



TRP POLYMER SOLUTIONS LTD. FLOUROELASTOMER MANUFACTURER

Report TR1094 – Non-Confidential submission

NON-CONFIDENTIAL

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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.

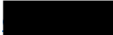
Citation

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

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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 XV¹.
 - Part two – Information requested for the proposed derogations contained within Annex XV¹ Table 8.
 - Part three – Derogations required which are not included within Annex XV¹ 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: 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 : FKM FFKM FEPM PTFE FVMQ 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 50°C to 300°C, 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: • A process aid for a polymer manufacture could be a surfactant, which assists the polymerisation process. • A process aid for a rubber mixer could be a chemical that aid mixing. • A process aid for a rubber manufacture could be used to aid mould release or increase the flow of a material. • A process aid for an end user could be a grease to assist the installation of an O-Ring 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. A double bond forms when 2 atoms share 2 pairs of electrons. 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: • Steam • Hot water • Alkali cleaning solution • Nitric acid • 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.

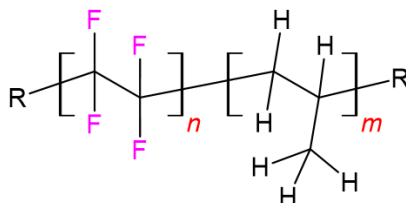
The chemical structures are provided below. (CAS numbers are not provided, since these can be commercially sensitive for manufacturers and can vary between suppliers.) Information such as cure site monomers and termination molecules have not been included:

FKM Type: 1 Synonym: Copolymer / Di-polymer / Viton® A Monomers used: HFP/VF2	
FKM Type: 2 Synonym: Terpolymer / Viton® B / Viton® F / Viton® GF / Tetrapolymer. Monomers used: HFP/VF2/TFE/(CSM)	
FKM type: 3 Synonym: LT FKM / Viton® GLT / Viton® GFLT. Monomers used: VF2/PAVE/TFE/(CSM)	
FKM Type: 4 Synonym: BRE / Tetrapolymer Monomers used: VF2/Propylene/TFE	
FKM Type: 5 Synonym : BRE Monomers used: VF2/HFP/TFE/PAVE/Ethylene used.	

FEPM Type: 1

Synonym: TFE/P Aflas®

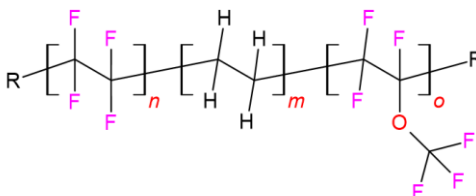
Monomers Used: TFE/Propylene



FEPM Type: 2

Synonyms: Viton® Extreme, Aflas® 200

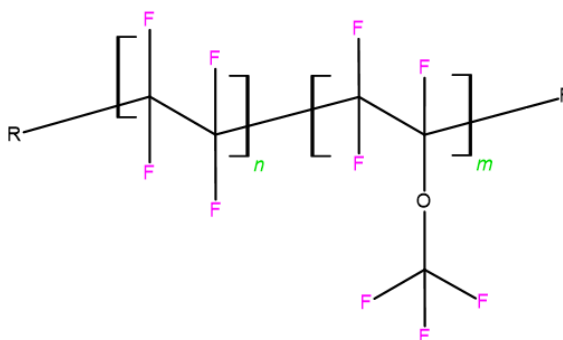
Monomers used: TFE/Ethylene/PAVE



FFKM type: Standard

Synonyms: FFKM / Perfluoroelastomer /
TRPlast® / Kalrez®

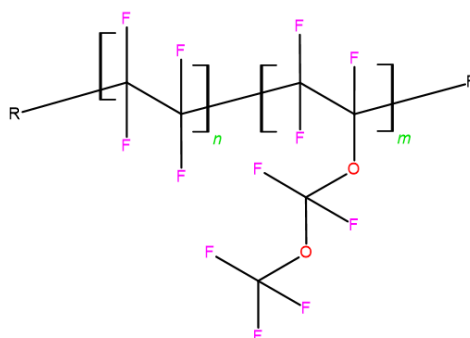
Monomers used: TFE/PAVE/CSM



FFKM type: Low temperature

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

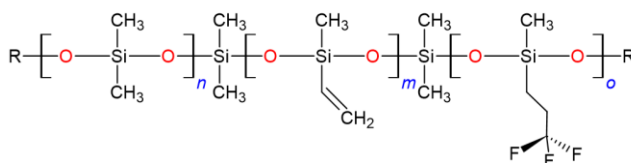
Monomers used: TFE/PAVE/CSM



FVMQ

Synonym: Fluorosilicone

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



The Carbon-Fluorine bond

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 bonds³

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 2230⁴.

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.

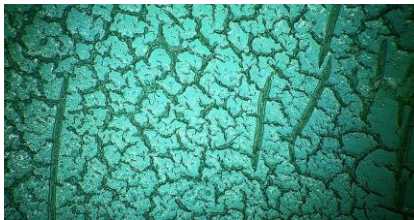
The bullet point below outlines the only derogation set out in Annex XV that is applicable to TRP:

- 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.

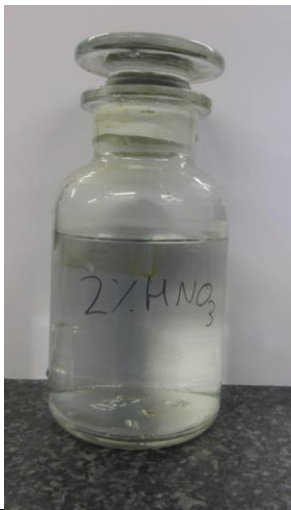
Food contact material and packaging

Sector and sub use	Food Contact materials & packaging. 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: Total tonnage of PFAS fluoroelastomer used <Confidential information has been redacted> Tonnage by material type: FFKM <Confidential information has been redacted> FKM and FEPM <Confidential information has been redacted> Note FVMQ is not suitable for food contact in accordance with FDA. Emissions Manufacture Phase: Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt) Use Phase estimate^a: • FFKM = <Confidential information has been redacted> (0.6% wt/wt) • FKM & FEPM = <Confidential information has been redacted> (1.5% wt/wt) 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. End of life phase: • Amount expected to be landfilled: <Confidential information has been redacted>^b • Amount expected to be incinerated: <Confidential information has been redacted>^b b. In accordance with regional waste disposal ratio's
Information relating to Q8.  Technical Report 1090 bisphenol FDA	The requirements by the customer of these seals are: • Blue colour - allowing identification in food. • The seal must be chemically resistant to SIP/CIP chemicals. Failure to meet these requirements would cause septic conditions. • 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. • Materials used to manufacture the seals must not leach into food. • The material must conform to 21 CFR 177.2600 d,e and f (FDA food contact standard). These requirements ensure that food is not spoilt, there are no adverse organoleptic effects and that the food is not toxic.

	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. 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. 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. 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: <u>168Hours @ 90°C in 2% HNO₃</u> FKM  No signs of deterioration EPDM  Severe bubbling of surface. Silicone  Colour loss, cracking and flaking of surface. NBR  Severe cracking of surface. 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. Formulation of PFAS fluoroelastomers can require few ingredients. For food contact applications the formulation can be as little as two to three ingredients.

	The formulation of an organic non-PFAS⁸ (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. 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. 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. An example of the hazards that can be associated with some of these chemicals are listed below: • Antioxidants: ○ H317 – May cause allergic skin reaction. ○ H334 – May cause allergy if inhaled. ○ H361 – Suspected of damaging fertility of unborn child. • Paraffinic oils: ○ H304 – may be fatal if swallowed and enters airways. • Curatives: ○ H302 – Harmful if swallowed. ○ H315 – Causes skin irritation. ○ H360 – May damage fertility of unborn child ○ H373 – May cause damage to organs. ○ H411 – toxic to aquatic life with long lasting effects 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. 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. 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°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:
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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.

	1 week at 90°C for FKM  1 week at 90°C for non-PFAS based materials. 
Case Study	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. 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. 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. 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. 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. 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.
Requested Derogation	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.

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 Fluoroelastomer applications
Section A	Tonnage: Total tonnage of PFAS fluoroelastomer used <Confidential information has been redacted> Tonnage by material type: FFKM <Confidential information has been redacted> FKM = <Confidential information has been redacted> Emissions Manufacture Phase: - Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt) Use Phase estimate^a: - FFKM = <Confidential information has been redacted> (0.6% wt/wt) - FKM = <Confidential information has been redacted> (1.5% wt/wt) 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. 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. 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. 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. 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>

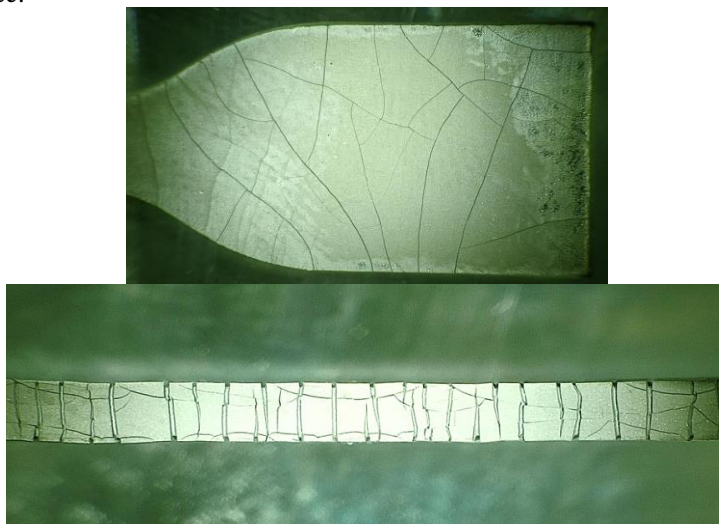
Section D

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 $\text{CF}_3\text{-CH=CH}_2$; 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 275°C 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 275°C 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.

	Unfortunately, 12,000Hours is 500Days, which is greater the 6months consultation period; therefore, no photos can be submitted for evidence for this aspect. A further requirement is that the material must have a maximum compression set of 15% after 22Hours @ 200°C. 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. • Economic feasibility ○ 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. ○ 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: ▪ 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. ▪ Silicone products contain D4, D5 and D6. 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. • Extent of which alternatives are offered: ○ HNBR and VMQ are not suitable alternatives. There are also supply chain issues with these materials which have been ongoing since around 2021. Astronautics: • Availability ○ 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. • Technical: ○ 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. • Economic feasibility ○ N/A. There is no alternative to PFAS products in this environment. • Hazards and risks ○ 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). • Extent of which alternatives are offered: ○ 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: • 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: • There are no non-PFAS alternatives to fluoropolymers where the materials must meet high temperature operating conditions or must operate in aggressive fluids.

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.
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Automotive – Fluoroelastomer applications

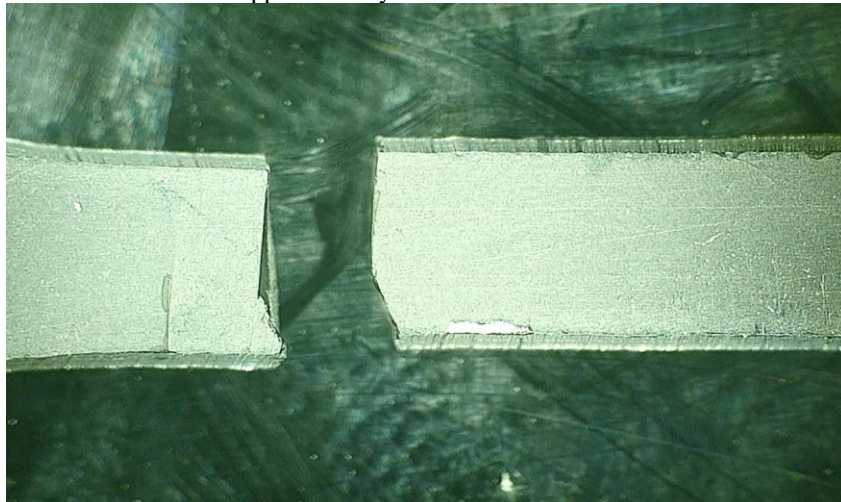
Sector and sub use	Automotive Fluoroelastomer applications This section also outlines aspects relating to renewable fuels.
Section A	Tonnage: Total tonnage of PFAS fluoroelastomer used <Confidential information has been redacted> Tonnage by material type: FFKM <Confidential information has been redacted> FKM = <Confidential information has been redacted> Emissions Manufacture Phase: - Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt) Use Phase estimate^a: - FFKM = <Confidential information has been redacted> (0.6% wt/wt) - FKM = <Confidential information has been redacted> (1.5% wt/wt) 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. 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. 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. 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> 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: HNBR: 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@250°C:

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.

	FKM: When tested at 72Hours@250°C, 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: • Availability ○ There are currently shortages for HNBR, which have persisted since around 2021. ○ Silicone is not considered an alternative. It is already used where possible. • Technical feasibility ○ 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. ○ 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. • Economic feasibility ○ Currently, the cost for HNBR, FKM and silicones are similar in these applications. • Hazards and risks ○ 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. ○ 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. • Extent of which alternatives are offered: ○ 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: • 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: • 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. 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. 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.

	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. 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 Fluoroelastomer applications.
Section A	<u>Tonnage:</u> Total tonnage of PFAS fluoroelastomer used <Confidential information has been redacted> <u>Tonnage by material type:</u> FFKM <Confidential information has been redacted> FKM = <Confidential information has been redacted> <u>Emissions</u> Manufacture Phase: - Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt) Use Phase estimate^a: - FFKM = <Confidential information has been redacted> (0.6% wt/wt) - FKM = <Confidential information has been redacted> (1.5% wt/wt) 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: - High chemical resistance - High temperature resistance - Proven service history in the above environments. 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. Chemical resistance: 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: 350,000 chemicals⁹ 20 types of elastomer¹⁰ 3 Temperatures, which would enable seal selection for a variety of operating conditions. - 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. 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. There are published chemical resistance guides, but these are not based on actual results and are a prediction.

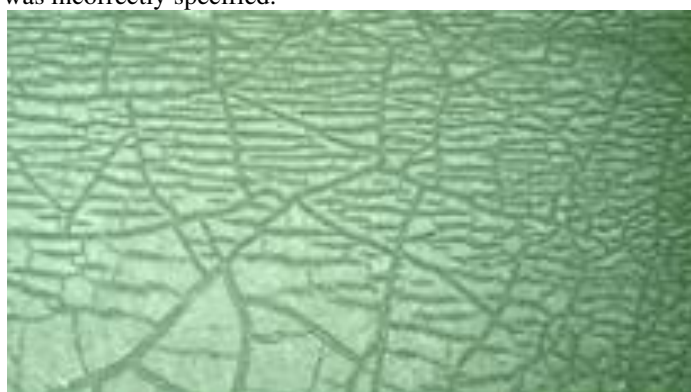
⁹Environ. Sci. Technol. 2020, 54, 5, 2575–2584, Publication Date: January 22, 2020, <https://doi.org/10.1021/acs.est.9b06379>

¹⁰NR, 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 275°C 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 300°C 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:

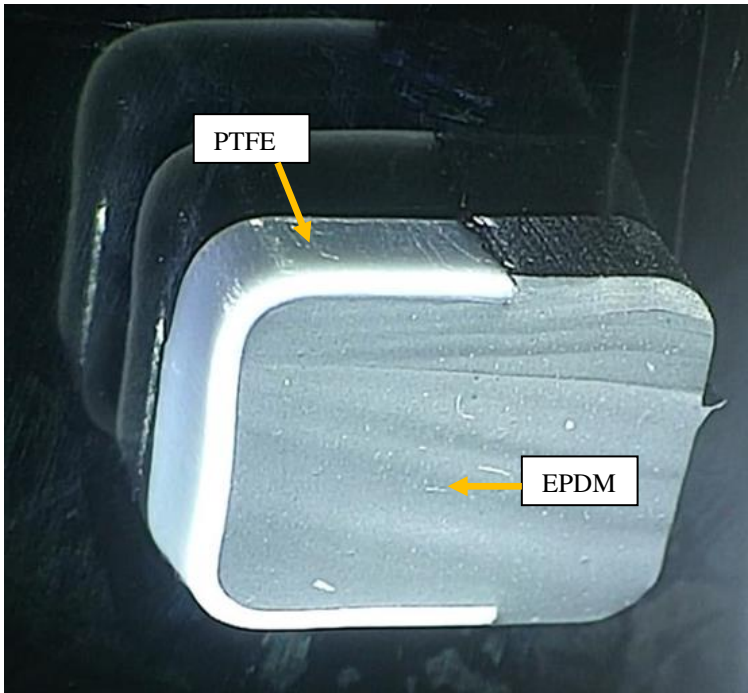
- TRPlast® 330B reaches 80% compression set in around 12,000Hours / 500 days.
- HNBR has reached over 80% compression set in less than 24Hours.
- High temperature silicone has reached over 80% compression set in less than 24Hours and has performed worse than HNBR.

	Compression set at 275°C The graph plots Compression set (%) on the y-axis (0% to 120%) against Time (Hours) on the x-axis (0 to 12,000). Three data series are shown: TRPlast 330B (blue line with circles), HNBR (orange line with circles), and HT Silicone (grey line with circles). TRPlast 330B starts at approximately 15% and rises to about 80% at 12,000 hours. HNBR starts at approximately 110% and remains relatively stable. HT Silicone starts at approximately 115% and remains relatively stable. An arrow labeled 'Better Performance' points to the right, indicating that lower compression set over time is better performance. 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.
Section C	Number of companies effected by restriction: <Confidential information has been redacted>
Section D	Alternatives: • Availability ○ 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. • Technical feasibility ○ 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. • Economic feasibility ○ 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. • Hazards and risks ○ Using seals with reduced performance in the chemical processing industry could potentially cause loss of life and environmental damage. • Extent of which alternatives are offered: ○ TRP does not consider PFAS to have alternatives for most applications where fluoroelastomers are currently specified.
Section E	Cases for which alternatives are not yet available: • 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.
Section F	Cases for which substitution is technically and economically feasible:

	The chemical industry is diverse. No two factories function at the same temperatures and conditions. An estimate of 350,000 chemicals¹¹ 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: - Any process which requires sealing at elevated temperatures and in aggressive chemicals such as: - Solvents - Acids - Alkali - Inorganic chemicals - Organic chemical etc.
Research and development progress	On the chemical resistance aspect of PFAS: - 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. On the service temperature and service interval: - Since the development of PFAS elastomers, the service temperature and service interval has been unrivalled. 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. From the guidance given by polymer suppliers, the maximum service temperature is increased by about 25°C. 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 25°C then we can calculate by extrapolation that there is still another 200 years of development to reach the 300-330°C an FFKM seal can reach. ^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 300°C, 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 Fluoropolymer applications.
Section A	Tonnage: Total tonnage of PTFE used = <Confidential information has been redacted> Emissions 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. 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:  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: • Availability ○ It is known that it's possible to use gaskets based solely on: ▪ EPDM ▪ FFKM ▪ FKM ▪ FEPM ▪ PTFE ▪ Polyethylene ○ In the current revision of the ECHA document; at the end of the restriction only EPDM, and polyethylene will be available for use within electrolyzers. • Technical feasibility:

	○ 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. ○ 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: <Confidential information has been redacted> Interestingly we also established chemical resistance of EPDM in <Confidential information has been redacted> at 95°C for 5 days (the same chemical composition and temperature of the electrolyser gasket), and the results are below: <Confidential information has been redacted> 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. 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. ● Economic feasibility: ○ 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. ○ 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. ● Hazards and risks: ○ Increased leakage of electrolyser fluids. ○ Possibility of gas leakage causing fire / asphyxiation / chemical hazards / harm to environment / harm to people. Gases produced in electrolyzers vary, but as an example can be hydrogen, chlorine, nitrogen, oxygen etc. ● Extent of which alternatives are offered: ○ 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: ● Industrial electrolyser gaskets.
Section F	Cases for which substitution is technically and economically feasible: In small commercial hydrogen electrolyzers 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 electrolyzers that require long sealing life and low leakage rates. All electrolyzers 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 Fluoroelastomer applications
Section A	Tonnage: Total tonnage of PFAS fluoroelastomer used <Confidential information has been redacted> Tonnage by material type: FFKM <Confidential information has been redacted> FKM = <Confidential information has been redacted> Emissions Manufacture Phase: - Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt) Use Phase estimate^a: - FFKM = <Confidential information has been redacted> (0.6% wt/wt) - FKM = <Confidential information has been redacted> (1.5% wt/wt) 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 - Proven historical use. - Long sealing life All these aspects are of importance when transporting chemicals.
Section C	<Confidential information has been redacted>
Section D	Alternatives: - Availability - 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. - Technical feasibility - Alternatives are not technically feasible. - Economic feasibility - 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. - Hazards and risks - The manufacture of alternatives polymers carries its own risks. For example, monomers of acrylonitrile can be toxic, fluorosurfactants are used in most polymer manufacturing

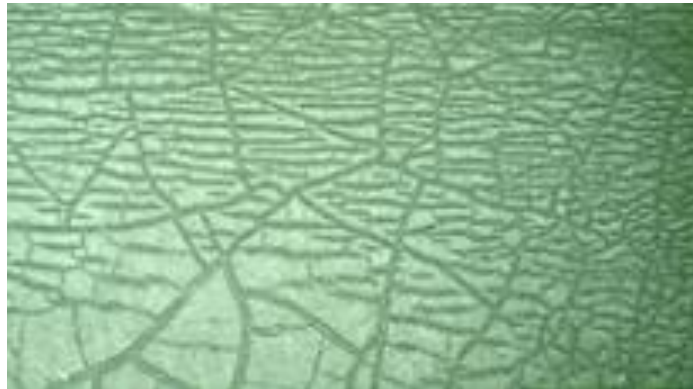
	processes, silicones can contain D4/D5/D6. There is no polymer that is hazard or risk free. ○ If toxic chemicals are accidentally released, the cost of decontaminating will be much greater than specifying a PFAS seal both economically and environmentally. • Extent of which alternatives are offered: ○ 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: • Applications where mixed chemical streams are used, where a non-PFAS would be chemically unstable in the fluids. • Applications where long service life is required. • High temperature applications above 200°C for extended periods. • Applications which require proven service history.
Request for derogation	A maximum derogation is requested.

Laboratory equipment – Fluoroelastomer applications

Sector and sub use	Laboratory equipment Fluoroelastomer applications.
Section A	Tonnage: Total tonnage of PFAS fluoroelastomer used = <Confidential information has been redacted> Tonnage by material type: FFKM <Confidential information has been redacted> FKM = <Confidential information has been redacted> Emissions Manufacture Phase: - Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt) Use Phase estimate^a: - FFKM = <Confidential information has been redacted> (0.6% wt/wt) - FKM = <Confidential information has been redacted> (1.5% wt/wt) 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: - High chemical resistance - High temperature resistance - Proven service history in the above environments. PFAS products provide this combination of properties due to the strength of the Carbon-Fluorine bond. Chemical resistance: 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. 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. There are published chemical resistance guides, but these are not based on actual results and are generally a prediction. 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 275°C 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 300°C 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.

	Compression set at 275°C The seal lifetime of an FFKM can be more than 500 times that of a HNBR or a 'High temperature silicone'. 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: • Availability ○ 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. • Technical feasibility ○ 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. • Economic feasibility ○ 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. • Hazards and risks ○ Using seals with reduced performance than PFAS in laboratory applications could cause safety hazards and environmental damage. • Extent of which alternatives are offered: ○ 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: 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 Fluoroelastomer applications
Section A	Tonnage: Total tonnage of PFAS fluoroelastomer used <Confidential information has been redacted> Tonnage by material type: FFKM <Confidential information has been redacted> FKM = <Confidential information has been redacted> Emissions Manufacture Phase: - Postcuring : estimated to be <Confidential information has been redacted> (0.27% wt/wt) Use Phase estimate^a: - FFKM = <Confidential information has been redacted> (0.6% wt/wt) - FKM = <Confidential information has been redacted> (1.5% wt/wt) 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. 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: - Availability - 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. - The customer described previously is industry leading within this sector, and they place emphasis on testing, research, development and qualification. - Technical feasibility - N/A - Economic feasibility - N/A - Hazards and risks - N/A - Extent of which alternatives are offered:

	○ N/A
Section E	Cases for which alternatives are not yet available: All cases requiring PFAS seals
Section F	Cases for which substitution is technically and economically feasible: It's not believed there is a technical substitution.
Section G	Cases which substitution is not feasible: 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. 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) 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 FTOH – CAS 678-39-7 APFO – CAS 3825-26-1 8:2 FTA – CAS 27905-45-9 PF-3,7-DMOA – CAS 172155-07-6
Sampling	2x BS312 O-Rings of approximate mass of 3.5g each 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-lc-qms-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 produced¹³:

Species	Boiling Point (°C)	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. Logothetis, 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°C. We also know that some of the chemicals within the elastomer matrix are water, acetone and methane¹⁴. Therefore, it was decided that that the material will be postcured first at 150°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°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.

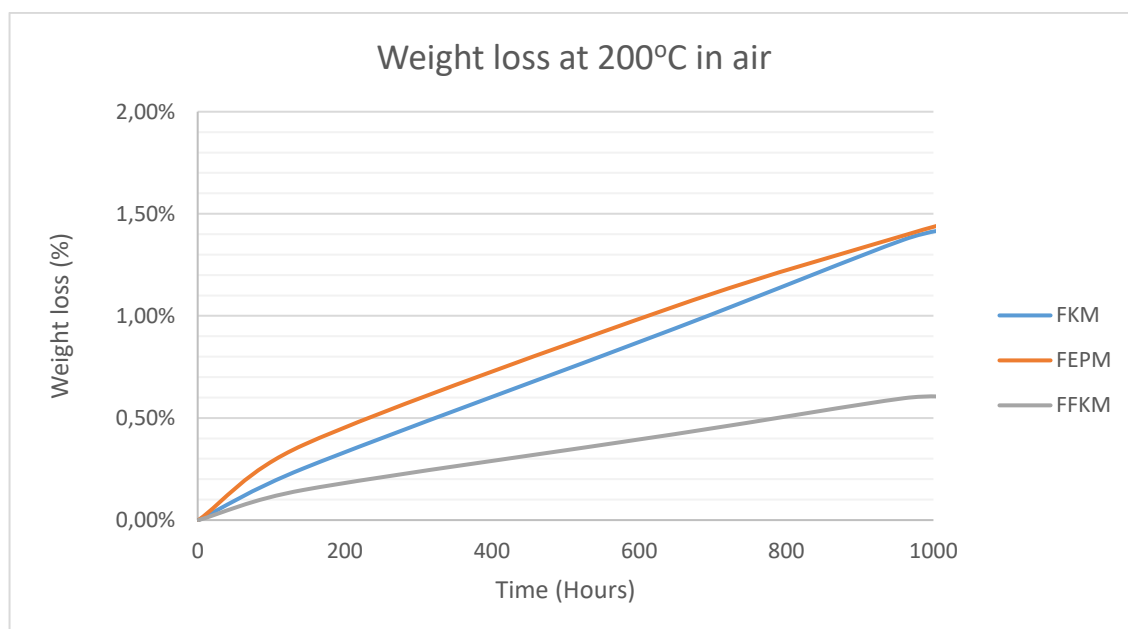
From studies conducted at TRP, we have found that for general purpose FKM and FFKM's the time to reach a compression set of 80% is around 1000Hours when tested on O-Rings at 200°C. This is believed to correlate with the service interval of the seal in the same conditions. (For readers who operate within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

