D | D | D | A |
| Naphthalenic Acid | D | D | D | D | B | D | D | A |
| Neville Acid | D | D | B | B | D | D | D | A |
| Nitric Acid (Conc.) | D | D | D | D | D | D | D | A |
| Nitric Acid (Dilute) | D | D | B | B | D | B | B | A |
| Nitric Acid-Red Fuming | D | D | D | D | D | D | D | A |
| Nitroethane | B | B | B | B | D | C | D | A |
| Nitromethane | B | B | B | B | D | B | D | A |
| Octachlorotoluene | D | D | D | D | D | D | D | A |
| N-Octane | D | D | D | D | B | B | D | A |
| Oleum Spirits | D | D | D | D | B | C | D | A |
| O-Dichlorobenzene | D | D | D | D | D | D | D | A |
| Oxygen-(200-400oF) | D | D | D | C | D | D | B | A |
| Paint Thinner, Duco | D | D | D | D | D | D | D | A |
| Perchloric Acid | D | D | B | B | D | B | D | A |
| Perchloroethylene | D | D | D | D | B | D | D | A |
| Petroleum-Above 250oF | D | D | D | D | D | B | D | A |
| Phenol (Carbolic Acid) | D | * | B | B | D | C | D | A |
| (Diphenyl) | D | D | D | D | D | D | D | A |
| Phenyl Ethyl Ether | D | D | D | D | D | D | D | A |
| Phorone (Diisopropylidene Acetone) | D | D | C | C | D | D | D | A |
| Pickling Solution | D | D | C | C | D | D | D | A |
| Pinene | D | D | D | D | B | C | D | A |
| Pine Oil | D | D | D | D | D | D | D | A |
| Piperidine | D | D | D | D | D | D | D | A |
| i-Propyl Acetate | D | D | B | B | D | D | D | A |
| n-Propyl Acetate | D | D | B | B | D | D | D | A |
| Propyl Nitrate | D | D | B | B | D | D | D | A |
| Propylene | D | D | D | D | D | D | D | A |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Propylene Oxide | D | D | B | B | D | D | D | A |
| Pydraul, 230E, 312C, 540C | D | D | D | D | D | D | D | A |
| Pyridine | D | D | B | B | D | D | D | A |
| Pyroligneous Acid | D | D | B | B | D | B | * | A |
| Pyrrole | C | C | D | C | D | D | B | A |
| Radiation | C | C | D | B | C | B | C | A |
| Steam Over 300oF | D | D | D | C | D | D | D | A |
| Stearic Acid | B | B | B | B | B | B | B | A |
| Styrene | D | D | D | D | D | D | D | A |
| Sulfite Liquors | B | B | B | B | B | B | D | A |
| Sulfur Chloride (Aqueous) | D | D | D | D | C | C | C | A |
| Sulfur Trioxide | B | B | B | B | D | D | B | A |
| Sulfuric Acid (Dilute) | C | C | B | B | C | B | D | A |
| Sulfuric Acid (conc.) | D | D | D | C | D | D | D | A |
| Sulfuric Acid (20% Oleum) | D | D | D | D | D | D | D | A |
| Sulfurous Acid | B | B | B | B | B | B | D | A |
| Tar, Bitruminous | D | D | C | C | B | C | B | A |
| Terpineol | D | D | C | C | B | D | * | A |
| Tertiary Butyl Alcohol | B | B | B | B | B | B | B | A |
| Tertiary Butyl Catechol | D | B | B | B | D | B | * | A |
| Tertiary Butyl Mercaptan | D | D | D | D | D | D | D | A |
| Tetrabromoethane | D | D | D | D | D | D | D | A |
| Tetrabromomethane | D | D | D | D | D | D | D | A |
| Tetrachloroethylene | D | D | D | D | D | D | D | A |
| Tetrahydrofuran | D | D | C | C | D | D | D | A |
| Tetralin | D | D | D | D | D | D | D | A |
| Thionyl Chloride | D | D | D | C | D | D | * | A |
| Titanium Tetrachloride | D | D | D | D | B | D | D | A |
| Toluene | D | D | D | D | D | D | D | A |
| Toluene Diisocyanate | D | D | B | B | D | D | D | A |
| Tributyl Mercaptan | D | D | D | D | D | D | D | A |
| Tributyl Phosphate | B | D | B | B | D | D | D | A |
| Trichloroacetic Acid | C | B | B | B | B | D | * | A |
| Trichloroethane | D | D | D | D | D | D | D | A |
| Trichloroethylene | D | D | D | D | D | D | D | A |
| Triethyl Aluminum | D | D | C | C | D | D | * | A |
| Triethyl Borane | D | D | C | C | D | D | * | A |
| Trinitrotoluene | D | D | D | D | D | B | * | A |
| Turbine Oil | D | D | D | D | B | D | D | A |
| Varnish | D | D | D | D | B | D | D | A |
| Vinyl Chloride | D | D | D | D | D | D | * | A |
| White Pine Oil | D | D | D | D | B | D | D | A |
| Xylene | D | D | D | D | D | D | D | A |
| Xylidine (Di-methyl Aniline) | C | C | C | B | C | C | D | A |

DENTONS GLOBAL ADVISORS

ESBAF
EUROPEAN SMALL BUSINESS ALLIANCE FOR FLUOROPOLYMERS

# Meeting with the Swedish Chemicals Agency on the PFAS restriction dossier

20 September 2023

KEMI
Swedish Chemicals Agency

# AGENDA



# The fluoropolymer supply chain

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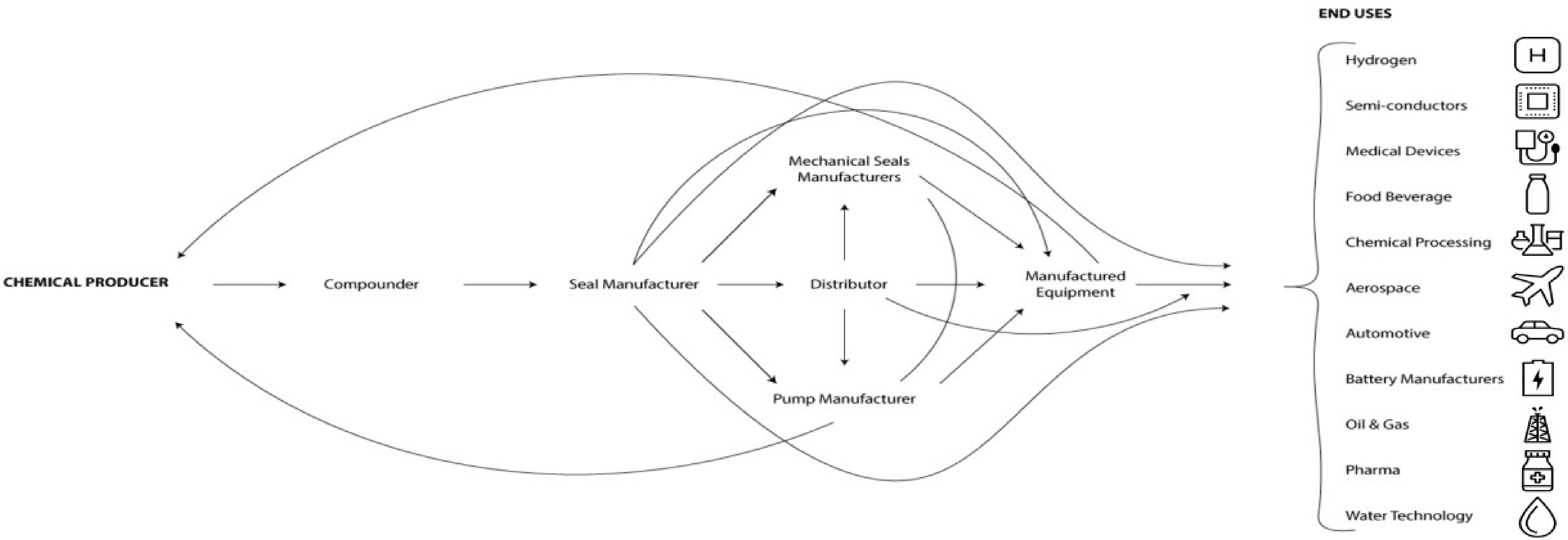


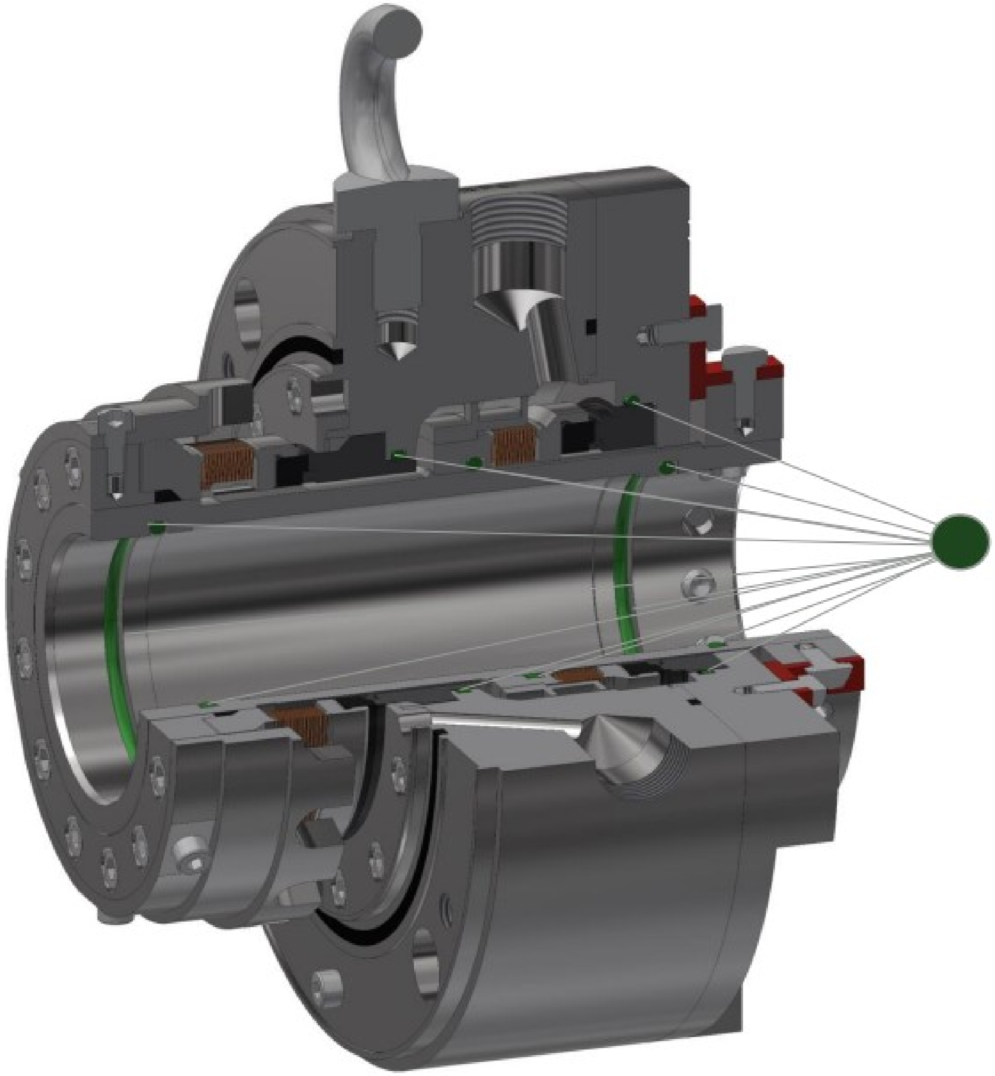

Manufacturer of Seals, Gaskets

Distributor

OEMs

# Fluorinated seals in a mechanical seal

DENTONS GLOBAL ADVISORS



# Our main concerns

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## A differentiated approach to regulating fluoropolymers is crucial to ensure a balanced, proportional, and evidence-based regulatory framework

- Fluoropolymers' structural properties ensure safe and sustainable product use in high-performance applications. Replacing fluoropolymers with lower-performing alternatives may lead to regrettable substitutions.

## The restriction would be impossible to implement for SMEs

- Complex and interconnected nature of fluoropolymer supply chains
- Lack of information transmission along the supply chain due to absence of harmonized classification for PFAS under the CLP Regulation

## The proposed restriction would have severe consequences for European industries, particularly SMEs

- Dependency on fluoropolymers in operations
- Ban on fluoropolymers could result in supply chain vulnerabilities, impacting the EU's access to critical materials for strategic technologies – For SMEs the ban results in business closures, job losses, and hindered economic growth

# Case study: the Centrifugal Pump

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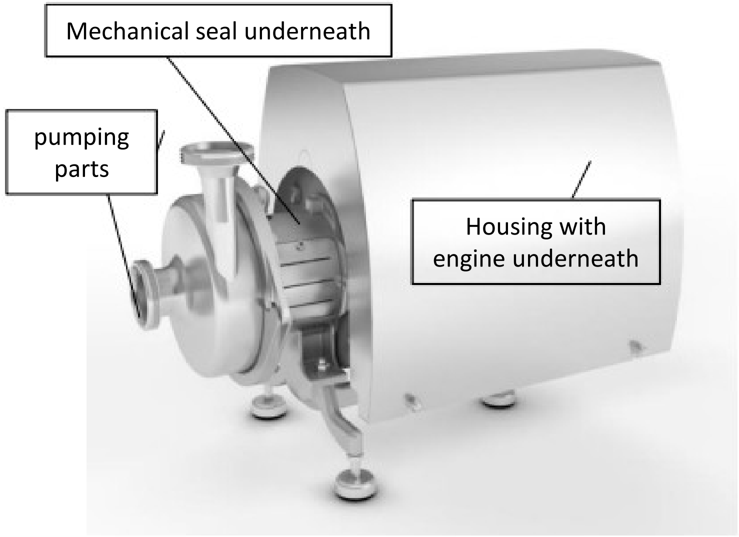
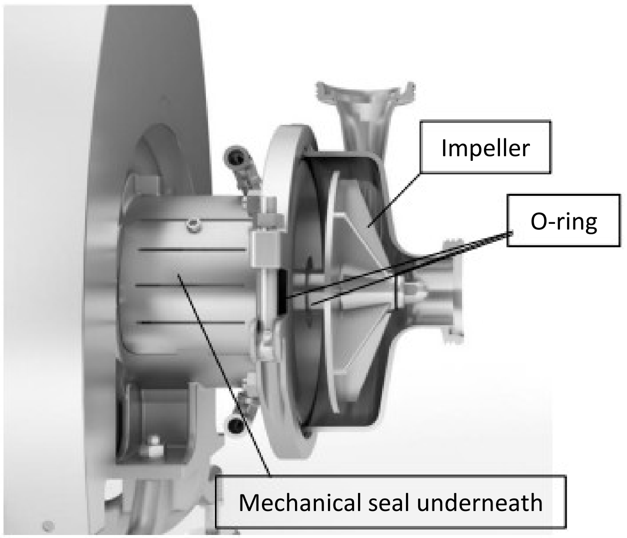
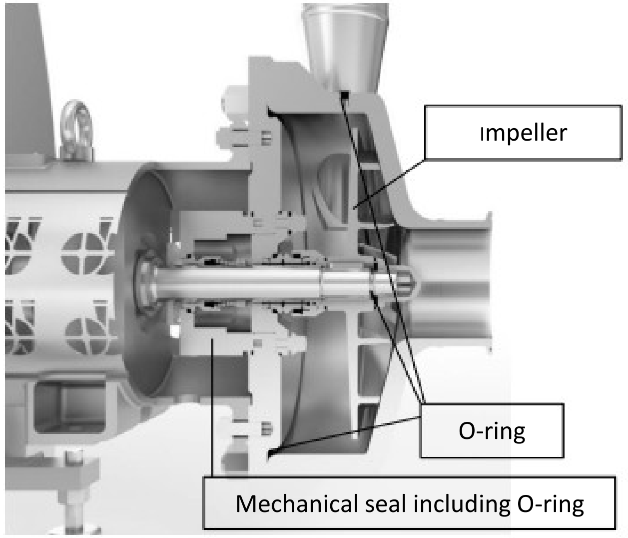
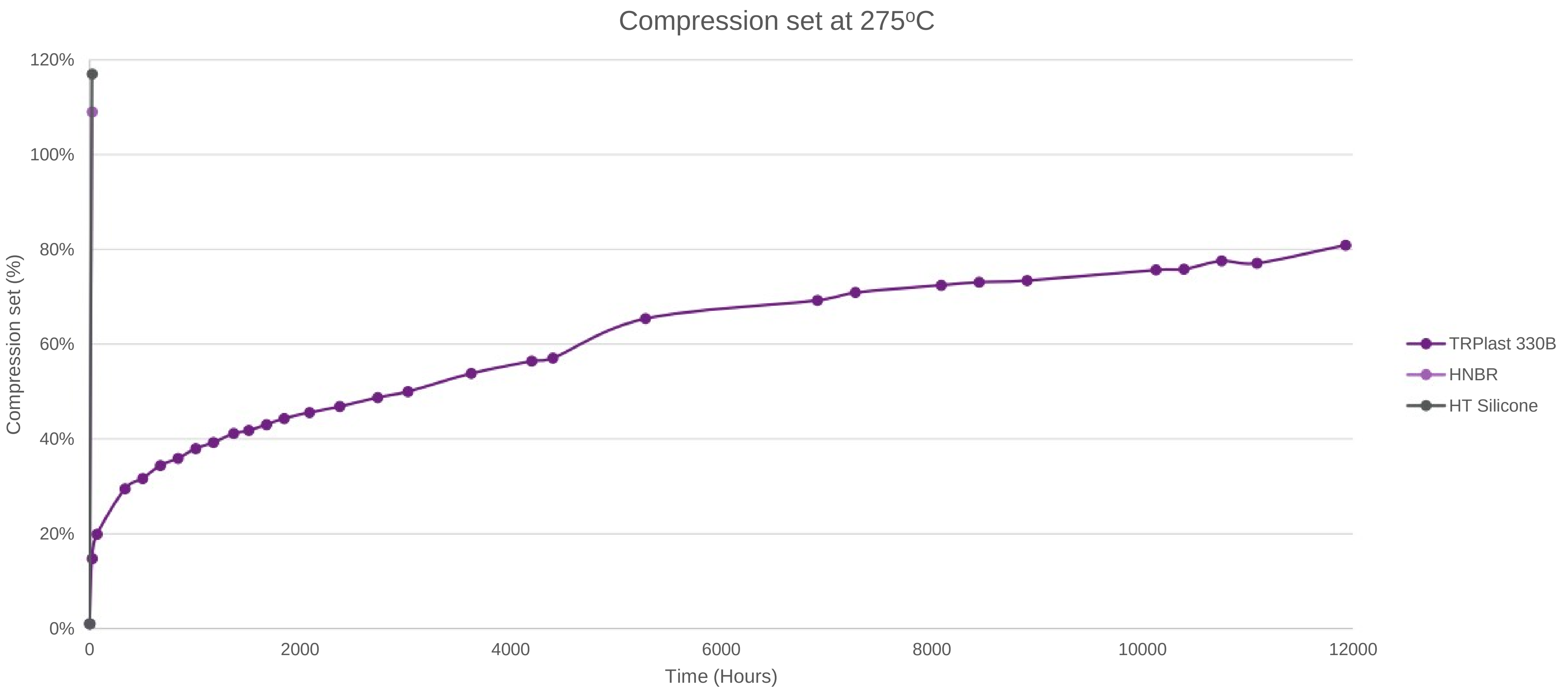


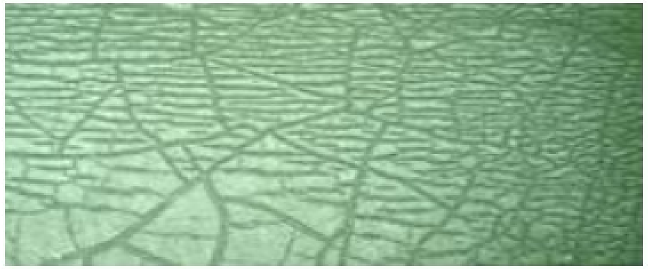
# Performance testing



# Impact on technical performance



Seal
swelling



Polymer
degradation

Polymer
dissolution

# DISCUSSION

**Dentons Global Advisors**
Rue du Luxembourg 22-24
B-1000 Brussels
+32 2 213 13 00
www.dentonsglobaladvisors.com

EU Transparency Register: 7028457765-59

# TRP POLYMER SOLUTIONS LTD. FLOUROELASTOMER MANUFACTURER

Report TR1094 – Non-Confidential submission

NON-CONFIDENTIAL

Written By: Charlie Cresswell Date: 18/09/2023

# Disclaimer

The Views expressed within this report are, unless otherwise stated, those of the authors and do not necessarily represent any official view of TRP.

# Citation

TRP Polymer Solutions Ltd - Cresswell C., September 2023, *TRP Polymer Solution Ltd - Fluoroelastomer Manufacturer*, TR1094 Confidential submission

# Contents



TRP POLYMER SOULUTIONS LTD
Netherwood Road, Rotherwas Industrial Estate, Hereford, HR2 6JU
Tel: 01432 268 899
Email: ccresswell@trp.co.uk
www.TRP.co.uk

# Aims of Report

TRP polymer solutions are an article producer for a diverse range of applications, mainly focusing on the manufacture of PFAS elastomers for such items as O-rings, gaskets and seals. The aim of this report is to provide information and evidence to ECHA on where we have identified areas that require derogations.

The report is organised in the following manner:

- Technical background information – This report assumes the reader has no knowledge of fluoroelastomer technology and aims to give the reader the necessary information to understand the report.
- Information relevant to the consultation:
    - Part one – Derogations given within ECHA Annex XV[1].
    - Part two – Information requested for the proposed derogations contained within Annex XV[1] Table 8.
    - Part three – Derogations required which are not included within Annex XV[1] Table 8.
    - Part four – Test methodology for the analysis of PFOA and PFOA related substances in elastomers.
    - Annex A – Methodology to estimate emissions from:
        - Primary curing within a press.
        - Secondary curing during postcure.
        - Service within application.
    - Annex B – information on the fluoroelastomer supply chain

[1] Annex XV Restriction report, Proposal for restriction of (PFAS), Version 2, 22/3/23

# Terminology:

| | |
|---|---|
| Aeronautic | The science or practice of building or flying aircraft. Within this report, it specifically means aircraft not for space use. |
| Article | An article within this report can generally be considered as the finished product for TRP. This may not be considered the same for our supply to OEM manufacturers. |
| Astronautic | The science and technology of space travel and exploration. |
| Bisphenol | A chemical that is used within the curing of specific rubbers. When a material is 'bisphenol' cured, it indicates that at least one component of the cure system is based on bisphenol or a variation of bisphenol. |
| Compound | A compound within this report means a material that has been mixed with the necessary ingredients to allow an article to be produced from it. |
| Compression set | The ratio of the change in height of a specimen against the compression it has been installed in. It gives an indication of the ability for a seal to maintain a seal in service. |
| Crosslinking | A term associated with high polymer products indicating the formation of a network, normally with a three-dimensional structure, by intermolecular bridges consisting of molecular chains with reactive groups. |
| Curing / vulcanisation | The conversion of rubber from a predominantly plastic condition to an elastic condition by three-dimensional cross linking. |
| Electron density | The measure of the probability of an electron being present at an infinitesimal element of space surrounding at a given point.[2] |
| FDA | Food and drug administration. In terms of rubber technology this is often used as a way of indicating food compliance. To FDA 21 CFR 177.2600 |
| Heat ageing | Exposure of an elastomer to high temperatures in air in accordance with BS ISO 188. |
| Heat resistance | The ability to withstand permanent changes in physical properties over prolonged periods at high temperature. The degree of heat resistance depends on the elastomer, the ingredients within the compound and conditions in which the article is used. |
| Inorganic | Chemistry based on chemicals that do not contain carbon. Typically used within rubber technology as materials containing a backbone of primarily Silicone and Oxygen (siloxane). |
| Non-PFAS elastomer | An elastomer that does not contain PFAS within the polymer itself. However, its known that some PFAS surfactants may be used within the manufacture of such materials. Examples of non PFAS elastomers are:<br>Natural Rubber, Styrene-butadiene Rubber, Butadiene Rubber, Acrylonitrile rubber, Butyl rubber, halobutyl rubber, EP, EPDM, ECO, CSM, HNBR, Polychloroprene, Polyurethane, Silicone |
| Organic | Chemistry based on carbon containing chemicals. Typically used within rubber technology as materials containing a backbone of carbon-carbon bonds. |
| Organoleptic | Involving the use of senses. In this document, when referring to something affecting the organoleptic properties, it means that something is affecting the taste, smell, visual or otherwise sensed properties. |
| PFAS elastomer | An elastomer that contains PFAS elements, such as :<br>FKM<br>FFKM<br>FEPM<br>PTFE<br>FVMQ<br>Specific definitions do not regard FVMQ as PFAS as its based inorganic technology. However, within this report FVMQ is regarded as a PFAS. |
| Postcuring | Postcuring is a process used in the manufacture of certain elastomers to complete the process. It ensures that maximum physical properties are reached, and certain chemicals are consumed or removed from the material. |

[2] *Electron density - Wikipedia*, https://en.wikipedia.org/wiki/Electron_density.

| | |
|---|---|
| | Temperatures can range from 50ºC to 300ºC, for a period of 1 hour to a few days, depending on the requirements. |
| Process aid | Can be used to mean a chemical that assists in the production of a product. However, the meaning can be different from polymer manufacturer, rubber mixer, rubber producer and end user. For example:<br>• A process aid for a polymer manufacture could be a surfactant, which assists the polymerisation process.<br>• A process aid for a rubber mixer could be a chemical that aid mixing.<br>• A process aid for a rubber manufacture could be used to aid mould release or increase the flow of a material.<br>• A process aid for an end user could be a grease to assist the installation of an O-Ring<br><br>The use of 'process aid' in some ECHA documents has been taken to mean surfactants (such as PFOA). But this is incorrect. ECHA should be scientifically labelling the chemical they are discussing, otherwise chemicals such as non-PFAS processing aids can also be the target of unnecessary restriction. |
| Single/Double/Triple Bond | A single bond forms when 2 atoms share a single pair of electrons.<br>A double bond forms when 2 atoms share 2 pairs of electrons.<br>A triple bond forms when 2 atoms share 3 pairs of electrons. |
| SIP/CIP cleaning chemicals | Fluids typically used within the food contact industry to sterilise and clean food contact equipment. Examples are:<br>• Steam<br>• Hot water<br>• Alkali cleaning solution<br>• Nitric acid<br>• Peracetic acid |
| Surface energy | A measure of the attraction of a materials molecules to another materials molecules. Typically referring to the attraction of a fluid to the surface of an elastomer within this report. |

# Technical Background information

TRP Polymer Solutions Ltd.’s role in the elastomer supply chain is to convert unvulcanised polymeric PFAS into a fully vulcanised articles. This process influences the final articles shape and physical properties. The type of PFAS converted within TRP are:

- Fluoroelastomers – which encompasses FFKM, FKM, FEPM and FVMQ (Fluorosilicone).
- Fluoropolymers – which encompasses PTFE.

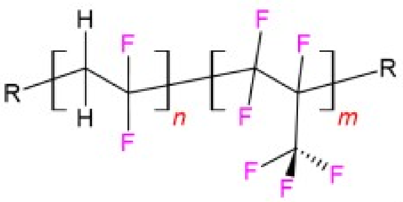
TRP formulate most of their own materials and have approximately 700 active recipes alongside 2000 non active recipes. These materials are individually formulated to give specific; chemical, physical, processing and dimensional properties.

The chemical structures are provided below. (CAS numbers are not provided, since these can be commercially sensitive for manufacturers and can vary between suppliers.) Information such as cure site monomers and termination molecules have not been included:

FKM Type: 1

Synonym: Copolymer / Di-polymer / Viton® A

Monomers used: HFP/VF2



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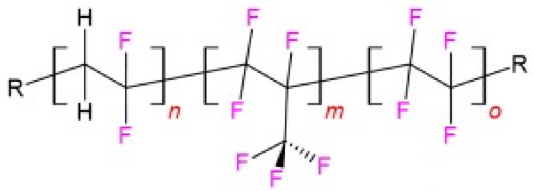
FKM Type: 2

Synonym: Terpolymer / Viton® B / Viton® F / Viton® GF / Tetrapolymer.

Monomers used: HFP/VF2/TFE/(CSM)



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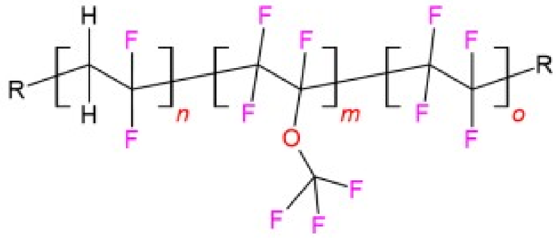
FKM type: 3

Synonym: LT FKM / Viton® GLT / Viton® GFLT.

Monomers used: VF2/PAVE/TFE/(CSM)



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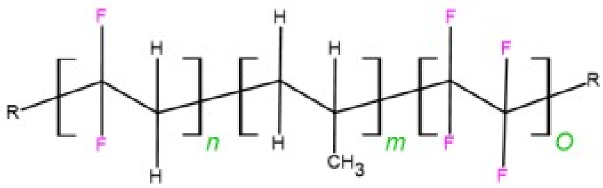
FKM Type: 4

Synonym: BRE / Tetrapolymer

Monomers used: VF2/Propylene/TFE



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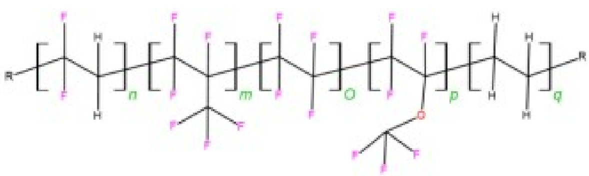
FKM Type: 5

Synonym : BRE

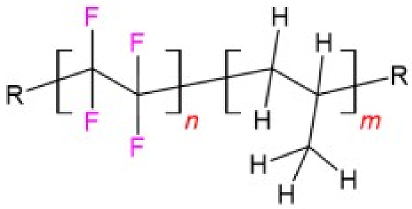
Monomers used: VF2/HFP/TFE/PAVE/Ethylene used.



FEPM Type: 1

Synonym: TFE/P Aflas®

Monomers Used: TFE/Propylene



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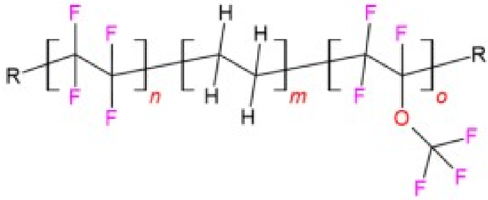
FEPM Type: 2

Synonyms: Viton® Extreme, Aflas® 200

Monomers used: TFE/Ethylene/PAVE



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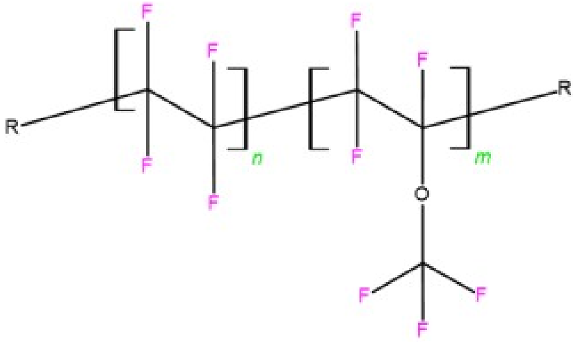
FFKM type: Standard

Synonyms: FFKM / Perfluoroelastomer / TRPlast® / Kalrez®

Monomers used: TFE/PAVE/CSM



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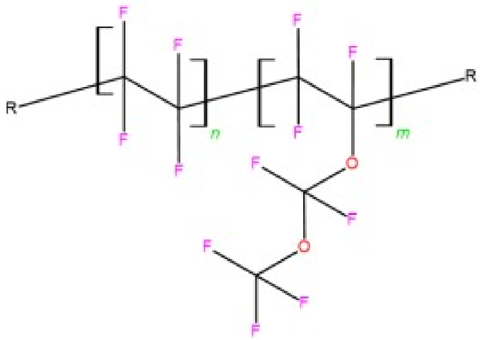
FFKM type: Low temperature

Synonyms: LT FFKM / Perfluoroelastomer / TRPlast® / Kalrez®

Monomers used: TFE/PAVE/CSM



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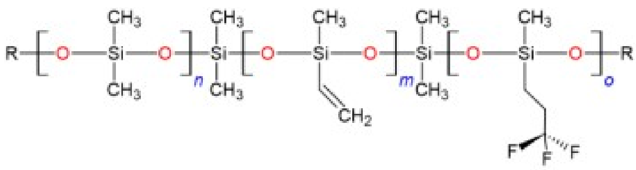
FVMQ

Synonym: Fluorosilicone

Monomers used: Vinyl-siloxane/ methyl-siloxane/ fluoro-siloxane



<u>The Carbon-Fluorine bond</u>

The carbon fluorine bond is the strongest single bond in organic chemistry. This strength makes it the most stable bond in organic chemistry. Because of this, a high amount of energy is required to deteriorate the bond between carbon and fluorine. This energy can be supplied thermally or chemically.

Due to the high quantity of carbon fluorine bonds in fluoroelastomers and fluoroplastics, and thus high stability, an unrivalled thermal and chemical resistance can be achieved. This aspect makes fluoropolymers persistent in both application and environment. Any subsequent material offering the same thermal and chemical characteristics should also be considered environmentally persistent.

Typically, non-PFAS materials contain a mixture of covalent bonds including carbon-hydrogen, carbon-nitrogen, carbon-chlorine, carbon-bromine. As can be seen in the table below these all have a lower bond energy than the carbon fluorine bond. Thus, there is a higher susceptibility to chemical and thermal degradation. Below outlines the bond energies of various organic single bonds:

| **Atom 1** | **Atom 2** | **Bond energy (KJ/Mol)** |
|---|---|---|
| Carbon | Carbon | 348 |
| Carbon | Nitrogen | 305 |
| Carbon | Oxygen | 360 |
| Carbon | Fluorine | 484 |
| Carbon | Chlorine | 338 |
| Carbon | Bromine | 276 |
| Carbon | Iodine | 238 |
| Carbon | Hydrogen | 435 |

Table 1 –Bond energies of various organic single bonds[3]

There are non-singular bonds in organic chemistry that have a higher bond energy. For example, a carbon-carbon double bond has a bond energy of around 602KJ/Mol. However, these bonds have more than 1 pair of shared electrons. This allows the bonds to be deteriorated by chemical species such as acids, air, oxygen and ozone. Evidence for this can be seen in service where a saturated rubber will have a greater resistance to ageing than an unsaturated rubber. This is referenced in BS ISO 2230[4].

There are additional aspects that make the use of fluorine so important in polymer technology:

1. The effect of a high fluorine content also strengthens adjacent carbon - carbon bonds within the material, further increasing temperature and chemical resistance.[5]
2. Because fluorine is small and forms a short bond length, it forms a ‘shell’ around the backbone that physically protects the carbon - carbon bonds from chemical attack and thus increases the chemical resistance.[6]

[3] Atkins. P, Paula. J, 2014, Atkins’ Physical Chemistry 10th Edition, Oxford University Press, Oxford, Page 985-986, Table 10C.2a and 10C.2b.
[4] BS Standards Institution (BSI), April 2002, “BS ISO 2230:2002 – Rubber products – Guidelines for storage”.
[5] Scheirs. J, 1997, Modern Fluoropolymers, John Wiley & Sons Ltd, page x
[6] Atkins. P, Paula. J, 2014, Atkins’ Physical Chemistry 10th Edition, Oxford University Press, Oxford, Page 985, Table 10AC.1.

3. Fluorine has few electron orbitals. This means the interaction between the fluorine nucleus and the electrons is very high. Therefore, if a chemical wishes to attack the fluorine atom, it must overcome this interaction. This enhances chemical resistance.[7]

# About TRP Polymer Solutions

TRP Polymer solutions Ltd specialise in the manufacture of components for critical applications in industries including nuclear, defence, motorsport, chemical processing and chemical transport. The articles manufactured for these industries are typically based on PFAS fluoropolymers due to their unique ability to resist heat and enhanced chemical resistance.

<Confidential information has been redacted>

[7] Atkins. P, Paula. J, 2014, Atkins' Physical Chemistry 10th Edition, Oxford University Press, Oxford, Page 984, Table 9B.2.

# **Part One – Derogations given within ECHA Annex XV Table 8.**

The bullet point below outlines the only derogation set out in Annex XV that is applicable to TRP:

- Food contact materials and packaging – industrial food and feed production – Industrial Applications – 5-year derogation

# Part two – Information requested for the proposed derogations contained within Annex XV Table 8.

## Food contact material and packaging

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| Sector and sub use | Food Contact materials & packaging.<br>Industrial food and feed production |
| Information relating to Q2 | It is believed that products are disposed in line with regional waste disposal guidelines. |
| Information relating to Q3 | No Information |
| Information relating to Q5 | Tonnage:<br>Total tonnage of PFAS fluoroelastomer used <Confidential information has been redacted><br><br>Tonnage by material type:<br>FFKM <Confidential information has been redacted><br>FKM and FEPM <Confidential information has been redacted><br><br>Note FVMQ is not suitable for food contact in accordance with FDA.<br><br>**Emissions**<br>Manufacture Phase:<br>Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt)<br><br>Use Phase estimate[a]:<br>• FFKM = <Confidential information has been redacted> (0.6% wt/wt)<br>• FKM & FEPM = <Confidential information has been redacted> (1.5% wt/wt)<br><br>a. Note the lifespan of PFAS can be several years and varies according to application. Therefore, an estimate is provided that encompasses the lifetime emissions that may be produced from a single year's produce. But it should be acknowledged that this value is the lifetime emission for that lot of material, rather than the emissions per Annum.<br><br>End of life phase:<br>• Amount expected to be landfilled: <Confidential information has been redacted>[b]<br>• Amount expected to be incinerated: <Confidential information has been redacted>[b]<br><br>b. In accordance with regional waste disposal ratio's |
| Information relating to Q8.<br><br>Technical Report 1090 bisphenol FDA termination.pdf | The requirements by the customer of these seals are:<br>• Blue colour - allowing identification in food.<br>• The seal must be chemically resistant to SIP/CIP chemicals. Failure to meet these requirements would cause septic conditions.<br>• The seal must be detectable by; visual contrast, X-Ray and electromagnetism. This is to protect from the release of particulates into food from seal damage, degradation or abrasion.<br>• Materials used to manufacture the seals must not leach into food.<br>• The material must conform to 21 CFR 177.2600 d,e and f (FDA food contact standard).<br>These requirements ensure that food is not spoilt, there are no adverse organoleptic effects and that the food is not toxic. |

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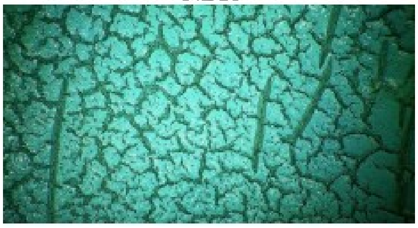
| | Attached (left) is a report undertaken by TRP on the performance of seals in food contact applications. The report focuses mainly on the SIP/CIP capability of fluoroelastomer and EPDM. It was produced when manufacturers would no longer authorise bisphenol cured elastomers to be used within food contact applications. The polymer manufacturers took this step due to impending ECHA restriction on bisphenol, and the possibility that bisphenol can cause harm to fertility in humans. As a responsible supplier, TRP transitioned to a technology with no known toxicity in advance of the restriction coming into effect.<br><br>The report outlines the following: TRP developed improved PFAS materials that did not contain bisphenol. The materials were compared to a commercial metal detectable blue EPDM grade that has previously been chosen for food contact applications alongside bisphenol incorporated FKM that was specified for use with food.<br><br>For the purposes of this report (TR1094), the experiment has been repeated and the performance of Silicone and NBR have also been evaluated. It was found that these materials did not meet the specifications outlined by customers and would not be considered suitable for CIP/SIP conditions.<br><br>A simple magnification shows the unsuitability of EPDM, NBR and VMQ when compared to FKM after testing in CIP media. Each of the tested grades are commercially available and are designed as blue metal detectable materials suitable for food contact:<br><br>**168Hours @ 90ºC in 2% $HNO_3$**<br><br>**FKM**<br><br>No signs of deterioration<br><br>**EPDM**<br><br>Severe bubbling of surface.<br><br>**Silicone**<br><br>Colour loss, cracking and flaking of surface.<br><br>**NBR**<br><br>Severe cracking of surface.<br><br>It can be visually observed above that only the PFAS based material (FKM) has the capability to meet the requirements of this application. |
| Supporting information on alternatives. | Although it's confirmed above that EPDM, silicone and NBR are not suitable for replacement due to their poor chemical performance; there is an additional aspect of using Organic Non-PFAS polymers that should be considered.<br><br>Formulation of PFAS fluoroelastomers can require few ingredients. For food contact applications the formulation can be as little as two to three ingredients. |

| | |
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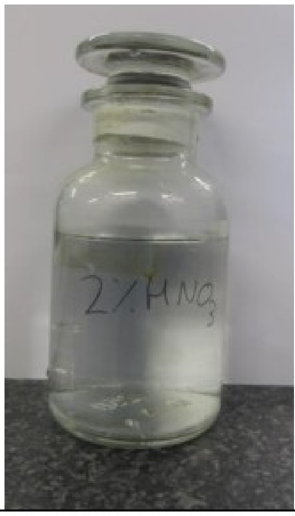
| | The formulation of an organic non-PFAS[8] (i.e., EPDM, NBR etc) is required to have multiple ingredients to optimise performance such as antioxidants, antiozonants, oils, waxes, process aids, metal oxides, silica, sulphur-based chemicals, curatives. These chemicals often have toxic and environmental hazards which can be avoided by using fluoroelastomers.<br><br>Some of these chemicals are intentionally designed to migrate to the surface (such as antioxidants, antiozonants and wax) where they provide optimal functionality. This has a high potential to transfer into food products. Antioxidants and antiozonants are reactive chemicals that often present health and safety hazards. ECHA has restricted the use of several of these recently and there are few left that are allowed to be used in food which are no longer SVHC's.<br><br>Some of the additional chemicals in non-PFAS material are not designed to be extracted, such as oil. But in a particular environment, these chemicals can be transferred into food. These chemicals can have a variety of toxicity and because of this, a large portion of our customers have made a switch to PFAS in food contact applications.<br><br>An example of the hazards that can be associated with some of these chemicals are listed below:<br>• Antioxidants:<br>o H317 – May cause allergic skin reaction.<br>o H334 – May cause allergy if inhaled.<br>o H361 – Suspected of damaging fertility of unborn child.<br>• Paraffinic oils:<br>o H304 – may be fatal if swallowed and enters airways.<br>• Curatives:<br>o H302 – Harmful if swallowed.<br>o H315 – Causes skin irritation.<br>o H360 – May damage fertility of unborn child<br>o H373 – May cause damage to organs.<br>o H411 – toxic to aquatic life with long lasting effects<br><br>On request TRP can give examples of chemicals that are used within elastomers that have the above associated health hazards, cross referenced with the food standard 21 CFR 177.2600 / EC1935/2004 which outlines ingredients that can be used in rubbers in repeated contact with food. To focus the report, these have not been included.<br><br>As an additional point, we have observed products containing oils that intentionally release into food; the purpose is to enable them to pass short term tests outlined by certain food standards. TRP do not stand behind this practice, and design food products with safety, cleanliness, performance and purity in mind. But if the end user is to specify a PFAS based material such as FEPM, FKM or FFKM, this practice can be avoided as they do not need to have complex formulations to pass food contact standards since the base polymer already meets the chemical and thermal requirements.<br><br>For a demonstration of the leaching of chemicals; overleaf is a photo showing the colour change of the fluid when testing in 2% nitric acid at 90$^{o}$C with non-PFAS materials, the PFAS materials do not change the colour of the fluid. The non-PFAS based materials do change the fluid colour. This is an indication that chemicals from non-PFAS materials are currently tainting food: |

[8] An exception is acknowledged in which inorganic polymers such as silicone do not require a large range of ingredients. However, they quickly break down in both CIP and SIP conditions making them unsuitable alternatives.

<table>
<tr><td></td><td>1 week at 90ºC for FKM 1 week at 90ºC for non-PFAS based materials.<br><br><br></td></tr>
<tr><td>Case Study</td><td>Initially our customer for the above application was using EPDM materials. They were blue magnetic materials but did not give a sufficient sealing lifetime. These seals were formulated by TRP.<br><br>TRP was requested to develop an improved EPDM grade with a greater sealing life, which was successful. The customer then tested and serviced this new EPDM grade.<br><br>Because the improved EPDM seals could be serviced for a longer period, the poor chemical resistance of the EPDM material became evident. Also, they were not able to operate in a diverse media range, such as with oils and fats.<br><br>TRP suggested that whilst an alternative material was developed, the customer should use an FKM (PFAS) seal. For two years TRP attempted to make a better performing non PFAS seal, but it was realised that these materials were at the limit of their performance. Any improvements in one particular area came at the cost of deterioration in another.<br><br>During the servicing of the FKM seal the customer had not observed any issues. Service life is excellent, the chemical resistance is universal, and the performance was overall improved. The long-term cost of the seal was lower than the repeated cost of buying new non PFAS seals and routinely replacing them, making FKM the more sustainable option.<br><br>Changing back to EPDM seals would no longer service the customer’s needs. They have been able to diversify by using FKM into different product areas and operating conditions, which is not currently possible using non-PFAS materials.</td></tr>
<tr><td>Requested Derogation</td><td>A maximum derogation is requested to allow the toxicological effect of non-PFAS leachate into food to be understood/regulated and to allow the effects of seal deterioration in food to be studied.</td></tr>
</table>

## Part Three – Derogations required which are not included within Annex XV Table 8.

For sub uses stated in question 6.

Proposed derogations:

1. Aerospace – Fluoroelastomer applications.
2. Automotive – Fluoroelastomer applications.
3. Chemical process industry – Fluoroelastomer applications.
4. Electrolysis technology – Fluoropolymer applications.
5. Chemical transport – Fluoroelastomer applications.
6. Laboratory equipment – Fluoroelastomer applications.
7. Printing inks – Fluoroelastomer applications.

<Confidential information has been redacted>

## Aerospace – Fluoroelastomer applications

| Sector and sub use | Aerospace<br>Fluoroelastomer applications |
|---|---|
| Section A | Tonnage:<br>Total tonnage of PFAS fluoroelastomer used <Confidential information has been redacted><br><br>Tonnage by material type:<br>FFKM <Confidential information has been redacted><br>FKM = <Confidential information has been redacted><br><br>**Emissions**<br>Manufacture Phase:<br>• Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt)<br><br>Use Phase estimate[a]:<br>• FFKM = <Confidential information has been redacted> (0.6% wt/wt)<br>• FKM = <Confidential information has been redacted> (1.5% wt/wt)<br><br>a. Note the lifespan of PFAS can be several years and varies according to application. Therefore, an estimate is provided that encompasses the lifetime emissions that may be produced from a single year's produce. But it should be acknowledged that this value is the lifetime emission for that lot of material, rather than the emissions per Annum. |
| Section B | PFAS are used within aerospace applications extensively. TRP manufacture FKM and FFKM products directly for the aerospace industry. FMVQ is also used in aerospace applications.<br><br>There are several SAE standards that outline the requirements of materials in aeronautics. For astronautic materials, components are typically tested in application. If material changes are required the whole vessel requires qualification, resulting in great cost and disruption.<br><br>Some of the aerospace companies supplied by TRP operate satellite products. These products use fuels such as nitrous oxide or high concentration hydrogen peroxide. FFKM is the only material that has the required characteristics for this environment. In fact, FFKM was initially produced to serve the space sector.<br><br>Furthermore, after extensive research on behalf of our customers, it's not been possible to find any laboratory that will be able to test materials within the same conditions as experienced within application. Since most of the chemicals used can spontaneously combust (for example Nitrous oxide), requalification comes at a significant cost and a significant hazard. When TRP researched testing in nitrous oxide for a customer, no laboratories could be found to undertake the testing. This indicates that standardised test procedures to determine elastomer compatibility with astronautic fuel are yet to be proposed.<br><br>Another use of PFAS is for diaphragms forming a partition between hydrogen peroxide and propellant (in the form of gas). The diaphragm must have a low permeation to gases and still be resistant to hydrogen peroxide. In addition, the surface energy must be low to prevent bubble formation and spontaneous chemical degradation. No non-PFAS can provide the required chemical resistance, physical properties, or dimensional stability within applications serviced by PFAS. |
| Section C | <Confidential information has been redacted> |

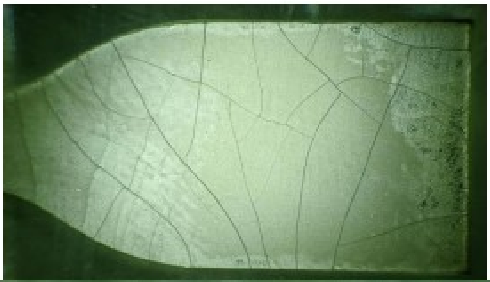
Section D

**Alternatives:**
**Aeronautics:**

- Availability
  - No alternatives are available that meet the rigorous requirements. A common suggestion by ECHA is typically HNBR;
    - HNBR has good oil resistance for a *non-PFAS* material and has one of the highest temperature resistances of an Organic non PFAS material. There are some applications where it's used in aerospace currently, but it does not have the capabilities to be used in more demanding applications at elevated temperatures or in modern aeronautic fluids that are designed to give longer service life to jet engines.
  - Another material often suggested by ECHA for PFAS replacement is silicone, however:
    - Silicone has poor oil resistance, and its upper temperature resistance is not suitable. This is demonstrated in the 'chemical process industry' section (Page 23).
  - Other submitters may claim that fluorosilicone is an alternative because *inorganic* fluorinated materials have previously not been considered to be PFAS by specific definitions. However, the fluorinated component comes from the monomer $CF_3$-CH=CH2; which is a PFAS. Therefore, you cannot consider fluorosilicone an alternative under the current restriction definition. In addition to the previous point, it also does not have the required thermal resistance.
- Technical feasibility
  - Non PFAS materials tested to the specification AMS7276 (which outlines the requirements for a 'high temperature high fluidic resistant material') were found not to meet the standard. Below outlines testing undertaken by TRP to AMS7276J:

In SAE AMS7276J, among other tests, the materials must be able to withstand 275ºC for <Confidential information has been redacted> to be considered suitable. This test evaluates suitability for a materials use in high temperature engine oil systems, fuel systems and hydraulic systems.

After exposing HNBR to 275ºC temperatures for just 16Hours, the following effect had taken place:



The pictures shows that the material has formed cracks, which will cause fluids to leak. Furthermore, the test took place over a time period four times less that the specification. In aircraft this would have a detrimental impact on safety.

From previous laboratory observations, FFKM's that are designed for high temperature applications do not show cracks at these temperatures for over 12,000Hours.

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| | Unfortunately, 12,000Hours is 500Days, which is greater the 6months consultation period; therefore, no photos can be submitted for evidence for this aspect.<br>A further requirement is that the material must have a maximum compression set of 15% after 22Hours @ 200ºC. When testing HNBR the compression set was 34% in the same time period. Overall, only FFKM can meet the requirments of aerospace specifications required for succsesfull operation in this industry.<br><br>• Economic feasibility<br>  o HNBR and VMQ (silicone) are both offered at a reduced price to PFAS products. However, neither meet the required technical specifications. Therefore, due to the costs that would occur from aerospace failure, a derogation needs to be given.<br>  o Aeronautic failure would likely lead to loss of life. However, if the hazards and risks of the material are to be scrutinised, especially at the manufacturing phase, also then the following should be considered:<br>    ▪ HNBR is manufactured using acrylonitrile. This is a toxic and carcinogenic chemical that may emitted on manufacture and thermal degradation. Another chemical released from this material at elevated temperature is hydrogen cyanide, which is also extremely toxic. Therefore, emissions from HNBR can have the potential to be carcinogenic.<br>    ▪ Silicone products contain $D_4$, $D_5$ and $D_6$. Whilst these chemicals can be removed as part of the manufacturing process (during postcuring), they are still emitted to the atmosphere in the form of gas.<br>• Extent of which alternatives are offered:<br>  o HNBR and VMQ are not suitable alternatives. There are also supply chain issues with these materials which have been ongoing since around 2021.<br><br>**Astronautics:**<br>• Availability<br>  o For astronautic use I do not believe there are any alternatives. In fact, FFKM was developed specifically for astronautical applications. There has not been any movement away from PFAS materials when in use with most propulsion fuels.<br>• Technical:<br>  o Non PFAS materials are not able to withstand the chemicals used in astronautics. They are not able to provide chemical resistance to such fuels as nitrous oxide, or high concentration hydrogen peroxide.<br>• Economic feasibility<br>  o N/A. There is no alternative to PFAS products in this environment.<br>• Hazards and risks<br>  o Non-PFAS materials may lead to auto decomposition of chemical products such as nitrous oxide and hydrogen peroxide due to the difference in surface energy and chemical structure. In fact, it's possible that hydrocarbons may act as fuel for such chemicals. This is how some rocket technologies work (solid rocket propulsion), by combining hydrocarbons and oxidisers (such as hydrogen peroxide).<br>• Extent of which alternatives are offered:<br>  o HNBR and VMQ are not suitable alternatives. They are also undergoing shortages which have been ongoing since around 2021. |
| Section E | Cases for which alternatives are not yet available:<br>• There are no non-PFAS alternatives to fluoropolymers where the materials must meet high temperature operating conditions or must operate in aggressive fluids. |
| Section F | Cases for which substitution is technically and economically feasible: N/A |
| Section G | Cases for which substitution is not feasible:<br>• There are no non-PFAS alternatives to fluoropolymers where the materials must meet high temperature operating conditions or must operate in aggressive fluids. |

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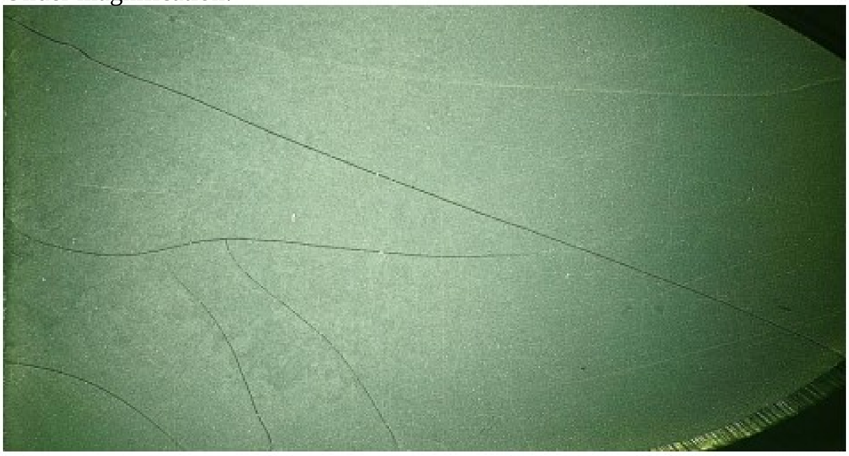
| Request for derogation | Since the invention of PFAS (in the 1960's) in aerospace they have been irreplaceable and invaluable. Therefore, a maximum derogation is requested to allow users and suppliers to develop alternatives for fluoroelastomers in aerospace applications. |

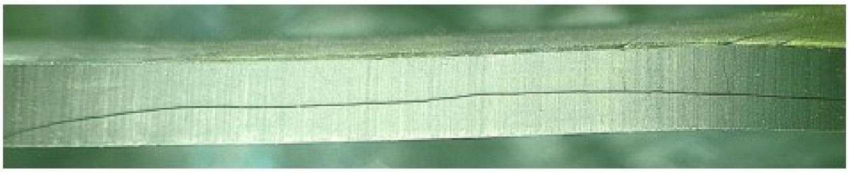
## Automotive – Fluoroelastomer applications

| | |
|---|---|
| Sector and sub use | Automotive<br>Fluoroelastomer applications<br><br>This section also outlines aspects relating to renewable fuels. |
| Section A | Tonnage:<br>Total tonnage of PFAS fluoroelastomer used <Confidential information has been redacted><br><br>Tonnage by material type:<br>FFKM <Confidential information has been redacted><br>FKM = <Confidential information has been redacted><br><br>**Emissions**<br>Manufacture Phase:<br>• Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt)<br><br>Use Phase estimate[a]:<br>• FFKM = <Confidential information has been redacted> (0.6% wt/wt)<br>• FKM = <Confidential information has been redacted> (1.5% wt/wt)<br><br>a.Note the lifespan of PFAS can be several years and varies according to application. Therefore, an estimate is provided that encompasses the lifetime emissions that may be produced from a single year's produce. But it should be acknowledged that this value is the lifetime emission for that lot of material, rather than the emissions per Annum. |
| Section B | PFAS materials are used extensively for sealing and fluid management in automotive applications. TRP manufacture primarily for high end automotive, where the technology may be eventually transferred to commercial automotive if improvements in performance and efficiency are observed.<br><br>In recent years TRP has seen a transition towards PFAS elastomers and away from non-PFAS elastomers. This revision has been coordinated by customers investigating high performance materials. PFAS materials are specified because higher performance and efficiency is required of modern engines, which in turn requires higher temperature and more aggressive conditions which can only be serviced by PFAS.<br><br>Another key requirement of automotive is the resistance to fuel blends containing petroleum and alcohols. Alcohols are typically produced from biomass in the form of ethanol and are a severe sealing challenge for non-PFAS when mixed with petroleum. Only PFAS materials can resist modern fuel blends sustainably, whereas non-PFAS elastomers such as HNBR, NBR, Silicone and EPDM are not suitable.<br><br>HNBR is generally considered the most suitable alternative to PFAS in automotive applications. To compare the performance of HNBR to a PFAS commonly used in automotive (FKM); HNBR and FKM was tested to a portion of specification: <Confidential information has been redacted><br><br>This specific test involves exposing the materials to heat for 72Hours at 250°C in an oven. The specification requires that the material does not lose 50% of elasticity in these conditions (in the form of elongation at break, tested to BS ISO 37) The results are below:<br><br>**HNBR:**<br>It was observed that there was a complete loss in elasticity. The material had severe cracks, couldn't be elongated past 1% strain, and could not be bent over a pencil without breaking. The pictures below outline the effects of temperature on HNBR: |

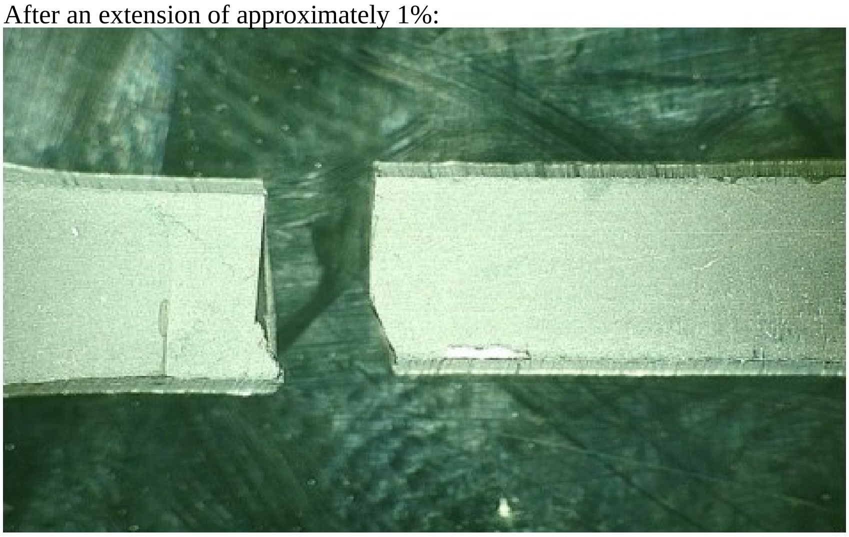
**After 72Hours@250ºC:**

Under magnification:





After an extension of approximately 1%:



**Attempting to bend over a pencil:**

HNBR failed to meet the requirement of this specification, as the change in elasticity (elongation at break) was over 99% and there was a significant reduction in volume. Therefore, it is not suitable for use within these environments.

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| | **FKM:**<br>When tested at 72Hours@250ºC, an elasticity change (elongation at break) of 4% was observed. This is significantly less than the specification, therefore this material is suitable within these environments. |
| Section C | <Confidential information has been redacted> |
| Section D | **Alternatives:**<br>• Availability<br>    o There are currently shortages for HNBR, which have persisted since around 2021.<br>    o Silicone is not considered an alternative. It is already used where possible.<br>• Technical feasibility<br>    o HNBR is manufactured using acrylonitrile. This is a toxic and carcinogenic chemical that may emitted on manufacture and thermal degradation. Another chemical released from this material at elevated temperature is hydrogen cyanide, which is also extremely toxic. Therefore, emissions from HNBR can have the potential to be carcinogenic.<br>    o Alternative materials such as silicone and EPDM are used where possible, but do not have the required fuel resistance or in some cases temperature resistance.<br>• Economic feasibility<br>    o Currently, the cost for HNBR, FKM and silicones are similar in these applications.<br>• Hazards and risks<br>    o HNBR is manufactured using acrylonitrile. This is a toxic and carcinogenic chemical that is emitted on thermal degradation. Therefore, emissions from HNBR can have the potential to be carcinogenic.<br>    o Silicone products contain D4, D5 and D6. Whilst these chemicals can be removed as part of the manufacturing procedure (postcuring), they are still emitted to the atmosphere.<br>• Extent of which alternatives are offered:<br>    o In our professional opinion, non-PFAS cannot be offered on health and safety or sustainability basis. They also cannot be used as they do not allow engines to reach efficiency and performance targets, therefore they directly undermine green energy objectives. |
| Section E | Cases for which alternatives are not yet available:<br>• Fluoropolymer application, specifically on seals separating fuel and water-cooling systems. Where the seals must resist both water and fuel at elevated temperatures. |
| Section F | Cases for which substitution is technically and economically feasible: N/A |
| Section G | Cases which substitution is not feasible:<br>• Fluoropolymer application, specifically on seals separating fuel and water-cooling systems. Where the seals must resist both water and fuel at elevated temperatures. |
| Information on sustainable fuels with modern elastomeric seals. | As motorsport progresses, there is a significant push to move towards sustainable fuels. This could be the use of methanol, or petrol made by reverse electrolysis combined with ethanol.<br>Alcohols causes most elastomers seals to deteriorate and can cause seal failure. However highly fluorinated PFAS materials such as some FKM's, or FFKM's are resistant to alcohol blends with fuel.<br>If sustainable fuels are to be utilised in future, then only FKM or FFKM have the chemical resistance to allow this transition. Silicone, EPDM, NBR, HNBR or other alternatives do not provide the required chemical resistance or thermal resistance for these applications involving fuels. |

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| | If higher temperature and more efficient engines are required in future, then only FKM or FFKM have the required temperature resistance. |
| Request for derogation | Therefore a 12-year derogation is requested to allow a full environmental analysis to be undertaken that compares the emissions from low efficiency engines to be compared to emissions from the manufacture of PFAS.<br>For the reader that believes that electric vehicles (EV's) are the solution to this problem, the point needs to be made that PFAS materials are used in many parts of EV's (i.e., batteries) and are also used during the manufacture of electronic components. |

## Chemical process industry – Fluoroelastomer applications

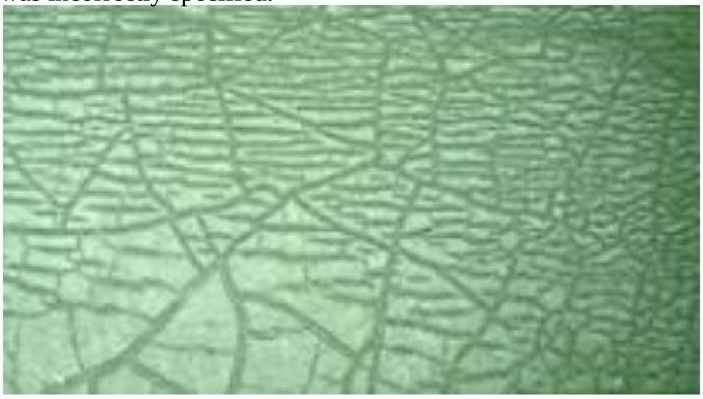
| | |
|---|---|
| Sector and sub use | Chemical Industry<br>Fluoroelastomer applications. |
| Section A | Tonnage:<br>Total tonnage of PFAS fluoroelastomer used <Confidential information has been redacted><br><br>Tonnage by material type:<br>FFKM <Confidential information has been redacted><br>FKM = <Confidential information has been redacted><br><br>**Emissions**<br>Manufacture Phase:<br>• Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt)<br><br>Use Phase estimate[a]:<br>• FFKM = <Confidential information has been redacted> (0.6% wt/wt)<br>• FKM = <Confidential information has been redacted> (1.5% wt/wt)<br><br>a.Note the lifespan of PFAS can be several years and varies according to application. Therefore, an estimate is provided that encompasses the lifetime emissions that may be produced from a single year's produce. But it should be acknowledged that this value is the lifetime emission for that lot of material, rather than the emissions per Annum. |
| Section B | TRP manufacture seals for the chemical processing industry. However, many of these seals are sold to distributors. The key functionalities of materials used in CPI are:<br>• High chemical resistance<br>• High temperature resistance<br>• Proven service history in the above environments.<br>PFAS products provide this combination of properties due to the strength of the Carbon-Fluorine bond as outlined in the technical background information section of this report.<br><br>**Chemical resistance:**<br>The consultation period does not give enough time to effectively evaluate the chemical resistance of all polymers to all chemicals. We estimate that it would take around 84million of laboratory trials to begin to evaluate suitability. This figure is derived from:<br>• 350,000 chemicals[9]<br>• 20 types of elastomer[10]<br>• 3 Temperatures, which would enable seal selection for a variety of operating conditions.<br>• For some elastomers, the polymer composition and architecture can vary the chemical resistance, therefore an estimated average of 4 types of each polymer should be tested.<br><br>This estimate does not consider contact time, pressure, variations in seal geometry, variations in equipment geometry or other factors. But the figure aims to show the reader of the complexity of re-evaluating the suitability of all polymers to applications.<br>There are published chemical resistance guides, but these are not based on actual results and are a prediction. |

[9] Environ. Sci. Technol. 2020, 54, 5, 2575–2584, Publication Date: January 22, 2020, https://doi.org/10.1021/acs.est.9b06379

[10] NR, IR, BR, CR, IIR, Halo-IIR, SBR, NBR, HNBR, EP(D)M, ECO, ACM, VMQ, FVMQ, FKM, FEPM, FFKM, CSM, EVA, PSR

Below are photos showing the effects of fluid incompatibility:

An O-Ring has swollen in fluid to the point of tearing. This seal failed prematurely in service as it was incorrectly specified.



The surface of a material has degraded heavily in fluid, such damage can cause early seal leakage or contamination.

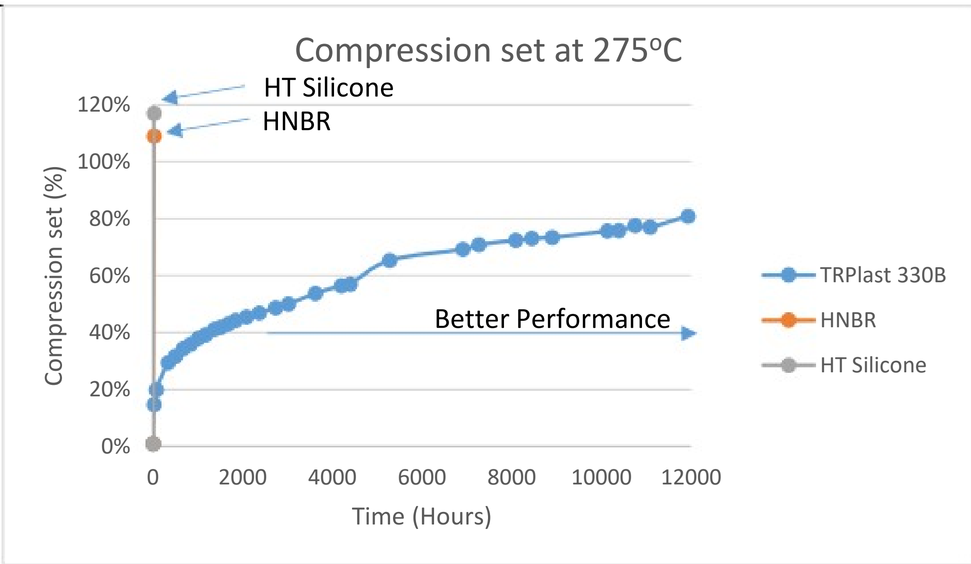
**Thermal Resistance:**

High temperature sealing life has been extensively tested at TRP. Our high temperature FFKM, TRPlast® 330B, has best in class temperature resistance. Tests indicate that at 275ºC the material can be used for almost 500 days in hot air, in fluid this could be extended.

The graph below shows a compression set for TRPlast® 330B, HNBR and a 'high temperature' silicone, which indicates a maximum temperature of 300ºC on the datasheet.
The compression set is an important indication of the amount of sealing force a material will lose at temperature, when a material reaches 80% compression set it is typically recommended to be replaced as leakage is likely. It's possible to get over 100% compression set since the material will thermally expand with temperature.

It can be observed on the below graph that:

- TRPlast® 330B reaches 80% compression set in around 12,000Hours / 500 days.
- HNBR has reached over 80% compression set in less than 24Hours.
- High temperature silicone has reached over 80% compression set in less than 24Hours and has performed worse than HNBR.

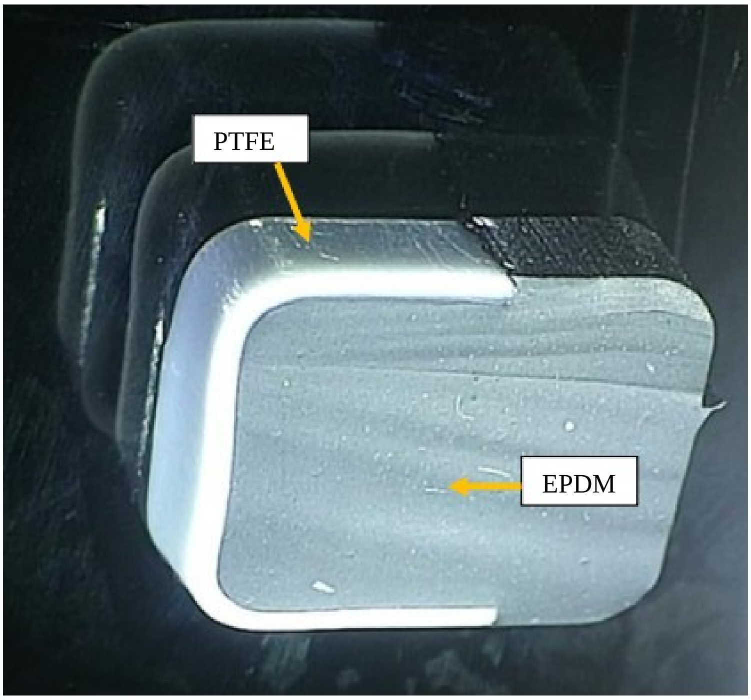
<table>
<tr><td></td><td>

The seal lifetime of an FFKM can be more than 500 times that of a HNBR or a ‘High temperature silicone’ (see information in research and development progress section overleaf[A]). For many chemical processes where the startup and shutdown of the process generates a loss in revenue, FFKM must be specified to ensure that the process is economic.
Overall PFAS elastomers provide many chemical applications with solutions for hazardous chemical at high temperature which protects both people and the environment. </td></tr>
<tr><td>Section C</td><td>Number of companies effected by restriction: <Confidential information has been redacted></td></tr>
<tr><td>Section D</td><td>Alternatives:
<ul>
<li>Availability
<ul><li>Alternative high chemical resistant materials are used where possible. This is because most FKM and FFKM products are sold at a higher cost than non PFAS products. However, for many applications there is no alternative.</li></ul></li>
<li>Technical feasibility
<ul><li>Alternatives do not provide the thermal or chemical resistance required. Therefore, for many applications no suitable alternative can be given. See information within previous section.</li></ul></li>
<li>Economic feasibility
<ul><li>FKM and FFKM have the largest investment cost of any other elastomer; but when you consider the improved efficiency that can be reached, reduced downtime and reduced replacement frequency; they often provide the largest economic benefit to the users.</li></ul></li>
<li>Hazards and risks
<ul><li>Using seals with reduced performance in the chemical processing industry could potentially cause loss of life and environmental damage.</li></ul></li>
<li>Extent of which alternatives are offered:
<ul><li>TRP does not consider PFAS to have alternatives for most applications where fluoroelastomers are currently specified.</li></ul></li>
</ul></td></tr>
<tr><td>Section E</td><td>Cases for which alternatives are not yet available:
<ul><li>Unknown. The reason why a customer requires a fluoroelastomer varies. In some cases, there may be alternatives where a non PFAS can be used, but in many cases the use of PFAS products are critical. This is because downtime of equipment to change seals can have a significant economic effect; or health risks due to leaking toxic chemicals can also have an impact on the operation of a company and the safety of their employees.</li></ul></td></tr>
<tr><td>Section F</td><td>Cases for which substitution is technically and economically feasible:</td></tr>
</table>

| | |
|---|---|
| | • The chemical industry is diverse. No two factories function at the same temperatures and conditions. An estimate of 350,000 chemicals[11] in use by industry was made by an independent researcher. Testing of all elastomers to these conditions is time consuming and may require specialised equipment. This makes it uneconomically feasible to change from PFAS materials. Furthermore, the replacement materials do not perform adequately for most applications, making them technically unsuitable. |
| Section G | Cases which substitution is not feasible:<br>• Any process which requires sealing at elevated temperatures and in aggressive chemicals such as:<br>    o Solvents<br>    o Acids<br>    o Alkali<br>    o Inorganic chemicals<br>    o Organic chemical etc. |
| Research and development progress | On the chemical resistance aspect of PFAS:<br>• PFAS have unrivalled chemical resistance when compared to non PFAS materials. There has been little if any improvements in the chemical resistance of non-PFAS materials.<br>On the service temperature and service interval:<br>• Since the development of PFAS elastomers, the service temperature and service interval has been unrivalled.<br><br>In the last decade there has been advancements in the sealing temperatures of some HNBR grades; however, this comes at trade-off of either chemical resistance or does not benefit sealing scenarios and only benefits direct heat ageing.<br><br>From the guidance given by polymer suppliers, the maximum service temperature is increased by about 25ºC. It has taken around 40 years to improve (see below[A]) this temperature limit. Therefore, if we assume that every 40 years there will be a max temperature increase of 25ºC then we can calculate by extrapolation that there is still another 200 years of development to reach the 300-330ºC an FFKM seal can reach.<br><br>[A](It is worth noting here there is no regulation or test method to establish the max temperature you can specify what an elastomer can operate to; therefore, we have seen claims of non PFAS materials that can operate at temperatures double what the polymer manufacturer would recommend. So, if there is another submission claiming that silicones can be used up to 300ºC, we are more than willing to send you the data and prove that it does not provide adequate or equivalent thermal resistance) |
| Request for derogation | A maximum derogation is requested. It's not believed the PFAS can be replaced successfully within 12 years. |

[11] Environ. Sci. Technol. 2020, 54, 5, 2575–2584, Publication Date: January 22, 2020, https://doi.org/10.1021/acs.est.9b06379

## Electrolysis technology – Fluoropolymer applications

| | |
|---|---|
| Sector and sub use | Electrolysis technology<br>Fluoropolymer applications. |
| Section A | Tonnage:<br>Total tonnage of PTFE used = <Confidential information has been redacted><br><br>**Emissions**<br>Not established |
| Section B | TRP use a unique technology for electrolyser gaskets. The result is a non-PFAS material that has a veneer of PFAS on the surface. This increases the service life and chemical resistance whilst reducing the quantity of PFAS used.<br><br>The composite seals operate by using the PFAS material as a chemical and thermal barrier, whilst the non-PFAS material energises the composite and forms the sealing profile. A photograph is included below for reference:<br><br><br><br>EPDM rubber (black solid) with a PTFE Venner (white solid) |
| Section C | Number of companies effected by restriction: <Confidential information has been redacted> |
| Section D | **Alternatives:**<br>• Availability<br>  ○ It is known that it's possible to use gaskets based solely on:<br>    ▪ EPDM<br>    ▪ FFKM<br>    ▪ FKM<br>    ▪ FEPM<br>    ▪ PTFE<br>    ▪ Polyethylene<br>  ○ In the current revision of the ECHA document; at the end of the restriction only EPDM, and polyethylene will be available for use within electrolysers.<br>• Technical feasibility: |

| | |
|---|---|
| | o Polyethylene is a plastic; in service this material reduces in sealing force at a high rate compared with elastomers. This is known as creep. Because of this the sealing life is significantly reduced over elastomeric components. Therefore, they do not provide a technical solution.<br>o EPDM can seal successfully in some electrolyser gaskets. But over time is known that the chemical fluids can break down the material. This not only encourages leaking but decreases service life and increases permeation across the gasket. For large industrial equipment where the aim is to maintain the seal for 10 years, this does not provide an alternative. The below photo shows an EPDM gasket that has been exposed to electrolytic conditions, it can be observed that it has started to dissolve:<br><Confidential information has been redacted><br>Interestingly we also established chemical resistance of EPDM in <Confidential information has been redacted> at 95ºC for 5 days (the same chemical composition and temperature of the electrolyser gasket), and the results are below:<br><Confidential information has been redacted><br>The above information shows that in the lab the deterioration of the material is very low compared to what is experienced in application. This indicates that laboratory conditions do not provide a complete simulation of an end application.<br>We also ran thermal gas analysis (TGA) on a degraded material in application against a tested material in the lab and found a significant difference. A TGA graph is available on request since they can be complicated to interpret and contain confidential information.<br>• Economic feasibility:<br>o On paper the replacement of composite gaskets by solely EPDM looks beneficial. But when gaskets are required to be changed more often, production rates are reduced and containment areas for leaking fluids must be built; then it's not economically feasible to replace PFAS materials.<br>o Another aspect to consider is the time taken for testing a new gasket, to fully qualify previous products it has taken up to 10 years.<br>• Hazards and risks:<br>o Increased leakage of electrolyser fluids.<br>o Possibility of gas leakage causing fire / asphyxiation / chemical hazards / harm to environment / harm to people. Gases produced in electrolysers vary, but as an example can be hydrogen, chlorine, nitrogen, oxygen etc.<br>• Extent of which alternatives are offered:<br>o Alternatives are used occasionally, especially in lower power cell units where a composite material is not practical, and replacement is more frequent. But these commercial units do not have the same requirements as industrial units. |
| Section E | Cases for which alternatives are not yet available:<br>• Industrial electrolyser gaskets. |
| Section F | Cases for which substitution is technically and economically feasible:<br>In small commercial hydrogen electrolysers where this composite technology was not feasible there may be opportunity to replace some gaskets with EPDM. Currently many use FKM. |
| Section G | Cases which substitution is not feasible: |

| | |
|---|---|
| | All electrolysers that require long sealing life and low leakage rates.<br>All electrolysers that can produce significant levels of toxic gas, or gas in levels large enough to cause asphyxiation. |
| Request for derogation | Since it can take up to 10 years to qualify a material, then a maximum derogation is requested. This may enable research and development for new materials and may educate customers on how they can manage higher costs associated with replacement / leakage / health and safety hazards that come from using non-PFAS gaskets. |

Chemical transport – Fluoroelastomer applications.

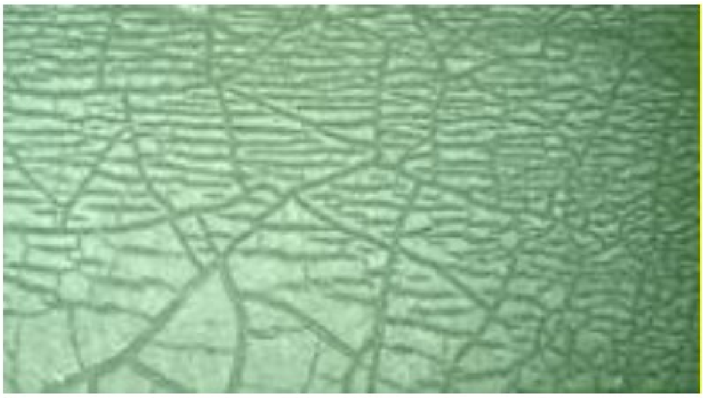
| | |
|---|---|
| Sector and sub use | Chemical Transport<br>Fluoroelastomer applications |
| Section A | Tonnage:<br>Total tonnage of PFAS fluoroelastomer used <Confidential information has been redacted><br><br>Tonnage by material type:<br>FFKM <Confidential information has been redacted><br>FKM = <Confidential information has been redacted><br><br>**Emissions**<br>Manufacture Phase:<br>• Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt)<br><br>Use Phase estimate[a]:<br>• FFKM = <Confidential information has been redacted> (0.6% wt/wt)<br>• FKM = <Confidential information has been redacted> (1.5% wt/wt)<br><br>a.Note the lifespan of PFAS can be several years and varies according to application. Therefore, an estimate is provided that encompasses the lifetime emissions that may be produced from a single year's produce. But it should be acknowledged that this value is the lifetime emission for that lot of material, rather than the emissions per Annum. |
| Section B | • Universal chemical use<br>• Proven historical use.<br>• Long sealing life<br><br>All these aspects are of importance when transporting chemicals. |
| Section C | <Confidential information has been redacted> |
| Section D | **Alternatives:**<br>• Availability<br>  ○ If alternatives were available with the appropriate chemical resistance, thermal resistance and had proven historical use they would be currently specified. This industry meticulously chooses materials specifically for their applications, and thoroughly tests them.<br>• Technical feasibility<br>  ○ Alternatives are not technically feasible.<br>• Economic feasibility<br>  ○ PFAS fluoroelastomers present an economic benefit to the end user because the life of the seals is improved. There is also a significantly reduced risk of leakage when transporting. Many of the chemical transport industries served by TRP manage the transport of fuels. The economic and environmental effect of fuel spillage at sea has been observed multiple times, such as on the occasion of the deepwater horizon spill.<br>• Hazards and risks<br>  ○ The manufacture of alternatives polymers carries its own risks. For example, monomers of acrylonitrile can be toxic, fluorosurfactants are used in most polymer manufacturing |

| | |
|---|---|
| | processes, silicones can contain D4/D5/D6. There is no polymer that is hazard or risk free.<br>o If toxic chemicals are accidentally released, the cost of decontaminating will be much greater than specifying a PFAS seal both economically and environmentally.<br>• Extent of which alternatives are offered:<br>o We offer non PFAS materials when suitable, some applications specifically request non-PFAS materials or composite materials. |
| Section E | Cases for which alternatives are not yet available: All cases specifying fluoroelastomer seals. |
| Section F | Cases for which substitution is technically and economically feasible: N/A |
| Section G | Cases which substitution is not feasible:<br>• Applications where mixed chemical streams are used, where a non-PFAS would be chemically unstable in the fluids.<br>• Applications where long service life is required.<br>• High temperature applications above 200ºC for extended periods.<br>• Applications which require proven service history. |
| Request for derogation | A maximum derogation is requested. |

Laboratory equipment – Fluoroelastomer applications

| | |
|---|---|
| Sector and sub use | Laboratory equipment<br>Fluoroelastomer applications. |
| Section A | Tonnage:<br>Total tonnage of PFAS fluoroelastomer used = <Confidential information has been redacted><br><br>Tonnage by material type:<br>FFKM <Confidential information has been redacted><br>FKM = <Confidential information has been redacted><br><br>**Emissions**<br>Manufacture Phase:<br>• Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt)<br><br>Use Phase estimate[a]:<br>• FFKM = <Confidential information has been redacted> (0.6% wt/wt)<br>• FKM = <Confidential information has been redacted> (1.5% wt/wt)<br><br>a.Note the lifespan of PFAS can be several years and varies according to application. Therefore, an estimate is provided that encompasses the lifetime emissions that may be produced from a single year's produce. But it should be acknowledged that this value is the lifetime emission for that lot of material, rather than the emissions per Annum. |
| Section B | TRP manufacture seals for laboratory equipment. The key functionalities of materials used are:<br>• High chemical resistance<br>• High temperature resistance<br>• Proven service history in the above environments.<br>PFAS products provide this combination of properties due to the strength of the Carbon-Fluorine bond.<br><br>**Chemical resistance:**<br>The consultation period does not give enough time to effectively evaluate the chemical resistance of all polymers to all chemicals. As described in the derogation request for the chemical process industry. We estimate that it would take around 84million individual laboratory trials to begin to evaluate suitability.<br><br>This estimate does not consider contact time, pressure, variations in seal geometry, variations in equipment geometry or many other factors. But the figure aims to show the reader of the complexity of re-evaluating the suitability of all polymers to applications.<br>There are published chemical resistance guides, but these are not based on actual results and are generally a prediction.<br>Below are photos showing the effects of fluid incompatibility: |

An O-Ring has swollen in fluid to the point of tearing. This seal failed prematurely in service as it was incorrectly specified.



The surface of a material has degraded heavily in fluid, such damage can cause early seal leakage or contamination.

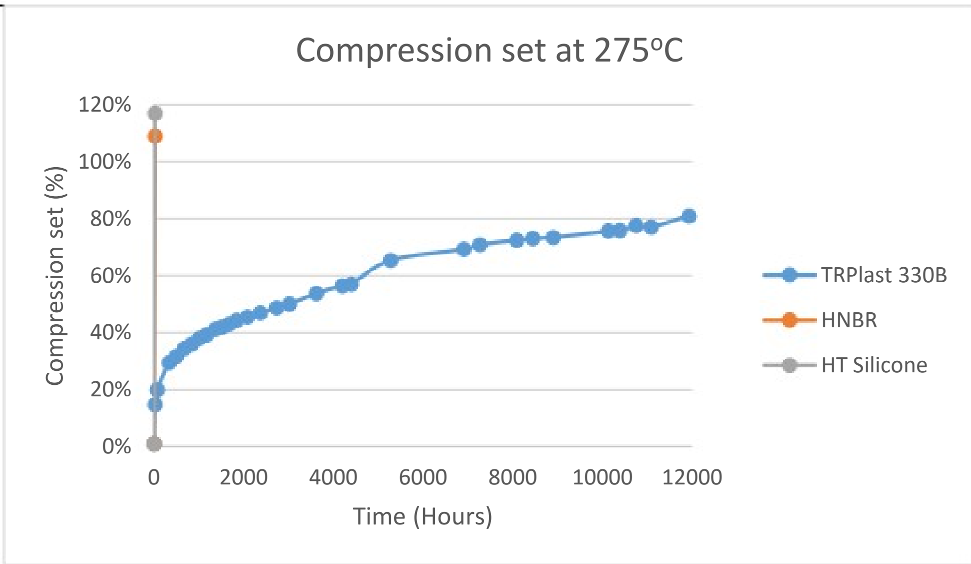
**Thermal Resistance:**

High temperature sealing life has been extensively tested at TRP. Our high temperature FFKM, TRPlast® 330B, has best in class temperature resistance. Tests indicate that at 275ºC the material can be used for almost 500 days in hot air, in fluid this could be extended.

The graph below shows a compression set for TRPlast® 330B, HNBR and a 'high temperature' silicone, which specifies a max service temperature of 300ºC on the datasheet. The compression set is an important indication of the amount of sealing force a material will lose at temperature, when a material reaches 80% compression set it is typically recommended to be replaced as leakage is likely. It's possible to get over 100% compression set since the material will thermally expand with temperature.

It can be observed on the below graph that:

- TRPlast® 330B reaches 80% compression set in around 12,000Hours / 500 days.
- HNBR has reached over 80% compression set in less than 24Hours
- High temperature silicone has reached over 80% compression set in 24Hours, and has performed worse than HNBR.

| | |
|---|---|
| | <br><br><br>The seal lifetime of an FFKM can be more than 500 times that of a HNBR or a ‘High temperature silicone’.<br><br>Overall PFAS elastomers provide many laboratory applications with solutions for hazardous chemical at high temperature which protects both people and the environment. |
| Section C | Number of companies effected by restriction: <Confidential information has been redacted> |
| Section D | **Alternatives:**<br>• Availability<br>  ○ Alternative high chemical resistant materials are used where possible. However, most laboratories use a range of different chemicals within their process, and they may need specialised assistance to change the seals within the equipment. Conducting multiple seal changes a day for a variety of chemical fluids and temperatures is not practical, especially when it may void warranties on equipment that can routinely cost over 100,000Euro’s or require calling out the manufacturers of the equipment to change the seal.<br>• Technical feasibility<br>  ○ Alternatives do not provide the thermal or chemical resistance required by most laboratories. Fluoroelastomers must operate at a wide range of temperatures, in a wide range of chemical media. Therefore, for many applications no suitable alternative can be given.<br>• Economic feasibility<br>  ○ The equipment used within labs are very expensive and are generally serviced by the suppliers. Seals used within the equipment are not typically allowed to be replaced by the laboratory operatives, otherwise the warranty of the equipment could become void. Therefore, in absence of PFAS seals, non-PFAS seals may have to be changed at an increased interval by calling out the equipment manufacturer. This may render the process uneconomical.<br>• Hazards and risks<br>  ○ Using seals with reduced performance than PFAS in laboratory applications could cause safety hazards and environmental damage.<br>• Extent of which alternatives are offered:<br>  ○ I do not consider PFAS to have alternatives for most laboratory fluoroelastomer applications. |
| Section E | Cases for which alternatives are not yet available: Most applications. |
| Section F | Cases for which substitution is technically and economically feasible: No known applications. |

| | |
|---|---|
| Section G | Cases which substitution is not feasible:<br>Any process which requires sealing at elevated temperatures and in aggressive chemicals. |
| Request for derogation | A maximum derogation is requested. It’s not believed the PFAS can be replaced successfully. |

## Printing inks – Fluoroelastomer applications

| Sector and sub use | Printing Inks<br>Fluoroelastomer applications |
|---|---|
| Section A | Tonnage:<br>Total tonnage of PFAS fluoroelastomer used <Confidential information has been redacted><br><br>Tonnage by material type:<br>FFKM <Confidential information has been redacted><br>FKM = <Confidential information has been redacted><br><br>**Emissions**<br>Manufacture Phase:<br>• Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt)<br><br>Use Phase estimate[a]:<br>• FFKM = <Confidential information has been redacted> (0.6% wt/wt)<br>• FKM = <Confidential information has been redacted> (1.5% wt/wt)<br><br>a.Note the lifespan of PFAS can be several years and varies according to application. Therefore, an estimate is provided that encompasses the lifetime emissions that may be produced from a single year's produce. But it should be acknowledged that this value is the lifetime emission for that lot of material, rather than the emissions per Annum. |
| Section B | Long term resistance to solvents without changing dynamic properties. TRP manufacture high performance printer ink wipers bonded to a metal carrier. These wipers can last throughout the life of the equipment without swelling or changing dynamic properties. This ensures that the solvent is wiped consistently, and the printing is consistent throughout the lifetime.<br><br>TRP also manufacture sealing elements for printing inks. Without PFAS this equipment could not function. |
| Section C | <Confidential information has been redacted> |
| Section D | **Alternatives:**<br>• Availability<br>    o From the testing TRP has observed from our customer, we do not believe there is an alternative. The meticulous testing of materials is what directed our customer towards FFKM, and in some cases FKM. If there had been another Polymer type that performed to the level they required then they would be using it.<br>    o The customer described previously is industry leading within this sector, and they place emphasis on testing, research, development and qualification.<br>• Technical feasibility<br>    o N/A<br>• Economic feasibility<br>    o N/A<br>• Hazards and risks<br>    o N/A<br>• Extent of which alternatives are offered: |

| | |
|---|---|
| | ○ N/A |
| Section E | Cases for which alternatives are not yet available:<br>All cases requiring PFAS seals |
| Section F | Cases for which substitution is technically and economically feasible:<br>It’s not believed there is a technical substitution. |
| Section G | Cases which substitution is not feasible:<br>All cases where PFAS is required. |

## Part 4 Test methodology for the analysis of PFOA and PFOA related substances in elastomers.

| | |
|---|---|
| Description | TRP undertook tests to determine the amount of PFOA and PFOA related substances contained within their fluoroelastomer and PTFE range.<br><br>Within these tests it was determines less than 25ppb of PFOA and PFOA related substances were contains within the materials |
| Hyperlink to the report | <Confidential information has been redacted> |
| Data for Annex E4 | |
| Title | Perfluorooctanoic Acid (PFOA) and PFOA-Related Substances Content - Entry 68 of Annex XVII of European Regulation (EC) No 1907/2006, No 552/2009 and No 2017/1000 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) |
| Author | N/A |
| Journal | N/A |
| Year | Tests conducted on 6/1/2020 |
| Comments | Method developed specifically for the analysis of PFOA and related substance content in FKM, FFKM and PTFE (Elastomers and PTFE)<br>Method in line with CEN/TS 15968:2010 / ISO23702-1 |
| DOI Link | CEN/TS 15968:2010 - Determination of extractable perfluorooctanesulphonate (PFOS) in coated and (iteh.ai)[12] |
| PFAS | PFOA – CAS: 335-67-1<br>FTOH – CAS 678-39-7<br>APFO – CAS 3825-26-1<br>8:2 FTA – CAS 27905-45-9<br>PF-3,7-DMOA – CAS 172155-07-6 |
| Sampling | 2x BS312 O-Rings of approximate mass of 3.5g each<br>PTFE used was etched on the one side and presented as a 0.5mm thick strip of width 25mm. |
| Sample amount used | Approximately 7g of each material |
| Pre treatment | <Confidential information has been redacted> |
| Extraction | Methanol |
| Clean up | N/A |
| Measurement | LC-MS/GC-MS // LC-tandemMS / LC-qMS |
| Quantification method | N/A |
| Working range | 0.5µg/l to 50µg/l |
| Matrices | BS312 O-rings for Fluoroelastomer – produced to specification, tape format for PTFE. |
| Reported level | For PFAS evaluated for (see PFAS), <25ppb was detected individually and in total. |
| Info – Method validation | N/A |
| Limitations | N/A |
| Limits of detection | 0.5µg/l to 50µg/l |

[12] *PD CEN/TS 15968:2010 Determination of extractable ...*, https://www.en-standard.eu/pd-cen-ts-15968-2010-determination-of-extractable-perfluorooctanesulphonate-pfos-in-coated-and-impregnated-solid-articles-liquids-and-fire-fighting-foams-method-for-sampling-extraction-and-analysis-by-lcqms-or-lc-tandem-ms/.

# Annex – A

## Calculation of emissions from primary curing within a press.

During press cure it is believed that no fluorinated emissions are generated. However, it is known that following volatiles are produced[13]:

| Species | Boiling Point (ºC) | Molar concentration (%) |
|---|---|---|
| Acetone | 56 | 30.73 |
| Water | 100 | 54.00 |
| Methane | -161 | 8.70 |
| Ethene | -103 | 0.84 |
| Propene/propane | -42 | 1.30 |
| Butene | -1 | 1.26 |
| 1-Bromomethane | 4 | 0.59 |
| Butanol | 117.7 | 2.24 |

Water, acetone and methane make up 93% of the mixture on a molar basis. None of the emissions at curing stage have been found to be fluorinated.

[13] L.Logothesis, 1989, *Chemistry of fluorocarbon elastomers*, Prog. Polym. Sci., Vol 14, 251-296, Pergamon press plc

## Calculation of emissions from secondary curing during postcure.

The purpose of a postcure is:

- To consume residual curatives
- To remove low molecular weight impurities which may otherwise outgas.
- Improve the properties of the material such as compression set, heat ageing or hardness.

TRP understand that weight is lost from the material on postcure. Some of the chemicals released are non PFAS such as residual acetone and water. We also know that some chemicals released must be PFAS from the tests conducted in Q10 investigating PFOA content of several PFAS materials.

<Confidential information has been redacted> PFAS <Confidential information has been redacted> are not removed until approximately 230$^{o}$C. We also know that some of the chemicals within the elastomer matrix are water, acetone and methane[14]. Therefore, it was decided that that the material will be postcured first at 150$^{o}$C for 16Hours to remove water, acetone, methane and other low molecular weight non PFAS materials. It was observed that a mass was released from the material which we believe was non-PFAS. We then postcured the material for 5Hours at 230$^{o}$C and observed a second loss in mass, which we believe was primarily PFAS based.

We found that for PFAS elastomers, 0.3% of the initial weight is expected to be emitted as low molecular weight PFAS.

| | **FKM Sample 1** | **FKM Sample 2** |
|---|---|---|
| Before Postcure weight | 31.8072 | 26.8486 |
| After 16Hours @ 150C | 31.6809 | 26.5790 |
| After 5Hours @ 230 PC | 31.5961 | 26.5059 |
| Percentage weight loss on higher temperature cure | 0.268% | 0.276% |

*Weight loss expected to be related to PFAS emissions on postcure.*

[14] L.Logothesis, 1989, *Chemistry of fluorocarbon elastomers*, Prog. Polym. Sci., Vol 14, 251-296, Pergamon press plc

## Calculation of emissions from service within application.

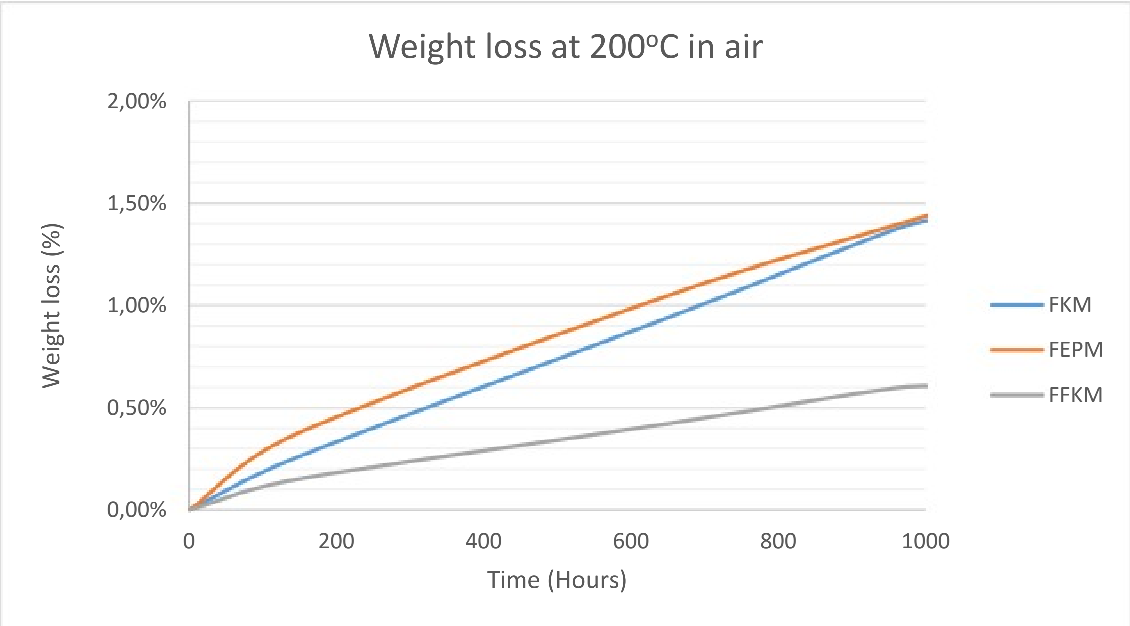
From studies conducted at TRP, we have found that for general purpose FKM and FFKM's the time to reach a compression set of 80% is around 1000Hours when tested on O-Rings at 200ºC. This is believed to correlate with the service interval of the seal in the same conditions. (For readers who operate within the industry, note that in fluid the service life is increased because of the absence of oxygen).

Therefore, it was decided that heat ageing of FFKM and FKM in the same conditions and recording the weight loss, would give us an indication of the emissions from the material.

It was found that for an FFKM, the weight loss in air for these conditions was around 0.6%. Therefore, we assume that the emissions for an FFKM throughout its service life is 0.6% of its initial mass.

It was found that for FKM and FEPM the weight loss in air for these conditions was around 1.5%. Therefore, we assume that the emissions for an FEPM throughout its service life is 1.5% of its initial mass.

A graph outlining the weight loss can be observed below:




It's not possible to determine what chemical species are being lost on thermal degradation. Like the derogation system, it's impossible to know all applications and uses. It is known that hydrofluoric acid is released, along with the following:

- Tetrafluoroethylene
- Carbonyl fluoride
- Carbon monoxide
- Carbon dioxide
- Perfluoro isobutylene
- Particulate matter

However, for each application there can be different products of thermal degradation. For example, if the seal is in a non-oxidative environment, then no oxidative emissions can be generated, which would be a different emission profile to a seal aged in a highly oxidative environment.

In addition to this, in certain applications the emissions may be scrubbed off such as in the chemical process industry or may be thermally degraded further by combustion such as in the automotive industry. Therefore, to truly verify these emissions a thorough range experiments needs to be undertaken inclusive off all derogations.

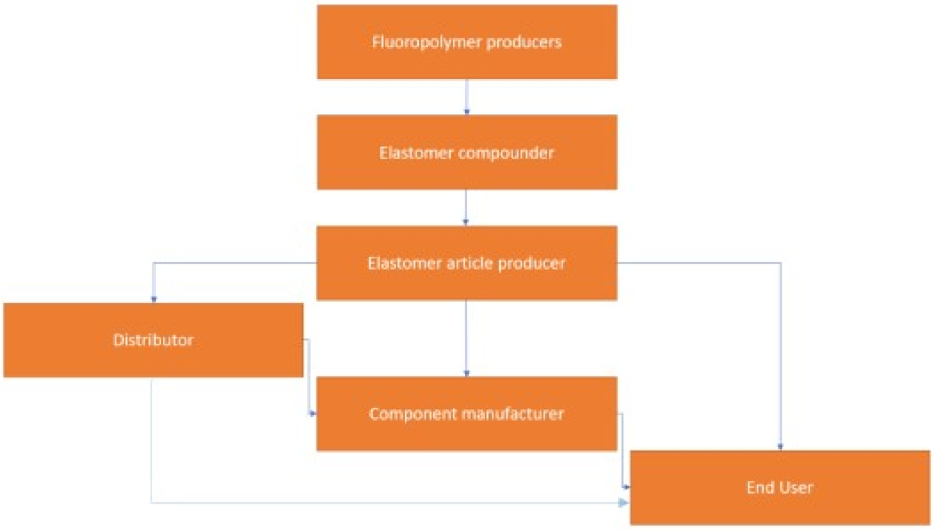
# Annex B - Fluoroelastomer supply chain

Much of the data requested by ECHA is difficult to establish. Whilst emissions have attempted to be calculated, the true impact on industrial consumers cannot be calculated. This is because a significant portion of the end users are choosing to ignore the restriction. This is because they do not have the funding or knowledge to complete a submission. Many manufacturers do not have designated regulator or compliance personnel therefore time is taken from technical departments, with some manufacturers this isn't possible. <Confidential information has been redacted>

To educate ECHA on the fluoroelastomer supply chain, a process and flowchart (below) have been produced:

1. Fluoropolymers are initially produced at manufacturing sites. This can be in the form of oil, plastics or fluoroelastomer.
2. At the elastomer compounding stage; the fluoropolymers are mixed with chemicals to give the optimal properties. At this stage it is uncommon for the compounder to know the application. In most cases they are designing a material to meet a specification. To TRP's knowledge most compounders have not made a submission.
3. The elastomer article producer is the stage of the supply chain that TRP is contained within. For most applications we know the composition of an article. The customers purchasing the article can be either a distributor, component manufacturer or an end user. Because of non-disclosure agreements and protection of intellectual property, most customers do not specify the end application. They simply request a material and design.

The flowchart below visualises the above process:



Den 12. juli 2024

# Aktdetaljer

## Akttitel: PFAS Info fra Dansk Planteværn
## Aktnummer:
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