W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH Restriction on PFAS

Request for Derogation: Fluoropolymers

Public consultation

July 2023

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Executive Summary

Fluoropolymers are non-hazardous, non-toxic, non-bioavailable[1], non-bioaccumulative, non-water soluble, non-mobile and they do not degrade to such substances under relevant environmental conditions. They play a crucial role in a range of highly technical and often demanding applications with high socioeconomic value. In many of these applications alternatives that can provide the same combination of critical performance properties, are not currently available and are unknown or unlikely to be identified or developed.

To that end we would like to highlight the need for a derogation of fluoropolymers in technically demanding applications. We believe that all the concerns of the Dossier Submitters in terms of manufacturing/processing, in-use-phase and end-of-life can be addressed without prohibiting fluoropolymers:

- Manufacturing and Processing – Emissions of fluoropolymers and non-polymeric PFAS used or created during manufacturing and processing of fluoropolymers should be effectively managed by emission control technologies. Fluoropolymer manufacturers have committed to continuously improve best available techniques in the manufacturing processes and management of environmental emissions related to fluoropolymers. In addition, emissions can and should be regulated by emission control laws.
- In-Use-Phase – Products manufactured from fluoropolymers do not pose a risk to people or the environment during the in-use-phase, since fluoropolymers themselves are non-hazardous/non-toxic. The amount of low molecular weight residuals and oligomers is already low in the large majority of commercially available fluoropolymers and can be further reinforced by a revised derogation to limit residuals as suggested herein.
- End of Life –The relevant end-of-life management of fluoropolymers do not pose an environmental concern and we will provide data to demonstrate this. Finally, we would like to highlight on-going progress in the recycling of fluoropolymers.

Gore appreciates the opportunity offered by the public consultation process to provide comments on the Proposal for a Restriction of Per- and polyfluoroalkyl substances (PFASs) (hereinafter '**Restriction Proposal**').

[1] Bioavailability means a category of absorption; referring to a drug or chemical which will enter the circulation when introduced into the body and so able to have an active effect. Size is often cited as a limiting factor to bioavailability, but other considerations such as molecular weight, chemical and structural properties, and an ability to bind to cell surface receptors or signal events within the cell also play a role.

First, we would like to stress that, consistent with Gore's commitment to environmental stewardship, we support initiatives to reduce PFAS emissions.

For over 60 years, we've used science and advanced materials capabilities to create products that improve lives. We carefully consider the effects of our products and operations on the environment, as well as on the health and well-being of people all around the world. We are committed to the responsible and safe management of chemicals throughout our value chain over our products' entire life cycle.

The term PFAS generally refers to aliphatic substances with at least one fully fluorinated carbon atom. This is a very broad chemical definition that includes thousands of substances with different properties: polymers and non-polymers; solids, liquids, and gases; persistent and non-persistent substances; highly reactive and inert substances; mobile and insoluble substances; and toxic and non-toxic chemicals.

The significant differences of the substances falling into the broad PFAS group have not been sufficiently considered in the current Restriction Proposal. In many highly technical and demanding applications, fluoropolymers are indispensable and add critical value to society. In addition, fluoropolymers are non-hazardous, are not bioavailable, and are not classified as hazardous under EU CLP Regulation. They also do not degrade to or release such substances under relevant environmental conditions. As fluoropolymers emissions during manufacturing and processing can be controlled, and fluoropolymers can be used, and disposed of safely, they do not pose an unacceptable risk. Therefore, **from our point of view a prohibition of fluoropolymers under REACH cannot be justified**. While we acknowledge the concern regarding emissions from fluoropolymer manufacturing and processing, we believe that emissions control law is the right instrument to address this concern.

Since production of polymers may result in low molecular weight residuals and oligomers, we would like to propose the following derogation to restrict the amount of non-polymeric species.

We respectfully request a new lit. d. in Paragraph 4 of the draft restriction which would read as follows:

> ***d. Fluoropolymers which contain less than 5 ppm of low molecular weight residuals[2] and less than 5% of oligomers[3] smaller than 1.000 Da and less than 2% of oligomers smaller than 500 Da.***

We will explain the suggested derogation and the significance of these criteria in Section I and Annex II below. Proposed definitions of the terms used in the derogation request can be found in Annex I. In Section II we will also address the concerns raised in the Restriction Proposal. We believe we can address all concerns that have been expressed.

[2] See definition in Annex I.
[3] See definition in Annex I.

I. Explanation of Suggested Derogation

1. Need for Derogation for Fluoropolymers/Fluoropolymer applications

a) Properties of Fluoropolymers and Importance of Persistency/Stability

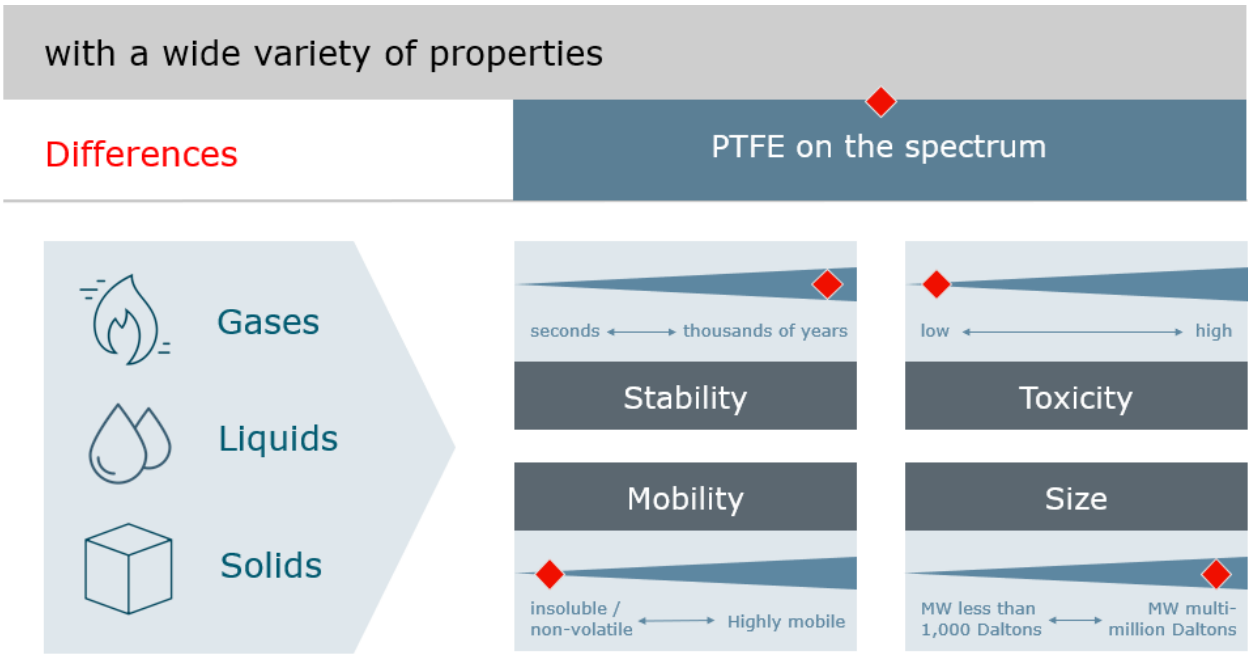
As already stated above there are significant differences of the substances falling into the broad PFAS group: polymers and non-polymers; solids, liquids, and gases; persistent and non-persistent substances; highly reactive and inert substances; mobile and insoluble substances; and toxic and non-toxic chemicals.

While fluoropolymers covered by this derogation request (e.g PTFE, ETFE, FEP and PFA) are persistent,

- they are not classified as hazardous under EU CLP Regulation and are non-toxic (see Annex II, Section III.5.);
- they have a high molecular weight meaning they are neither bioavailable[4] nor bioaccumulate in cells or organs since they cannot be absorbed into the blood stream through the lung, across the skin, or across the digestive tract (see Annex II, Section III.4.);
- they are non-water soluble and non-mobile molecules; this means they do not have the potential to become widespread in the environment (see Annex II, Section III.1.);
- and they do not degrade to such substances under relevant environmental conditions (see Annex II Section IV).

The wide variety of properties and where fluoropolymers such as PTFE are located in this broad spectrum is illustrated by the chart below:

[4] Bioavailability means a category of absorption; referring to a drug or chemical which will enter the circulation when introduced into the body and so able to have an active effect. Size is often cited as a limiting factor to bioavailability, but other considerations such as molecular weight, chemical and structural properties, and an ability to bind to cell surface receptors or signal events within the cell also play a role.



Further, we would like to stress that persistency, or stability, as it could also be called, is a critical property for technically demanding applications where fluoropolymers are used. Durable products, particularly those that must perform in harsh environments and/or where ongoing maintenance is a challenge or not possible, leverage the attribute of persistency to maintain needed performance over the lifetime of the product.

Persistence does not predict long-range transport potential, mobility, water solubility or ability to partition to air, water, sediment, or soil, toxicity, and bioaccumulation. Further, persistence does not equate to degradation. On the contrary, persistency is a degree of resistance to degradation or environmental transformation (see Annex II Section IV.).

While on the one side persistence is a characteristic of a substance indicating relative longevity in the environment, on the other side it ensures durable products even in harsh environments.

b) High Value to Society

Fluoropolymers play a crucial role in many applications with high socioeconomic value. In many cases, these substances are irreplaceable to meet all the needs of demanding applications. Among others, this applies to many applications in the field of green energy such as electrolysers for hydrogen production, hydrogen fuel cells and lithium-ion batteries. Fluoropolymers also play a key role in the medical technology sector, especially in endoscopy and minimally invasive surgery. Substitute materials are often unsuitable for the specific medical application such as cardiovascular implantable devices that save many patients' lives or/and increase their quality of life. These and many other applications clearly have high and indispensable value to society at large.

Gore will submit several proposals for end-use derogations that demonstrate the critical role that fluoropolymers play in a range of industries. The list is provided in Annex III.

c) Comparison to other Polymers

Like the broad PFAS group, properties of polymers vary greatly depending on factors such as molecular structure. As highlighted above, fluoropolymers are stable/persistent. Persistence is a property that they share with many other non-fluoro polymers such as high-density polyethylene (HDPE), polyether ether ketone (PEEK), polypropylene (PP) and polyethyleneterephthalate (PET).

Polymers for technical applications are selected for a broad range of performance criteria, for example,

- Chemical resistance – Table 1
- Thermal stability (Low and high temperatures), including continuous use and maximum operating temperatures – Table 2
- Surface energy which indicates hydrophobicity and oleophobicity: Lower surface energy indicates a more oleophobic and hydrophobic material – Table 3

Fluoropolymers are selected based on their ability to meet multiple challenging performance criteria of various end-uses. Please note that depending on the specific end use there are many other performance criteria.

Table 1 Chemical Resistance[5]; Please note that PTFE is referred to as TFE.

	ETFE	FEP/TFE/PFA	FLPE	FLPP	HDPE	LDPE	PC	PETG	PP	PVC	TPE***
Acids, Dilute or Weak	E	E	E	E	E	E	E	G	E	E	G
Acids, **Strong/Concentrated	E	E	G	G	G	G	G	N	G	G	F
Alcohols, Aliphatic	E	E	E	E	E	E	G	G	E	G	E
Aldehydes	E	E	G	G	G	G	G	G	G	G	G
Bases/Alkali	E	E	F	E	E	E	N	N	E	E	F
Esters	G	E	G	G	G	G	N	G	G	N	N
Hydrocarbons, Aliphatic	E	E	E	G	G	F	G	G	G	G	E
Hydrocarbons, Aromatic	G	E	E	N	N	N	N	N	N	N	N
Hydrocarbons, Halogenated	G	E	G	F	N	N	N	N	N	N	F
Ketones, Aromatic	G	E	G	G	N	N	N	N	N	F	N
Oxidizing Agents, Strong	E	E	F	F	F	F	F	F	F	G	N

*Not for tubing chemical resistance (except PVC) **Except for oxidizing acids (See oxidizing agents, strong) ***TPE gaskets

EXCELLENT	GOOD	FAIR	NOT RECOMMENDED
30 days of constant exposure causes no damage. Plastic may tolerate for 30 years.	Little or no damage after 30 days of constant exposure to the reagent.	Some effect after 7 days of constant exposure to the reagent. The effect may be crazing, cracking, loss of strength or discoloration.	Immediate damage may occur. Depending on the plastic, the effect may be severe crazing, cracking, loss of strength or discoloration, deformation, dissolution or permeation loss.

[5] Eason, M., & Vogel, R. (2022, May). Sealing Devices and the need for PFAS. Valve World, 20-22.

Table 2 Thermal Stability[6]

Polymer Name	Minimum operating temperature (°C)	Maximum operating temp (°C)
ABS - Acrylonitrile Butadiene Styrene	80.0	86
ETFE - Ethylene Tetrafluoroethylene	-100.0	140
EVA - Ethylene Vinyl Acetate	-60.0	45
FEP - Fluorinated Ethylene Propylene	-150.0	205
HDPE - High Density Polyethylene	-70.0	100
HIPS - High Impact Polystyrene	-20.0	60
LCP - Liquid Crystal Polymer	-50.0	200
LDPE - Low Density Polyethylene	-70.0	80
PA 6 - Polyamide 6	-20.0	80
PA 66 - Polyamide 6-6	-65.0	80
PAI - Polyamide-Imide	-196.0	220
PAR - Polyarylate	-95.0	130
PBT - Polybutylene Terephthalate	-40.0	80
PCTFE - Polymonochlorotrifluoroethylene	-250.0	150
PEEK - Polyetheretherketone	-70.0	154
PET - Polyethylene Terephthalate	-40.0	80
PP (Polypropylene) Homopolymer	-10.0	100
PSU - Polysulfone	-100.0	150
PTFE - Polytetrafluoroethylene	-200.0	260
PVC, Plasticized	-5.0	50
PVDF - Polyvinylidene Fluoride	-40.0	70
UHMWPE - Ultra High Molecular Weight Polyethylene	-30.0	110

Table 2 lists the minimum and maximum working temperatures (a.k.a. continuous use temperature), where the required properties are maintained.

[6] https://omnexus.specialchem.com/polymer-properties/properties/min-continuous-service-temperature.

Table 3 Surface Energy[7]

Polymer abbr.	Polymer Name	Surface Energy (dynes/cm)	Contact Angles (degrees)
PES	Polyethersulfone	46	90
	Styrene butadiene rubber	48	
PPO	Polyphenylene oxide	47	75
	Nylon 6/6 (polyhexamethylene adipamide)	46	
PC	Polycarbonate	46	75
	Nylon-6 (polycaprolactam)	38	
PET	Polyethylene terephthalate	42	76
PMMA	Polymethylmethacrylate	41	82
SAN	Styrene acrylonitrile	40	74
	Polyimide	40	83
PVC r	Polyvinyl chloride, rigid	39	90
	Polyester	41	70
	Acetal	36	85
ABS	Acrylonitrile butadiene styrene	35	82
PPS	Polyphenylene sulfide	38	87
PVA	Polyvinyl alcohol	37	10
	Polyacrylate (acrylic film)	35	
PVC p	Polyvinyl chloride, plasticized	35	89
PS	Polystyrene	34	72
	Nylon-12	36	
	Surlyn ionomer	33	80
PBT	Polybutylene teraphthalate	32	88
CTFE	Polychlorotrifluoroethylene	31	
PP	Polypropylene	30	88
PU	Polyurethane	38	85
PE	Polyethylene	30	88
PVF	Polyvinyl fluoride	28	
PVDF	Polyvinylidene fluoride	25	80
	Natural rubber	24	
PDMS	Polydimethyl siloxane (silicone elastomer)	23	98
FEP	Fluorinated ethylene propylene	20	98
PTFE	Polytetrafluoroethylene	19	120

Table 3 lists surface energy which is a measure of oleophobicity and hydrophobicity, with a lower number indicating that the polymer is more oleophobic and hydrophobic.

In summary, stability (or persistence) is a common attribute of many different types of polymers, not just fluoropolymers. One of the benefits of fluoropolymers is that it retains this stability over a broader array of use conditions. Regulation of fluoropolymers on the grounds of persistence alone is not appropriate nor is it consistent with treatment of other persistent polymers or other substances.

[7] https://www.tstar.com/blog/bid/33845/surface-energy-of-plastics

2. Criteria referred to in Suggested Derogation

In the following we would like to explain the criteria referred to in the suggested derogation.

a) Low Molecular Weight Residuals

As indicated above and in Annex II, Fluoropolymers themselves are non-hazardous and non-bioavailable.

Without bioavailability there can be no toxicity or bioaccumulation. It is well established that, in general, as the molecular weight of the substance increases, bioavailability and toxicity decrease, and that at a molecular weight › 1.000 Da, bioavailability is negligible.[8] Fluoropolymers typically have a molecular weight significantly above 1.000 Da ranging from 7.000 to millions of Da (see Annex II Section III.4.).

While fluoropolymers are non-bioavailable, low molecular weight residuals might be present in the polymer due to processing aids, monomers, other substances used in the polymerization process as well as any unintentional by-products created during the polymerization process.

Most of these residuals are removed in post polymerization processing/washing steps and destroyed or captured by emission control technologies (see Section II.1.a) below). To ensure purity of polymers, processors of fluoropolymers like Gore, oblige their suppliers to meet stringent specifications regarding fluorinated residuals.

However, it is mentioned in the Restriction Proposal that there are fluoropolymers on the market which do not meet these stringent specifications. This may be due to the fact that stringent specifications are not applied everywhere as such purity may not be requested for less technical applications. Our understanding seems to be confirmed by the examples mentioned in Annex B (p 208) of the Restriction Proposal, where it is referred to studies which reported 1-10 ppm of residuals in PTFE fine powder and much higher amounts in aqueous dispersion and up to 15-1000 ppm in personal care articles containing intentionally added PTFE fine particles.

To ensure that fluoropolymers manufactured in or imported to the EU contain limited levels of low molecular weight residuals, we suggest restricting the low molecular weight residuals content to less than 5 ppm. 5ppm is an appropriate limit for these residuals since Henry et al., 2018, and Korzenowski et al., 2022 demonstrated that polymers with less than 5ppm residuals have a low hazard profile and that 96% of all commercially available fluoropolymers have residuals below 5ppm.

b) Oligomers

In addition, we suggest restricting the oligomer content to less than 5% of oligomers smaller than 1.000 Da and less than 2% of oligomers smaller than ‹500 Da. Oligomers are short chains made up of a few monomers and are formed during all polymerization reactions. Our proposal

[8] BIO by Deloitte, 2015; De Mello, 1987; Beyer, 1993; Alberts et al., 2002; Schwarzmann et al., 1981; Birgit et al. 1977 Chemservice, RMOA prepared for Fluoropolymers Group (FPG) of Plastics Europe, 2021, p. 32 f; see also Annex II Section III.4.

results from current understanding of the various expert statements.[9] We also want to note that studies on a broad range of fluoropolymers demonstrated negligible oligomers in the range below 1.000 Da.[10] This limitation is recommended to apply to all polymers, not only fluoropolymers, where there are multiple studies which highlight the benefit of limiting oligomer content due to their small molecular size and potential bioavailability.

3. Possible Additional Criteria

Fluoropolymers are non-hazardous and not bioavailable, are not classified as hazardous under EU CLP Regulation and do not pose a risk to human health or the environment. They also do not degrade to or release such substances under relevant environmental conditions. Data which demonstrate this are provided in Section III.5 and Section IV of Annex II. Therefore, we believe a REACH Restriction prohibiting fluoropolymers cannot be justified.

We note that the Dossier Submitters raised concerns relating to consumer products. A potential response to this concern could be to align the fluoropolymer derogation with the latest draft of the PFHxA restriction published by the Commission on June 14, 2023, to exclude from the scope of the derogation wide dispersive product uses supplied to the general public, where it is difficult or not possible to implement risk management measures to minimize releases. Technically demanding products with high societal value and where alternatives are in general unlikely to be available or developed due to chemical limitations of alternatives, would remain unaffected by such addition. Dispersive non-professional/consumer uses where substitution might be more likely would be excluded from the scope of the proposed fluoropolymer derogation but remain subject to case-by-case assessment for consideration of use-specific derogations.

In any case, it needs to be ensured that components used in complex products used by the general public, such as components in automobiles or electronics, would remain in scope of the derogation because they are non-dispersive and technically demanding uses.

For clarity, even though the wide-dispersive use criterion is offered to address concerns stated by the Dossier Submitters, we believe that a ban of such products would not comply with REACH requirements for a restriction since fluoropolymers are non-hazardous/non-toxic.

[9] BIO by Deloitte, 2015; US EPA 1997; OECD 2009; EU Commission 2012; Wood 2020, CARACAL-48 (28 March 2023) AP 4.1.
[10] Korzeniowski et al., 2023.

II. Addressing Concerns Raised in the Restriction Proposal

In the Restriction Proposal, concerns regarding fluoropolymers were raised. This section provides information that we believe addresses all the concerns that have been expressed.

Hazards associated with fluoropolymers are addressed Section B.7.6 of Annex B of the restriction proposal where it is stated that fluoropolymers are indirectly of concern because monomers, oligomers, and by-products *"are emitted into the environment"* during their production and use and during waste incineration *"non polymeric PFAS may be formed and emitted"*. In particular, it refers to potential emissions of PFAS-based processing aids. Further, it is stated that fluoropolymers, as other polymers, pose an environmental hazard due to microplastics that can be formed during their use or end-of-life phase.

In the following section we would like to demonstrate that based on the life cycle of fluoropolymers, the potential emissions during manufacturing and processing of fluoropolymers can be controlled, and fluoropolymers can be used and disposed of safely and in accordance with environmental standards. Hence, there is no unacceptable risk.

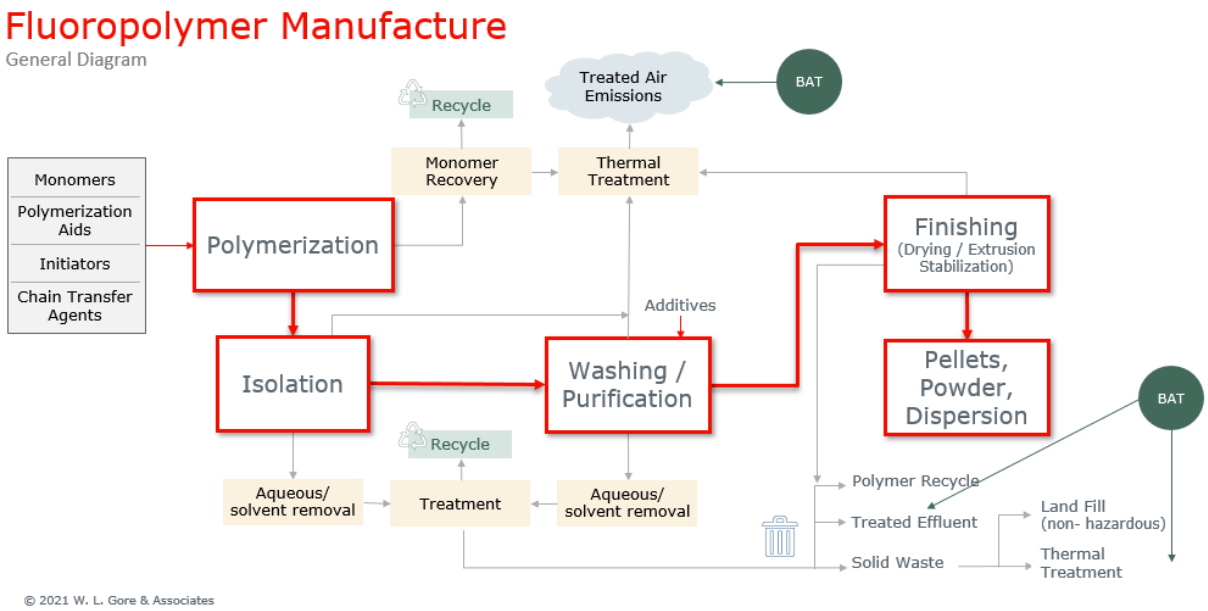
While it is true that non-polymeric PFAS have the potential to be released during manufacturing and processing of fluoropolymers, they can be effectively controlled by emissions control technologies. Therefore, a restriction is not the right instrument to regulate fluoropolymers, which are intrinsically non-hazardous. Emission control laws should be used to address potential emissions from manufacturing or processing.

1. Manufacture of Fluoropolymers

We believe that emissions from fluoropolymer manufacturing can be effectively controlled throughout all the manufacturing stages.

a) Emissions of non-polymeric PFAS

To manufacture fluoropolymers, substances like monomers, polymerisation aids, initiators, and chain transfer agents are needed which may fall under the broad PFAS group. The diagram below shows an overview of a generalised fluoropolymer manufacturing process and the potential sources for emissions:



As demonstrated, in the diagram above there is a potential for emissions to water and for emissions to air that can occur if effluent water and exhaust air are not sufficiently captured and treated.

To our knowledge, all EU fluoropolymer manufacturers have emission control measures as well as monitoring programs in place. This applies to both the exhaust air and the wastewater stream. Releases from post-polymerization steps (e.g. drying, sintering, compounding, washing) – which are referenced in Lohmann et al., 2020, and mentioned as a concern in Annex B, Section B.9.2.5 of the restriction proposal – are also captured by these emission control measures.

Gore only manufactures very small amounts [redacted] of PTFE, PFA, FEP, at its site in Burgkirchen, Germany, which are further processed into articles at other Gore sites. Even though Gore's small-scale polymerization facility might not be comparable to large manufacturing sites, additional information including information on emissions, emission control and monitoring can be found in Annex IV.

While the most common technology to control PFAS from exhaust air are thermal oxidizers where the PFAS destruction efficiency has been demonstrated to be 99,9%[11], there are different technologies to control PFAS from water effluent.

In September 2021, the members of the Fluoropolymer Group of the Plastics Europe, which represents all EU fluoropolymer manufacturers, committed themselves to responsible manufacturing principles to minimize emissions, which include the following[12]:

[11] See https://www.chemours.de/-/media/files/corporate/fayetteville-works/2020-0320-thermal-oxidizer-efficiency-results-announced.pdf?rev=87dbfd0ebb9c45aeaa475fddd2a899b4.
[12] ChemService, RMOA prepared for Fluoropolymers Group (FPG) of PlasticsEurope, 2021, page 169f.

1. To maintain, continuously improve and/or develop best available techniques in the manufacturing processes and management of environmental emissions related to fluoropolymers.

2. To maintain and continuously improve and develop containment, capture, and recycle technologies to minimize emissions into the environment from PFAS substances intentionally and non-intentionally present in fluoropolymers including fluorinated raw materials, polymerization aids, monomers, intermediates, and process chemicals as well as by-products.

This is now to be cemented by a commitment to establish a fluoropolymer platform to share good practice and support the deployment of state-of-the art technologies in emissions control across the industry. In addition, the platform participants committed to institute an exchange forum with key stakeholders and legislators. This exchange forum will guarantee transparency, accountability and supervises the implementation of the FPG Responsible manufacturing program. The exchange forum shall meet formally twice per year with a first meeting by the end of 2024.[13]

This commitment will further contribute to the continuous improvements in emission reduction. A restriction based solely on emissions that have occurred in the past is not justified.

Gore acknowledges that there are currently legally binding limits for emissions for only a small number of PFAS substances and that the EU BREF for polymer production of 2007[14] does not contain information specific to production of fluoropolymers. This regulatory gap should be closed, and emission control law is the right instrument to close this gap.

b) Emissions of Polymeric PFAS

During normal operation, releases of the manufactured polymer are not to be expected due to effective control measures such as filters to capture polymer particulates and separate drains and collection points for post-processing treatment.

In case of an unintended release (e.g., accident) of non-negligible quantities during manufacturing there is no risk of dispersal over long distances, as fluoropolymers are solid and practically insoluble in water (see Section III.1. of Annex II). Due to their poor solubility, polymers can be effectively removed physically from sewage water. There are many proven waste-water treatment technologies available to effectively remove particles of different sizes from wastewater streams.

c) Emission Estimates in Restriction Proposal

Regarding emissions in EU from manufacturing of PFAS in general (not only fluoropolymers), it is stated in the Restriction Proposal that relatively accurate information is available due to permits

[13] Commitment being finalized at time of writing

[14] Available at https://eippcb.jrc.ec.europa.eu/reference/production-polymers.

and enforcement information. Since emission estimates for manufacture of fluoropolymers are not provided in the Restriction Draft, the accuracy of the emission estimates could not be evaluated.

2. Processing of Fluoropolymers

Since processing takes place at closed sites, a release of fluoropolymers/polymeric PFAS is not to be expected due to particle filters and general EH&S practices. Releases of non-polymeric PFAS during any processing can also be effectively controlled.

Although fluoropolymers do not degrade under relevant environmental conditions, processing of fluoropolymers, in some cases, can lead to degradation and release of non-polymeric PFAS. Degradation and release depend on a variety of factors including heat, state change of the material, and time, and in particular on the type of the fluoropolymer.

Since processing often takes place at temperatures above typical continuous use temperatures, emission control technologies like ventilation systems leading to thermal oxidizers need to be used to destroy PFAS before the exhaust air is released into the environment. Thermal oxidation is a state-of-the-art process for cleaning exhaust air. The exhaust air is fed into a combustion chamber and oxidized (burned) at temperatures between 800 °C and 1.200 °C. This is a regenerative process that ensures elimination of pollutants and recovers up to 97% of the heat generated. These control technologies capture and destroy non-polymeric residuals that may be released during processing.

For all Gore's fluoropolymer processing activities in Europe, efficient emission control technologies and in particular oxidizers for its extrusion applications are in place.

However, the RMOA prepared by ChemService for the Fluoropolymers Group (FPG) of PlasticsEurope acknowledges that not all fluoropolymer processors have implemented these types of emissions control technologies. [15] This once again highlights a regulatory gap that should be closed through emissions control laws. Emission control laws should be amended to require appropriate control technologies be implemented in all fluoropolymer processing facilities to limit the potential for non-polymer emissions that may result from high-temperature (i.e., above typical continuous use temperature) processing to address facilities where such abatement technology may not already be in place. As a prior precaution, the FPG members have already committed themselves to help inform downstream users/processers by providing additional information on safe fluoropolymer processing by updating the Guide for the Safe Handling of Fluoropolymer Resins published in 2021 to include information on prevention of environmental releases.

Therefore, processing of fluoropolymers does not constitute a reason for a REACH restriction.

[15] ChemService, RMOA prepared for Fluoropolymers Group (FPG) of PlasticsEurope, 2021.

3. In-Use-Phase

Fluoropolymers used to manufacture products do not pose a risk to people or the environment during their use.

As stated above and demonstrated in Section III.5 of Annex II, fluoropolymers are non-hazardous/non-toxic. The inclusion of the suggested limitation of low molecular weight residuals and oligomers in the fluoropolymer resin, ensures in a legally enforceable manner that residuals cannot pose a risk either.

Risks due to degradation products are also not to be expected. As indicated above, fluoropolymers do not degrade or release substances under relevant environmental conditions.

Finally, we would like to address the concerns raised with regard to microplastics from fluoropolymers, as other synthetic polymers, which can according to the Dossier Submitter pose an environmental hazard if formed and released during their use or end-of -life phase. Such synthetic polymer microplastics that are intentionally added to products including uses where the release of microplastics is to be expected will, if appropriate, be regulated by the instruments the Commission is already working on. Considering this, from our point of view, it is neither appropriate nor required to discuss within the framework of the PFAS restriction.

4. End-of-Life

In this section we would like to demonstrate that the relevant end-of-life treatments of fluoropolymers do not pose an environmental concern. In particular, we would like focus on waste incineration to address the concern of the Dossier Submitters that non polymeric PFAS might be formed and emitted when incinerating PFAS.

a) Waste Streams

Based on the Study on Fluoropolymer waste in Europe 2020 prepared by Conversio for the industry association Pro-K which was published in January 2023,[16] there is a detailed understanding on how and where fluoropolymer containing products and corresponding wastes are generated as well as on the different treatment routes (recycling, energy recovery and landfill). The Study covers the following sectors Automotive, Aerospace, Electronics & Semiconductors, Chemicals, Medical, Pharma and Others (including cookware, lubricants, architectural and wearable textiles, military/defence, photovoltaic and wind power), which had been identified as main applications and products, where fluoropolymers are used.

According to the Study, in 2020 almost 84% of the assessed fluoropolymer applications were incinerated at the end of their life in energy recovery (MSWI ~72%) or thermal destruction (metal recycling ~12%) processes. 13% of the collected fluoropolymer waste was landfilled and around 3% was recycled.

[16] Final report, Fluoropolymer waste in Europe 2020– End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams, January 2023.

b) Incineration

Regarding waste incineration of fluoropolymers, the Dossier Submitters are concerned that non-polymeric PFAS will be formed and emitted. While it is understood that decomposition end products, from fluoropolymer incineration, will be fractions like HF, CO_2 and H_2O it was considered uncertain if full breakdown would be achieved under typical operational conditions of waste incinerations plants.

This uncertainty seems to be based on certain statements, primarily that the effectiveness of incineration to destroy PFAS is not well understood[17] and the assumption that insufficient studies have been conducted. Available studies have been considered insufficient since

- only a limited number of PFAS were studied,
- most were laboratory-based studies which do not necessarily represent circumstances in reality
- full fluorine mass balances were not provided (see Annex B, Section 1.1.5.5).

In addition, Tetrafluoromethane (CF_4) and hexafluoroethane (C_2F_6) are explicitly referenced by the Dossier Submitters. The Dossier Submitters point out, that according to literature review,[18] these substances may be formed when incinerating fluoropolymers. With CF_4 considered most stable, it is only destroyed at temperatures above 1.400 °C.

We believe that the literature references the Dossier Submitters rely on do not correspond to the current state of knowledge and that the references to destruction temperature for CF4 is based on a misinterpretation of Tsang et al., 1998. We would like to take this opportunity to further elaborate on this in the following:

aa) Study conducted by KIT / Alexandrov et al., 2019

Effectiveness of incineration to destroy fluoropolymers like PTFE has been demonstrated by a study commissioned by Gore and conducted by the Institute of Technical Chemistry at the Karlsruhe Institute for Technology (KIT), Germany. PTFE pellets were incinerated in the pilot size municipal incineration plant of KIT at temperatures typical of a municipal waste incinerator. **The study was published in the July 2019 issue of Chemosphere, a peer reviewed scientific journal (hereinafter Alexandrov et al., 2019) and concluded that incineration of PTFE does not contribute to emissions of the 31 PFAS identified in the study.**

The incineration was performed at following conditions:

- 870 °C and residence time of 4.0 s in partial load scenario and
- 1020 °C for 2.7 s in full load scenario.

[17] Reference is made to Lohmann et al., 2020; Stoiber et al., 2020; Goldenman et al., The cost of inaction: A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS Nordic Counsel. 2019 (http://norden.diva-portal.org/smash/get/diva2:1295959/FULLTEXT01.pdf); US EPA/Gullet et al., 2020.
[18] Reference is made to Huber et al., 2009, US EPA/Gullet et al., 2020.

These conditions were set by the combustion technology working group of the Karlsruhe Institute for Technology (KIT)[19] lead by Dr.-Ing. Hans-Joachim Gehrmann. The conditions were defined to correspond with typical incineration conditions. Art. 50 of Directive 2010/75/EU on industrial emissions specifies the minimum temperature and residence time for waste incineration plants in the EU as 850 °C for at least two seconds. The temperature and residence time relates to the gases generated after the combustion process. These minimum requirements also need to be met under unfavorable conditions, e.g., lower calorific value of waste. To meet these temperature and residence time and avoid shutdowns, operators need to balance multiple factors resulting in running at temperatures above 850°C.

In the study, the input materials were natural gas (mixture of gases including methane), commercial premium wood pellets, PTFE Polymer pellets and air. A control run using only natural gas, wood pellets and air was also assessed.

Flue gas samples were collected after the heat exchanger and before the pollution control equipment. This location was chosen since it represents the worst-case scenario, because the combustion gases have been thermally treated and reduced in temperature to 250-300 °C which allows for any potential condensation reactions to occur (i.e., new species formation). The samples were analyzed by independent commercial laboratories.

The flue gases were tested for 31 different PFAS substances. The substances were selected due to their occurrence in the environment, literature citation, and availability of validated methods from commercial laboratories.

To avoid false positive results due to contamination of samples from the environment, paired t-testing was utilized to determine if the addition of PTFE created a statistical difference from background levels. Paired t-testing is a standard statistical procedure used to determine whether there is a difference between two populations.

Of the 31 PFAS substances studied, 11 were detected. However, based on results of combustion process with wood pellets and PTFE compared to wood pellets only, 'the control run', no statistically significant evidence was found that low molecular weight PFAS were created. Since positive results were found in both pairs and even more in the control group without PTFE,[20] it was concluded that these signals are due to contamination of the samples from the environment.

The recovery rate of fluorine was 56 to 78%. Based on this it has been speculated that a wide variety of other PFAS could have been released.[21] This speculation has no scientific basis. Fluorine is the most reactive non-metal of all elements. This means it readily reacts with the masonry or steel of the incineration plant in the high heat region as well as forming HF. Therefore, a mass balance of 100% cannot be achieved. The high level of HF captured, 56–78%, was even higher than expected for the authors of the study. This study demonstrates that

[19] KIT resulted from the cooperation between the University of Karlsruhe and the Helmholtz Research Centre Karlsruhe and is the largest German research institution.
[20] See results in Annex V.
[21] Lohmann et al., 2020.

incineration is an effective method of fluoropolymers disposal when operated at permit conditions.

Alexandrov et al., 2019 is not mentioned in the Restriction Proposal and the papers that are referred to in the Restriction Proposal either (1) do not take the study into account[22] or (2) demonstrate that that the study was not fully understood. Regarding the first point, in particular US EPA/Gullet et al., 2020 needs to be mentioned. Although detailed information is now available, the statement that the effectiveness of incineration to destroy PFAS compounds is not well understood continues to be cited and distributed.[23] The second point is true for Stoiber et al., 2020 where the study by Alexandrov et al. was considered a laboratory study even though the study was conducted in a pilot size municipal incineration plant. Likewise, for Lohmann et al., 2020 where operation conditions were considered to be optimized, and the results based on paired-t-testing and fluorine mass balance were misinterpreted. Lohmann suggests that the Alexandrov et al. results were inconclusive with respect to stack emissions of PFAS, and with regard to the fluorine mass balance of 56-78% Lohmann concluded that the non-capture of fluorine could mean that a wide variety of other PFAS were released. As demonstrated above, the operation conditions correspond with typical incineration conditions and there is no experimental evidence or valid speculation that suggest that the Karlsruhe Institute of Technology's pilot size municipal incineration plant would operate differently or generate different flue gases from a full-size commercial operation. Stack emissions were not tested, but flue gas samples were collected after the heat exchanger and before the pollution control equipment to capture worst-case scenario. Paired-t-testing was used to avoid false positive results due to contamination of samples from the environment. The tests confirmed that incineration of PTFE does not contribute to emissions of the tested 31 PFAS since a statistically relevant difference between incineration of wood pellets and PTFE and wood pellets without PTFE could not be observed. Finally, the speculation drawn from the incomplete mass balance has no scientific basis. Due to the reactivity of fluorine, a mass balance of 100% or close to 100% cannot be achieved.

bb) Degradation Products and Formation of CF_4 and C_2F_6

The decomposition paths fluoropolymers will take in waste incinerations plants are difficult to predict due to the numerous materials they might react with.

In the Restriction Dossier, based on literature review, the following degradation products belonging to the large group of PFAS are referred for the incineration of fluoropolymers including PTFE (see Annex B, Table B.50): CF_4, C_2F_6, CHF_3, C_3F_6, $CClF_3$, C_4F_8, $C_2Cl_3F_3$, TFA and C_2F_4. Based on the Alexandrov et al., 2019 and stability of these substances, we believe that only CF_4 and C_2F_6 are relevant degradation products. CHF_3 and unsaturated PFAS such as C_2F_4/TFE, C_3F_6 and C_4F_8/HFP if formed during incineration, due to their molecular structure, will be destroyed shortly after formation.[24] TFA was tested by Alexandrov et al. and could not be detected. $CClF_3$, $C_2Cl_3F_3$ are not tested as they were not expected to be formed from the PTFE incinerated in this study.

[22] See US EPA/Gullet et al., 2020; NORDIC COUNCIL 2019. The cost of inaction: A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS.
[23] E.g. Lohmann et al., 2020.
[24] Bakker et al., 2021(RIVM report 2021-0143), p. 62.

Geertinger et al., 2019 theorize the possibility of CCl_3F (CFC-11) or $C_2Cl_3F_3$ (CFC-113) as decomposition products, which was based on a more diverse waste source. However, they also reference 99.9% destruction efficiency for these materials in both pilot and full-scale incineration plants. We could not find a reference to $CClF_3$(CFC-13) in any of the papers; we assume this is based on a mis-citation in the Restriction Proposal.

Real world data demonstrate that formation of CF_4 and C_2F_6 in larger quantities is unlikely at temperatures above 850 °C with excess of oxygen, i.e., under typical conditions of municipal waste incineration plants.[25]

The importance of the operational conditions like presence or absence of oxygen, the presence or absence of other chemical substances and temperature is acknowledged by the Dossier Submitters (see Section 1.1.5.5 of the Restriction Draft). However, the understanding that CF_4 and C_2F_6 may be formed when incinerating fluoropolymers is solely based on reference to García et al., 2007 and Huber et al., 2009.

García et al., 2007 tested incineration of PTFE under pyrolysis and fuel-rich conditions. Pyrolysis means without oxygen and fuel-rich means that there is not enough oxygen to burn all the fuel (< 60% of oxygen). Both scenarios are not comparable to conditions in waste incineration plants where incineration is done in an excess of oxygen environment. We believe that this is also part of the reason why García found so many non-fluorinated hydrocarbons.

Huber et al., 2009, is a literature review focusing on decomposition products of fluoropolymers at temperatures below 600 °C. Just two references on decomposition products at temperatures above 850 °C are cited.[26] One reference is García et al., 2007, and the other one is the *Guide to the Safe Handling of Fluoropolymer Resins* from the Society of the Plastics Industry, which is not comparable either since it does not consider conditions in waste incineration plants but considers heating during manufacturing process and fire scenarios.[27]

In addition, based on the recommendation of Huber et al., 2009, to conduct on-site studies in Norwegian waste incineration plants to better understand contribution of incineration of fluoropolymers to global warming, the Norwegian Climate and Pollution Agency commissioned Norsk Energi to specifically measure CF_4 and C_2F_6 at the Klemetsrud Waste-to-Energy Plant on two different dates. The analysis laboratory (Eurofins MiljØanalyses AS) was not able to quantify CF_4 or C_2F_6 and used quantification limits for the worst-case predictions. By their estimates the maximum amount emitted from all of Norway's incinerators account for less than 0.01% of Norway's greenhouse gas budget.[28]

The only analysis of CF_4 and C_2F_6 in an actual municipal incineration facility showed that CF_4 and C_2F_6 were not detected at the detection limit available. We believe that this study demonstrates

[25] This is confirmed by Norsk Energi for Norwegian Climate and Pollution Agency, 2011 (see further information below).
[26] See Table 9 on page 22f.
[27] The Society of the Plastics Industry (2005), The Guide to Safe Handling of Fluoropolymer Resins – fourth edition. BP-101. Washington, SPI. P. 14, 76 (available at https://intechservices.com/content/SPI_Guide_for_Safe_Handling_of_Fluoropolymer_Resins.pdf).
[28] Otterlie ET, et al. Norsk Energi for Norwegian Climate and Pollution Agency, 2011.

the importance of operational conditions such as the presence or absence of oxygen, the presence or absence of other chemicals, and temperature, as also acknowledged by the Dossier Submitters

cc) Destruction of CF_4 / Tsang et al., 1998

The statement that CF4 will only be destroyed at temperatures above 1400°C seems to originate from Gullet et al. 2020 and is based on a reference to Tsang et al.,1998. We would like to highlight that the Tsang paper does not give a minimum incineration temperature for PTFE, but it does **demonstrate a model for** predicting destruction rates of these materials in a combustion environment. According to Tsang et al.,1998 this model is an extension of previous work on hydrocarbon combustion in Tsang and Hampson, 1986. It involves adding into the data, base reactions of the **fluorinated compounds and their decomposition products with each other, as well as reactions with the fuel and combustion generated radicals.**

Tsang et al. 1998 utilized the data in Table II and Table III below (labelled), to create the model. Please note, we have added Celsius table to the right of Table II for your convenience.

TABLE II Rate expressions for unimolecular decomposition at the high pressure limit. In the high temperature combustion environment they will be subject to fall-off effects. Thus actual rate constants may be somewhat smaller. Except for those marked with superscript (a) which are from Rodgers (1978), values are derived from Tsang (1986, 1990)

Reaction	*Rate Expression* s^{-1}	*Temp to achieve 4 nines destruction in 1 sec*	Kelvin	°C
a. Elimination (1,1 and 1,2)				
$C_2H_5Cl \longrightarrow C_2H_4 + HCl$	$1.6\times10^{13}\exp(-28400/T)$	1008	1008	735
$C_2HCl_5 \longrightarrow C_2Cl_4 + HCl$	$1.3\times10^{13}\exp(-30000/T)$	1072	1072	799
$C_2H_5F \longrightarrow C_2H_4 + HF$	$2.5\times10^{13}\exp(-30200/T)$	1068	1068	795
$C_2HF_5 \longrightarrow C_2F_4 + HF$	$4\times10^{13}\exp(-36000/T)$	1137	1137	864
$CF_3H \longrightarrow CF_2 + HF$	$1.3\times10^{14}\exp(-36340/T)$	1200	1200	927
b. C—C bond cleavage				
$CH_3—CH_3 \longrightarrow 2CH_3$	$5\times10^{16}\exp(-45000/T)$	1242	1242	969
$CCl_3—CCl_3 \longrightarrow 2CCl_3$	$6\times10^{17}\exp(-34400/T)$	888	888	615
$CF_3—CF_3 \longrightarrow 2CF_3$	$1.0\times10^{17}\exp(-45600/T)$	1234	1234	961
$CF_2=CF_2 \longrightarrow 2CF_2$	$2\times10^{15}\exp(-34700/T)$	1050	1050	777
c. C—X (H, Cl, X) bond cleavage				
$CH_4 \longrightarrow CH_3 + H$	$3.8\times10^{15}\exp(-52400/T)$	1557	1557	1284
$C_2Cl_6 \longrightarrow C_2Cl_5 + Cl$	$1\times10^{16}\exp(-34500/T)$	985	985	712
$CF_4 \longrightarrow CF_3 + F$	$1.5\times10^{17}\exp(-64000/T)$	1714	1714	1441
d. Radical Decomposition				
$CF_2CF_3 \longrightarrow CF_2 + CF_3$	$8\times10^{15}\exp(-28100/T)$	817	817	544
$CF_2CF_3 \longrightarrow CF_2CF_2 + F$	$1.7\times10^{14}\exp(-36400/T)$	1191	1191	918
$CF_3CF_2CF_2 \longrightarrow CF_3CF_2 + CF_3^a$	$1\times10^{16}\exp(-26300/T)$	759	759	486
$CF_2CF_2CF_3 \longrightarrow CF_2CF_2 + CF_3^a$	$8\times10^{13}\exp(-22700/T)$	761	761	488
$CH_2CH_3 \longrightarrow C_2H_4 + H$	$2\times10^{13}\exp(-19540/T)$	687	687	414
$CH_2CH_2CH_3 \longrightarrow CH_2CH_2 + CH_3$	$1.3\times10^{13}\exp(-15200/T)$	543	543	270
$CCl_2—CCl_2Cl \longrightarrow CCl_2CCl_2 + Cl$	$3\times10^{15}\exp(-8960/T)$	310	310	37
$CH_2—CH_2CL \longrightarrow CH_2CH_2 + Cl$	$4\times10^{13}\exp(-11180/T)$	384	384	111

TABLE III Rate expressions for some abstraction reactions of H and OH. Except for those marked with superscript (a) and (b) which are from Westenberg and deHaas (1975) and Stull and Prophet (1971), all other values are from Tsang (1986, 1990)

Reaction	*Rate Expression (cc/mol-s)*	*log (Rate Constant)* 900 K	1500 K
a. Abstraction by OH			
$OH + H_2 \rightarrow H_2O + H$	$6400 \times T^2 \exp(-1490/T)$	11.3	12.3
$OH + CH_4 \rightarrow H_2O + CH_3$	$4200 \times T^2 \exp(-1282/T)$	11.3	12.2
$OH + HCl \rightarrow H_2O + Cl$	$2.25 \times 10^{12} \exp(-514/T)$	11.9	12.1
$OH + CH_3Cl \rightarrow H_2O + CH_2Cl$	$2100 \times T^2 \exp(-585/T)$	11.7	12.4
$OH + HF \rightarrow H_2O + F$[16]	$1.9 \times 10^8 T^{1.6} \exp(-8360/T)$	8.9	10.9
$OH + CH_3F \rightarrow H_2O + CH_2F$	$2.6 \times 10^8 T^{1.5} \exp(-1480/T)$	11.4	12.3
$OH + CH_2F_2 \rightarrow H_2O + CHF_2$	$2.8 \times 10^7 T^{1.7} \exp(-1278/T)$	11.2	12.1
$OH + CHF_3 \rightarrow H_2O + CF_3$	$5.8 \times 10^6 T^{1.8} \exp(-2160/T)$	10.0	11.2
b. Abstraction by H			
$H + CH_4 \rightarrow H_2 + CH_3$	$22500 \times T^3 \exp(-4406/T)$	9.0	11.4
$H + HCl \rightarrow H_2 + Cl$	$8 \times 10^9 \exp(-1710/T)$	11.3	11.9
$H + CH_3CL \rightarrow CH_2Cl + H_2$ $\rightarrow HCl + CH_3$[a]	$3.7 \times 10^{10} \exp(-4680/T)$	11.3	12.2
$H + HF \rightarrow F + H_2$[b]	$5 \times 10^{11} T^{.75} \exp(-16310/T)$	6.0	9.4
$H + CF_4 \rightarrow CF_3 + HF$	$1.1 \times 10^{15} \exp(-22446/T)$	4.2	8.5
$H + CF_3H \rightarrow HF + CF_3$	$9000T^3 \exp(-4680/T)$	8.3	10.8
$H + CF_2H_2 \rightarrow HF + CF_2H$	$1650T^3 \exp(-2818/T)$	9.3	11.1
$H + CFH_3 \rightarrow HF + CFH_2$[a]	$2 \times 10^{13} \exp(-4953/T)$	10.9	11.9

The data in Table II are for unimolecular reactions (i.e., only CF_4 without oxygen or fuel) and while maybe accurate for pyrolysis, they are inadequate to predict incineration behavior on its own. In addition to these reactions in Table II the researchers included the data from the reactions from Table III to estimate decomposition rates in a combustion environment (i.e., with oxygen and fuel). Based on this Tsang et.al., 1998, estimate that CF_4 and C_2F_6 would be 99% destroyed at 927 °C (= 1.200 Kelvin) in tenths of seconds (0.225 and 0.1s respectively) in the presence of combusting fuel (methane 5%) and excess oxygen (O_2) as demonstrated in Figure 2 below.

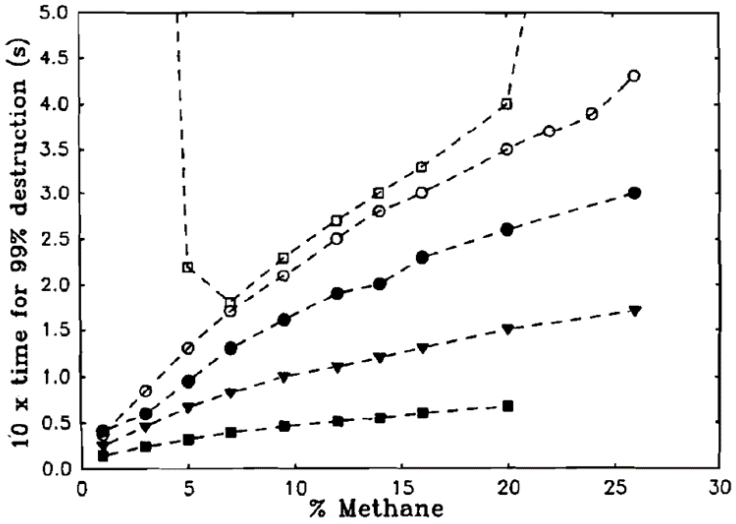


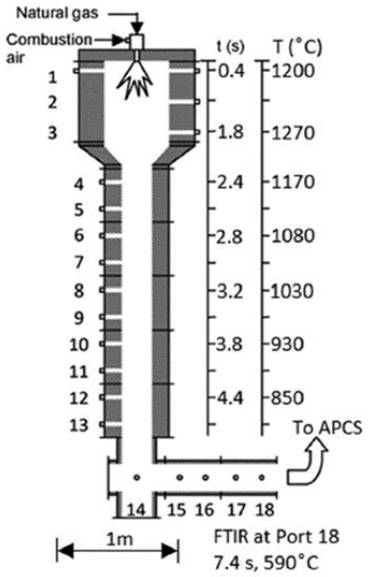
FIGURE 2 Time to achieve 99% conversion as a function of percentage of methane at 1 atm (open circle) and with 1% CF_4, (open square) CF_3H, (filled triangle) C_2F_6, (filled circle) C_2F_5H, (filled square) respectively. Initial temperature is 1200 K.

Tsang et.al 1998 theorized "*The strong beta C-F bond in the radical means that fluorine can readily displace hydrogen and practically all other groupings. In view of the strong H-F bond strengths, the only other alternative reaction channel, and undoubtedly very important, is the abstraction of a hydrogen atom by a fluorine atom."* This means that combustion products from the oxygen and fuel are needed to drive destruction, or in other words, that the addition of a fuel

such as methane in the calculations provides a source of Hydrogen radicals that drives a degradation of CF_4.

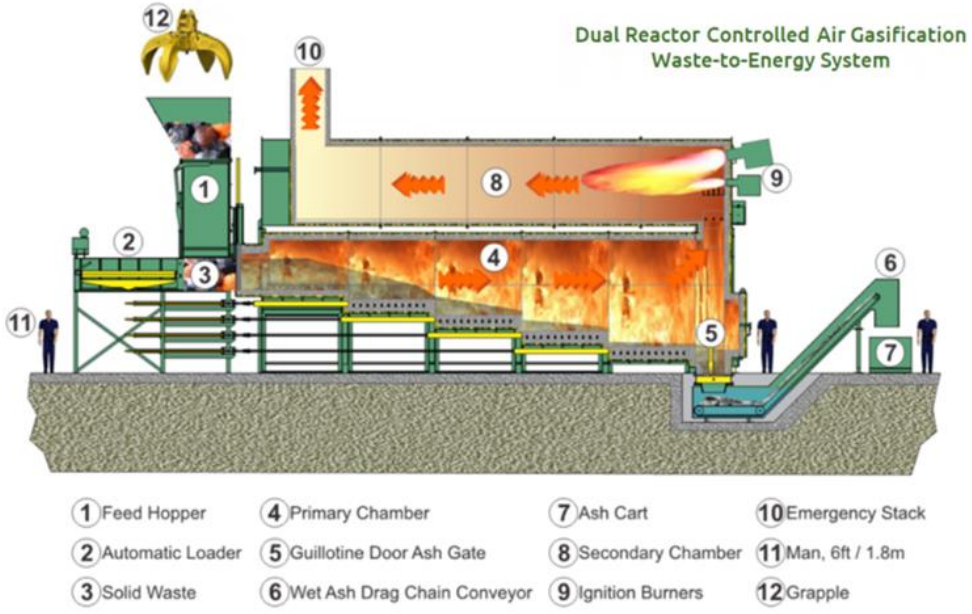
In short, using unimolecular reaction rates alone is inadequate to predict combustion behavior. Fuel, excess oxygen, and their combustion products (which are all present in waste incineration plants) are important components driving destruction of CF_4 and C_2F_6. **Tsang et al. 1998, demonstrates that while unimolecular thermal degradation of CF_4 takes place at temperatures around 1.400 °C, destruction of CF_4 under typical conditions in waste incineration plants will take place at much lower temperatures.**

The importance of combustion radicals was also demonstrated by Krug et al. (2022). Krug et al. "*utilized the EPA Rainbow furnace, which is a single burner combustor and did not incorporate an afterburner as part of this study."* The results of Krug et.al. showed approximately 90% destruction efficiency for CF_4 when introduced through the natural gas inlet, but the values dropped off significantly the farther the compound is injected from the combustion zone (see diagram below). In this case, use of the available afterburner could have helped provide the needed combustion radicals to break the CF_4 bonds.



These results correspond with the results of Tsang et al. 1998 and confirm that if CF_4 is formed it will be destroyed if combustion radicals (i.e., oxygen and fuel) are included in the process. It also demonstrates the importance of the post combustion flame as well as incinerator design considerations.

In the most common incineration designs, “Moving Grate” and “Rotary Kiln”, the waste materials will burn prior to leaving the primary combustion chamber. Once entering the post combustion chamber most designs have another set of burners to ensure the final post combustion chamber is greater than 850 ºC. The image below shows an IWI Waste-to-Energy incinerator design illustrating that flames from burners below the grates and in the post combustion or secondary chamber have ample combustion of fuel and oxygen to supply the radicals needed for destruction.



dd) Other Fluoropolymers

Thermal decomposition of PTFE is achieved at a temperature of about 800 °C. Since PTFE is the most thermally stable of all fluoropolymers, it can be assumed that other fluorine-containing polymers also thermally decompose completely at such temperature.[29] Since the most stable decomposition product (CF_4) is expected to decompose at typical conditions of municipal waste incineration plants, we can presume that all decomposition products of fluoropolymers will be destroyed. This is borne out by the analysis completed in Alexandrov et al (2019).

ee) Capacity of Waste Incineration Plants

Finally, it is pointed out in the Restriction Proposal that incineration plants can only tolerate limited amounts of fluoropolymers due to the corrosive nature of the hydrogen fluoride released during decomposition of fluoropolymers.

[29] See also Bakker et al., 2021(RIVM report 2021-0143), p. 62.

This is a question of the durability of the incineration plant. Due to the small proportion of fluoropolymers in the total post-user waste stream (less than 0.01% by weight[30]), we see little risk of premature corrosion of waste incineration plants.

c) Landfill

With regard to landfilling, the Dossier Submitters are concerned that non-polymeric PFAS that could be released from fluoropolymers or formed due to their degradation could contaminate soil and groundwater. Further, it is stated that this could contribute to release of microplastics.

According to the 2020 Pro-K Study on Fluoropolymer waste, only a small amount (13%) of fluoropolymers is disposed of via landfills at end-of-life.

Currently, there are no standardized tests to assess leaching of fluoropolymers from landfills. However, based on recent testing (see reference to Charles River Data below and in Annex II), data indicates that deposition of fluoropolymers covered by this derogation request will not cause an environmental concern. The most significant vectors of pollutants from landfills into the surrounding environment are water/solvent solubility, which then migrate into soil or groundwater. Our data and published literature[31] demonstrate that fluoropolymers like PTFE

- are insoluble in water (OECD105 and 120),
- do not partition between water/octanol (OECD107, 117, 122),
- and are neither adsorbed/desorbed into soil (OECD106) nor into sludge (OECD121).

In addition, due to the limited amount of residuals (< 5ppm), the leaching potential of low molecular weight residuals is very low.

Data supports the stability of fluoropolymers like PTFE and lack of biodegradation to other PFAS. Our data demonstrate no microbial biodegradation (OECD301B, 302C, 306), including no microbial biodegradation in sludge (unaudited preliminary report, 301F) as well as no growth inhibition to microbes in sludge (OECD301 Annex II).

Finally, preliminary tests suggest that PTFE is photolytically stable so degradation due to exposure to sunlight is also not expected (unaudited preliminary report, OECD316).

Detailed information on our data can be found in Section III.1., 2. and 3 and IV. of Annex II below.

With regards to microplastics we would like to refer Section II above. This is not a topic specifically related to fluoropolymers. On the contrary, compared to other types of plastic, fluoropolymers account for a negligible proportion of total plastic waste (0,01% of total post-user waste stream; see Section b(ee) above) which is also reflected in the very small percentage of fluoropolymers found in the environment. For example, based on samples taken at nine locations near the Norwegian HAUSGARTEN observatory, Bergmann et al., 2017, concluded that

[30] Conversion Study prepared for ProK, Fluoropolymer waste in Europe 2020 – End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams, January 2023.

[31] McKeen LW. 2012. p255; Hanford WE and Joyce RM. 1946. Vol. 68 (10), p2082; Tuminello WH. 1999. pp 137-143.

polyethylene, polypropylene, and nylon are by far the largest contributors of microplastics in the environment (75%), while PTFE contributed 0.1 – 0.6%. If appropriate, microplastics should be regulated by the instrument the Commission is already working on.

d) Recycling

With regard to recycling there are mainly two concerns mentioned or indicated in the Restriction Proposal:

1. That fluoropolymers are not sufficiently recyclable and therefore do not meet the requirements of the circular economy.
2. The potential for PFAS emissions from recycling facilities.

We believe that the use of fluoropolymers does support the principles of the circular economy and in particular the waste hierarchy. As highlighted above, the use of fluoropolymers provides durability and reliability which extend product life, thus preventing waste across a range of products and industries as demanded by the waste hierarchy.[32]

ProK[33] categorize two physical recycling methods for fluoropolymers, namely grinding or thermo-mechanical recycling. Even though these two options are limited, due to the presence of fillers, colorants, and other materials in the composition of the products, they are well established processes for dealing with manufacturing waste. In addition to these physical methods, industry is making progress in chemical recycling processes:

- In 2015, Dyneon in Burgkirchen established a pilot plant with a capacity of 500 t/year, where PTFE, PFA and FEP processing waste and end-of-life components – for example tubes and pump linings, cable isolations – can be converted into their monomers (TFE and HFP) with a recovery rate of 90-95%. After distillation, TFE with purity of 99.99+ is obtained and can be used to manufacture new fluoropolymers with no loss in performance. Thus, this process has great potential to recycle waste to valuable raw materials for high performance products.[34]
- InVerTec is also able to provide turn-key chemical recycling plants for fluoropolymer end-of-life applications.
- The manufacturer BAUM is currently also working on a closed-loop solution for the recovery of PTFE and other EOL products.[35]

[32] See information that will be provided in application-based derogation requests; overview of request in Annex III.
[33] Pro-K Fluoropolymergroup, Recycling of fluoropolymers, 2018, Technical Brochure 10. https://www.pro-kunststoff.de/assets/Merkbl%C3%A4tter%20und%20Co/FP%20TM-10-Recycling-of-fluoropolymers.pdf,
[34] Schlipf M, Schwalm T. 2014. Closing the recyling loop. Kunststoffe Intl 2014/06. [cited 2023 May]. https://www.kunststoffe.de/en/journal/archive/article/up-cycling-of-end-of-life-fluoroplastics-841786.html; InVerTec. 2017. Pilot project: Recycling of fluoropolymers (PTFE). [cited 2023 May]. https://www.invertec-ev.de/en/projects/environmental-care/ptfe-recycling/; Final report, Fluoropolymer waste in Europe 2020– End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams, January 2023.
[35] Final report, Fluoropolymer waste in Europe 2020– End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams, January 2023, P. 59.

[redacted]

It should be noted that recycling might not work for all end-of-life components regardless of their PFAS content, in particular when they are used in small components of larger finished articles. Dismantling for recycling might not be feasible nor economically viable for complex objects. However, it must also be noted that one of the largest shares of fluoropolymer waste is related to plant and production – industrial – equipment[36] where fluoropolymers are used as larger components with higher potential for recycling where such technology and capacity exists.

As far as emissions from recycling facilities are referred to as a concern, we would like to reiterate that these concerns can be addressed by using emission control technologies.

[36] Final report, Fluoropolymer waste in Europe 2020– End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams, January 2023, p. 23.

Annex I – Definitions

Residuals: means substances, such as monomers, polymer processing aids, crosslinkers, some oligomers, and by-products that can leach out of the polymer. They can be identified by chemical analysis, by techniques such as thermal gravimetric analysis (TGA), gas chromatography mass spectrometry (GC-MS), or liquid chromatography mass spectrometry (LC-MS).

By-products: means substances that are created in the polymerization and finishing of fluoropolymers.

Oligomers: means a molecule of intermediate relative molecular mass, the structure of which essentially comprises a small plurality of constitutional units.[37]

[37] See Glossary of Basic Terms in Polymer Science, Commission on Macromolecular Nomenclature, Macromolecular Division, International Union of Pure and Applied Chemistry, draft: May 13, 1991.

Annex II – Properties of Fluoropolymers: Hazard Assessment and Degradation

In this Annex we will provide information on fluoropolymers, with supporting laboratory reports and publications (available at your convenience[38]), to demonstrate

- That persistency is not an appropriate basis for a REACH restriction since equating of increased environmental stock of a persistent substance with increased bioavailable exposure, and thus risk, lacks a scientific basis.
- The supporting concerns raised by the Dossier Submitters do not apply to fluoropolymers.
- Fluoropolymers such as PTFE will not degrade under environmental conditions to substances which could entail a risk.

Unless otherwise stated, the information refers to those fluoropolymers which are covered by our proposed derogation for fluoropolymers, and which are further described in Section I. below.

[38] Please note that most of the data have already been submitted in the public consultation on the restriction of PFAS in firefighting foams.

I. FLUOROPOLYMERS HAVE A LOW HAZARD PROFILE

We believe that the fluoropolymers meet the following requirements and therefore have a low hazard profile:

Criteria[39]		Comments relating to Derogation
High number-average molecular weight (Mn).	The number average molecular weight (Mn) and oligomer content are the most commonly used criteria for the hazard assessment of polymers. Most potential health concern polymers have a number average molecular weight, Mn, ‹ 1000 Da and oligomer content ›1%).[40]	Fluoropolymers have MW › 7000 to 45,000,000 Da
Low number of low molecular weight oligomeric species	Different jurisdictions differ widely on the level of oligomeric species that are permitted in the PLC category. Some nations specify limits for just ‹1000 Da content, whereas others regulate both ‹1000 Da and ‹500 Da.	Specifies Oligomer content ‹5% of ‹1000 Da and ‹2% of ‹500 Da species[41]
Reactive functional groups (RFGs) in the polymer	These are specific functional groups that are known to be associated with toxicity of polymers and include cationic species that are known to result in aquatic/environmental toxicity. Limits on RFG content can be defined in terms of the Functional Group Equivalent Weight (FGEW), a measure of the "dilution" of an RFG amongst the polymer's other components. RFGs or the FGEW are not universally considered for establishing a PLC. [42]	Fluoropolymers do not contain reactive functional groups of high concern[43]
Other criteria that are used by some jurisdictions to define a PLC include the polymer's stability, solubility (in water and other solvents), chemical/polymer class,	**Korzeniowski et al 2022 elaborates on these and highlights the following considerations**	
	Ionic character – Electrical charge or ionic character can be anionic, cationic, amphoteric, or nonionic. Specifically, cationic polymers have been associated with aquatic toxicity.	Not relevant for fluoropolymers. Fluoropolymers are neutral/non-ionic.[44]

[39] https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf; https://www.oecd.org/env/ehs/oecddefinitionofpolymer.htm.
[40] BIO by Deloitte, 2015.
[41] OECD, 2009, p. 24; COM(2015)
[42] OECD, 2009.
[43] According to Henry et al.,2018, and Korzeniowski et al., 2023 there are no reactive functional groups of high concern in the assessed fluoropolymers. These papers cover approximately 96% of the fluoropolymers on the global market.
[44] See Henry et al.,2018, and Korzeniowski et al., 2023. These papers cover approximately 96% of the fluoropolymers on the global market.

Criteria[39]		Comments relating to Derogation
residual monomer content and human health hazard classification.	**Low MW Residuals** – High number of low MW residuals has been associated with risk of toxicity.	Covered by limitation of low MW residuals to ‹ 5ppm
	Particle size – Particle size of ‹ 5 µm were seen as a concern because they can reach the deep lung	Fluoropolymers have a particle size ›5 µm.[45]
	Water and lipid solubility and the octanol -water partition coefficient	Not relevant for fluoropolymers due to their insolubility.
	Stability (abiotic biotic and thermal)	Not relevant for fluoropolymers since fluoropolymers are stable and do not degrade under relevant environmental conditions

These criteria are closely aligned with those highlighted in the Wood report[46] specifically ionic character, molecular weight, oligomers, reactive functional groups and polymer degradability. While the Wood report is focused on Polymers Requiring Registration under REACH we wanted to highlight the alignment and overlap here.

These requirements are scientifically recognized criteria to identify polymers of low concern. Since most of the criteria are inherent to fluoropolymers, we believe only the criteria mentioned in the derogation request need to be specified. This is confirmed by Henry et al.,2018, and Korzeniowski et al., 2023. These papers cover approximately 96% of the fluoropolymers on the global market.

Additional criteria that could be considered for additional specification could be ionic and reactive functional groups. Based on our understanding of the fluoropolymers on the market today, we believe that these are not relevant, and we have not included them in the proposed derogation.

[45] See Henry et al.,2018, and Korzeniowski et al., 2023. These papers cover approximately 96% of the fluoropolymers on the global market.

[46] European Commission, Directorate-General for Environment, Bougas, K., Corden, C., Crookes, M.et al., Scientific and technical support for the development of criteria to identify and group polymers for registration/evaluation under REACH and their impact assessment – Final report, Publications Office, 2020, available at https://data.europa.eu/doi/10.2779/890644.

II. MAIN CONCERN OF DOSSIER SUBMITTERS: PERSISTENCE

According to the Restriction Proposal the main concern for all PFAS and/or their degradation products is their very high persistence. Due to the persistency, continued PFAS emissions will result in an increased environmental stock which is considered equivalent to increased exposure by the Dossier Submitters. This is the reason why the Dossier Submitters suggest treating PFAS as non-threshold substances: It is considered likely that known as well as unknown PFAS thresholds to cause adverse effects will be exceeded at some point in time. Therefore, release of PFAS is considered as proxy for risk by the Dossier Submitters.

We believe that persistency is not an appropriate basis for a REACH restriction. First, this is not supported by EU Chemicals Law. Persistence alone is not a hazard property under REACH and CLP Regulation.

Furthermore, the equating of increased environmental stock with increased exposure, and thus risk, lacks a scientific basis. It is well established that a risk is a function of both hazard *and* exposure. A hazardous substance with no exposure potential has a low risk, and similarly exposure to a substance that is non-hazardous has a low risk. As will be demonstrated in the Section on (Eco)Toxicological Effects below, fluoropolymers like PTFE are not hazardous. Also, it is well established that exposure to chemicals requires bioavailability of the respective substance. **Persistence does not contribute to potential exposure if the substance is not bioavailable**. As will be demonstrated in the Section on Bioavailability and Bioaccumulation below, fluoropolymers like PTFE are not bioavailable.

To demonstrate that the scientific community is not aligned on the concept that persistence alone is a hazard, we would like to offer the following discussion and would supply full text reprints upon request.

- Donald Mackay and colleagues (2014) believe that persistence is "[…] only one of several factors that influence exposure and risk." They stated that the blanket assertion that long persistence leads to high risk can be erroneous because risk is dependent on the quantity released, uptake in biota and toxicity (Mackay D et. Al., 2014). Uptake in biota can only occur if the chemical is bioavailable.
- Ehlers and Loibner (2006) agree: "Most risk assessment procedures consider the total pollutant concentration in soil as bioavailable resulting in an overestimation of risk." (Ehlers and Loibner, 2006).
- Jarkko Akkanen et al., 2012 assert "It has been established that the total concentration of a given contaminant in a given environment does not translate well into uptake or toxicity in organisms living in that environment. Ecotoxicological effects due to organic chemicals are *usually the result of uptake and bioaccumulation* of the chemical from the ambient environment or food, followed by toxicodynamic processes which actually result in eliciting the final effect. […] Uptake of contaminants is a complex interplay among biological, chemical, and physical factors and processes. Properties of chemicals,

environmental conditions, and characteristics of the organisms and the interaction among these ultimately dictate the exposure." (Akkanen et al., 2012).

- In explaining the importance of bioavailability, Semple et al., 2004 looked at contaminated land regulations. Where contaminated land is defined such that just the presence of substances of concern is not sufficient; there must be harm because toxic effects require that an organism takes up the contaminant (Semple et al., 2004). Semple et. Al. (2004) offers the definition (of bioavailability) (which is supported by Ehlers and Loibner) as "…the fraction of a contaminant that is free to be taken up by organisms (i.e., *free to pass through biological membranes*)."
- Factors such as polarity, aromatic content, aliphatic content, and molecular weight effect bioavailability of chemicals, per Akkanen (2012).
- Akkanen (2012) argues that "[…] bioavailability estimations would take us *closer to reality* and help with the management decisions." The National Research Council (Washington, DC, USA) agrees: "Explicitly *incorporating bioavailability routinely and rigorously into the risk assessment process* would offer the possibility of demonstrating in some cases that *only a fraction of a contaminant's total mass* contained in a soil or sediment actually *has the potential to enter potential receptors (biota)*." (National Research Council 2003).

III. SUPPORTING CONCERNS OF DOSSIER SUBMITTERS

Besides persistence, the following supporting concerns are mentioned in the Restriction Proposal: mobility, long range transport potential (LRTP), accumulation in plants, bioaccumulation, and (eco)toxicological effects. **In the following we would like to demonstrate that none of these supporting concerns referred to by the Dossier Submitters is relevant for fluoropolymers.**

Most of the data provided in this section are from studies commissioned by Gore and performed at Charles River Labs in Den Bosch, the Netherlands, to provide consistent evidence that any persistence of PTFE does not imply or indicate toxicity or bioaccumulation, nor does any persistence of PTFE imply future degradation, nor release or transformation into a continuous source of substances of concern. A fine powder PTFE test material that meets the specification ASTM D4895-18 and the OECD polymer of low concern criteria, was tested according to numerous OECD guidelines. An overview of the performed studies and summarized test results can be found below and will be addressed in more detail in the following sections. The challenges of analytical chemistry for certain OECD tests have delayed their full completion. Therefore, interim data will be provided for those studies, and separate submissions will be made when final results are received.

Due to size limitation on submission to the present public consultation (20MB) and that we already submitted the full test reports to the firefighting foam restriction proposal in 2022, we are not submitting them along with this derogation but have provided references in Annex VI.

Table A.1. Environmental Fate Testing of PTFE by Charles River Labs

Test Title (OECD Test Guideline Designation)	Status/Results	Relevance for PTFE
Melting Point/Melting Range (OECD 102)	The melting temperature of the test item was determined using differential scanning calorimetry (DSC). Melt transition observed at ~350 °C (662 °F), no further melting/decomposition below 400 °C	To support thermal stability at environmentally relevant temperatures.
Determination of the Number-Average Molecular Weight and the Molecular Weight Distribution of Polymers using Gel Permeation Chromatography (OECD 118)	Not sufficiently soluble to be evaluated by GPC even after sonication and stirring (19 hr) in representative lab solvents. By alternative methods MW is › 500.000 Da	To determine if low molecular weight fractions are available for migration out of the polymer.
Vapor Pressure (OECD 104)	‹1 x 10-10 mm Hg @ 20 °C; indicating very low potential of PTFE to partition to the air as a gas or vapor. The vapour pressure of the test item (PT) was determined by the isothermal thermogravimetric effusion method.	Volatility will help predict likelihood of partitioning to air and long-range transport potential.
Henry's Law Constant	Expert Statement; Due to the insolubility of PTFE, this test could not be performed.	Henry's law constant (HLC), a measure of the concentration of a chemical in air over its concentration in water, reflects volatility and likelihood to partition to air from water. High HLC means likely to volatize and have long range transport.
Water Solubility (OECD 105) and Water Solution/Extraction Behavior of Polymers in Water (OECD 120)	PTFE is not soluble in water.	Soluble substances may contaminate drinking, surface and ground water and move with the water.
Behavior in water system	Final report; PTFE was not soluble in water.	Supports lack of extraction/leaching of migrants from the polymer into water.
Determination of pH, Acidity, and Alkalinity (OECD 122)	Final report; PTFE was not soluble in water, thus modified methods were followed. Test results demonstrated PTFE is not corrosive, caustic, or ionizable.	Soluble and ionizable substances may contaminate drinking, surface and ground water and move with the water.

Test Title (OECD Test Guideline Designation)	Status/Results	Relevance for PTFE
Adsorption Coefficient on Soil and Sludge using HPLC (OECD 121)	Expert Statement: Due to the insolubility of PTFE in organic solvent, this test was not feasible.	Soluble substances may adsorb to soil or sludge, and then contaminate drinking, surface and ground water and move with the water.
Adsorption - Desorption Using a Batch Equilibrium Method (OECD 106)	Expert Statement: PTFE is not soluble in water or conventional organic solvents. Therefore adsorption/desorption behaviour determination was not possible.	To determine the likelihood of the substance partitioning to soil and/or sediment.
Partition Coefficient (n-octanol/water): Shake Flask Method (OECD 107)	Expert Statement: PTFE is not soluble in octanol or water. Therefore, no Partition Coefficient determination was possible.	Substances that are more soluble in n-octanol may be more likely to be fat soluble and bioaccumulative. Substances with Partition Coefficient tend to adsorb more readily to organic matter in soils or sediments because of their low affinity for water. Chemicals with very high Partition Coefficients (i.e., >4.5) have the potential to bio-concentrate in living organisms. N-octanol/water partition coefficient (Kow) is a screening test for bio-accumulation.
Partition Coefficient (n-Octanol/Water), High Performance Liquid Chromatography (HPLC) Method (OECD 117)	Expert Statement: PTFE is not soluble in octanol or water. Therefore, no Partition Coefficient determination was possible.	Substances that are more soluble in n-octanol may be more likely to be fat soluble and bioaccumulative. Substances with Partition Coefficient tend to adsorb more readily to organic matter in soils or sediments because of their low affinity for water. Chemicals with very high Partition Coefficients (i.e., >4.5) have the potential to bio-concentrate in living organisms. N-octanol/water partition coefficient (Kow) is a screening test for bio-accumulation.
Octanol-air partition coefficient (log K_{oa})	Expert Statement: PTFE is not soluble in octanol. Therefore, no Partition Coefficient determination was possible.	Useful for predicting partitioning behavior between various matrices (e.g., air and soil, vegetation)

Test Title (OECD Test Guideline Designation)	Status/Results	Relevance for PTFE
Hydrolysis as a Function of pH (OECD 111)	Analytical method development in progress	Abiotic stability – test for degradation in water.
Phototransformation of Chemicals in Water - Direct Photolysis (OECD 316)	Preliminary tests suggest that PTFE is photolytically stable so degradation due to exposure to sunlight is also not expected (unaudited preliminary report, OECD316).	Abiotic stability – test for degradation in sunlight
Phototransformation of Chemicals on Soil Surfaces (OECD draft document)	Preliminary tests suggest that PTFE is photolytically stable so degradation due to exposure to sunlight is also not expected (unaudited preliminary report, OECD316).	Abiotic stability – test for degradation in sunlight
Screening Test for Thermal Stability and Stability in Air (OECD 113)	Stable at continuous processing temperature 260 °C and only 5% loss in weight at 549 °C (1020 °F). PTFE is considered stable at room temperature when no decomposition or chemical reaction is observed ‹ 150 °C (302 °F).	Test for degradation from heat (relevant environmental temperatures)
Ready Biodegradability (OECD 301B)	Did not reach 60% degradation threshold at 28 days. Not readily biodegradable.	Biotic stability – test for biodegradability within 28 days
Inherent Biodegradability OECD 302 C (METI)	No inherent biodegradability. Did not reach biodegradation threshold in 28 days.	Biotic stability – test for biodegradability
Biodegradation of organic chemicals in Aerobic Sewage Treatment (OECD 303A)	Analytical method development in progress	Biotic stability – test for biodegradation in the presence of aerobic bacteria in sewage treatment
Biodegradability in Seawater (OECD 306)	PTFE was not sufficiently soluble for evaluation by guideline even after sonication (15mins) and stirring (83mins). PTFE does not degrade in seawater.	Biotic stability – test for biodegradation in seawater
Aerobic and Anaerobic Transformation in Soil (OECD 307)	Analytical method development in progress	Biotic stability – test for transformation in the presence of aerobic and anaerobic bacteria in soil

Test Title (OECD Test Guideline Designation)	Status/Results	Relevance for PTFE
Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD 308)	Analytical method development in progress	Biotic stability – test for transformation in the presence of aerobic and anaerobic bacteria in sediment
Ready Biodegadability: Manometric Respirometry in Activated Sludge (unaudited preliminary report, OECD 301F)	No biologically relevant biodegradation of PTFE was observed. PTFE is completely inert and is non-growth inhibitory to activated sludge.	Biotic stability - test for biodegradation, inertness, or inhibition in sewage treatment.

Definitions and Descriptions of Terminology used in the Charles River Labs studies.

ASTM D4895-18 Standard Specification for PTFE Resin from Dispersion

- covers homopolymers of tetrafluoroethylene or modified homopolymers containing not more than 1% by weight of other fluoromonomers
- covers dry-powder resins of polytetrafluoroethylene (PTFE) resin produced from dispersion
- specifies resin shall be uniform and shall contain no additives or foreign material
- specifies color of the material as shipped by the supplier shall be natural white
- does not include:
    - mixtures of PTFE with additives such as colors, fillers, or plasticizers
    - reprocessed or reground resin or any fabricated articles because the properties of such materials have been irreversibly changed when they were fibrillated or sintered.
    - PTFE mixtures with additives

1. Mobility and Long-Range Transport Potential

Mobility and long-range transport potential of PFAS is stated as a supporting concern by the Dossier Submitters. They point out that the high persistence in the environment will lead, inevitably, after release to distribution of PFASs from one environmental compartment to another (e.g. from soil to freshwater to marine environment). PFASs may concentrate in the respective compartment into which PFASs partition according to their specific properties (e.g. water-soluble substances concentrate in water, while volatile substances partition to air) and that PFAS can be transported by air, water and matrices to which they are adsorbed or absorbed, such as dust, sediments, migratory animals, or through matrices in which it is included as additive, e.g. polymers. With regard to mobility, it is pointed out that PFAS that are volatile will be distributed via air and substances with a moderate to high solubility in water and a low adsorption potential are considered to have a high mobility in the aqueous environment. Further, it is pointed out that, mobility of PFAS in water contributes to their long-range transport and drinking water contamination potential.

In the following, we would like to demonstrate that none of these considerations apply to fluoropolymers such as PTFE. On the contrary, the data presented below prove the opposite. PTFE is non-volatile with low potential to partition to air, and non-water soluble and therefore not to be considered mobile in the aqueous environment. Therefore, the potential to contaminate drinking water is very low.

Upon deposition to soil and sediment its presence and persistence will depend on the physical movement through the system via mechanical transport processes rather than on chemical properties of the fluoropolymer because PTFE does not readily bind to organic matter.

In sum, long-range transport potential is very low based on air, water, and soil data.

a) Volatility

The likelihood that a liquid or solid will become a gas or vapor is described by volatility. Volatility helps predict the likelihood of a substance partitioning to air if it becomes a gas or vapor, and long-range transport potential of a substance once partitioned in air as a gas or vapor. With respect to the volatility and potential for long-range transport in air of fluoropolymers such as PTFE, as a gas or vapor, the following tests are relevant: OECD 104, OECD 113, Henry's Law and Log $K_{oa.}$

All tests confirm a lack of volatility under relevant environmental conditions of the tested PTFE. In detail:

aa) OECD 104: Vapor Pressure Testing

The vapor pressure, determined by the isothermal thermogravimetric effusion method, was <1 x 10^{-10} mm Hg @ 20 °C, indicating very low potential of PTFE to partition to the air as a gas or vapor.

bb) OECD 113: Thermal Gravimetric Analysis

In addition, thermal gravimetric analysis was performed to determine the mass of PTFE lost to air as a function of temperature and time, per OECD 113. This analysis resulted in

undetectable weight loss at temperatures less than 140 °C and 5% weight loss observed at 549 °C. A mass loss to the air as a gas or vapor under any global temperature environmental condition was therefore confirmed to be unlikely. OECD113 test results indicate PTFE's **lack of volatility under ambient environmental conditions**.

cc) Henry's Law Constant

Henry's Law Constant is a measure of a dissolved substance's ability to evaporate from water. It reflects volatility and the likelihood to partition to air from water. A high Henry's Law Constant means the substance is likely to volatilize and long-range transport potential increases the higher the volatility and Henry's Law Constant. Low Henry's Law Constant substances tend to stay in water and may be adsorbed onto soil or sediment. Henry's law constant is an important parameter that plays a fundamental role in predicting the transport, behavior, and fate of substances of concern in the environment and it is required to model the chemical transfer between air and water. OECD does not provide guidelines for Henry's Law testing, thus other guidance (REACH, 2017; Technical Guidance Document on Risk Assessment 2003) was followed.

PTFE is not soluble in octanol or water. Therefore, Henry's Law could not be determined. However, the vapor pressure results also demonstrated very low potential of PTFE to partition to the air as a gas or vapor. The lack of water solubility combined with the lack of volatility indicate that PTFE is not a continuous source of substances of concern, via the route of volatilization into a gas or vapor and partitioning to air from water.

dd) Log K_{oa}: Octanol–Air Partition Coefficient

Log K_{oa} or octanol–air partition coefficient is one of the key descriptors of chemical partitioning between various matrices, such as air, soil, and vegetation (Odabisi et al., 2006). The octanol–air partition coefficient is also a key descriptor of chemical partitioning between the atmosphere and other environmental organic phases such as soil and vegetation (Harner et al., 2000; Shoeib and Harner, 2002). The octanol-air partition coefficient is similar to the Henry's Law Constant, but instead measures the concentration of a test substance in air over its concentration in octanol. Also similar to the Henry's Law Constant, the octanol-air partition coefficient is an important parameter that plays a fundamental role in predicting the transport, behavior, and fate of substances of concern in the environment and it is required to model the chemical transfer between air and organic phases. OECD does not provide guidelines for octanol-air partition coefficient testing, thus other guidance was followed (Henry et al.,2018).

PTFE is not soluble in octanol or water. Therefore, the octanol–air partition coefficient could not be determined However, the vapor pressure results also demonstrated PTFE is not volatile in air as a gas or vapor. These two results combined indicate that PTFE is not a continuous source of substances of concern partitioning between air and other environmental media high in naturally occurring organic compounds, such as soil.

b) Water Solubility

Water solubility is very important to consider because water-soluble substances may migrate into drinking, surface, and ground water, and move with the water.

The water solubility of the tested PTFE was attempted to be measured as per OECD 105. The detection limits of the methods specified by OECD105 are 10^{-6} g/L, and it is well known to the chemical literature that **PTFE is insoluble in water** at concentrations much lower than 10^{-8} g/L. Thus, PTFE is practically insoluble in water according to the guidelines of OECD105, making PTFE **highly unlikely to be a water-soluble drinking, surface, or ground water contaminant, or to move with water as a water-soluble substance**.

Further efforts to characterize the ability of fluoropolymers to partition to water are shown in OECD 120, Solution/Extraction Behavior of Polymers in Water being conducted with a sample of the same fine powder PTFE. This study was performed to further investigate fluoropolymer behavior in water and confirmed insolubility.

c) pH Value

OECD 122 provides procedures to obtain data on pH, acidity and alkalinity of aqueous solutions or aqueous dispersion of chemicals (substances and mixtures). The data are used to assess the effects that the chemical may pose to human health and the safety and potential impact upon the environment. Substances which are highly acidic or highly alkaline can be corrosive or caustic and can pose a threat via physical contact. Furthermore, these substances tend to be ionizable, and can bind via ionic bonds with other compounds in the environment. Furthermore, these substances tend to be soluble or partly soluble in water and can have mobility in water or in organic matter such as soils or sediments.

OECD 122 requires that the test substance be soluble or dispersible in water. As mentioned above, PTFE is not soluble in water. Furthermore, data from Charles River Labs demonstrate that PTFE's dispersion in water is ‹ 0.5%. Thus, the guidance from OECD122 as written cannot be applied to PTFE, so modified methods were followed using mixtures of PTFE and water, rather than solutions or dispersions of PTFE.

The test results demonstrated that an aqueous mixture of PTFE and water had a mean **pH value of 6.9, which is neither acidic nor alkaline**, and is well within the normal pH range for surface water of 6.5 to 8.5, and for groundwater of 6.0 to 8.5. These results demonstrated that PTFE is neither corrosive nor caustic, is not ionizable, and is further evidence that PTFE is not soluble in water. **These results further demonstrate the lack of potential impact via water solubility of PTFE on drinking water, plants and crops, and long-range transport in water.**

2. K_{OW}: Octanol-Water Partition Coefficient

K_{OW} or octanol-water partition coefficient is a physical–chemical property used to represent the lipophilic or hydrophilic nature of a substance. Substances that are more soluble in n-octanol may be more likely to be fat soluble and stored in fat (e.g., bioaccumulate). The K_{OW} is useful in determining the tendency of substances to adsorb more readily to organic matter in soils or sediments because of their low affinity for water. Chemicals with very high K_{OW} (i.e., ›4.5) have the potential to bio-concentrate in living organisms. OECD does not provide guidelines for octanol-water partition coefficient testing, thus other guidance was followed (Henry et al, 2018).

OECD 107, Partition Coefficient (n-octanol/water): Shake Flask Method, and OECD 117 Partition Coefficient (n-Octanol/Water), High Performance Liquid Chromatography (HPLC) Method were performed for the fine powder PTFE sample.

PTFE is insoluble in water and is insoluble in octanol. Therefore, the octanol–water partition coefficient could not be determined. However, these two results combined indicate that PTFE is not fat soluble nor likely to bioaccumulate in fat via adsorption to organic matter in soils or sediments.

3. Uptake and Accumulation in Plants

Other than low molecular weight perfluoroalkyl acids (PFAAs), uptake and accumulation of fluoropolymers like PTFE in plants is not to be expected. While high water solubility, anionic ionizable form, and negligible vapor pressure combine to make low molecular weight perfluoroalkyl acids (PFAAs) candidates for uptake and accumulation in crops (Gredelj et al., 2020), PTFE has negligible water solubility and would not move through the plant via mechanisms such as transpiration of water-soluble compounds, as PFAAs would. Furthermore, fluoropolymers, like PTFE, are neutral and not anionic as per the results from the modified OECD122 tests (see also Henry et al., 2018).

There are studies that show that soil adsorption could enable a substance in the soil contacting the root to be transported and accumulate in plant tissues (Xu et al., 2022). Since PTFE is not sufficiently soluble the OEDC 106 and 121 could not be performed to prove that transport via the roots will not take place. However, due to insolubility, soil adsorption and transport via the roots is highly unlikely.

OECD 106: Adsorption/desorption using a batch equilibrium method, and OECD 121: Estimation of the Adsorption Coefficient on Soil and Sludge using High Performance Liquid Chromatography (HPLC) Method were conducted. Such studies are useful for generating essential information on the mobility of chemicals and their distribution in soil, water, and air. They are also useful for measuring the binding capacity of a substance to soil and sludge. For example, OECD 106 has been employed by Gredelj et. al. 2020 to study portioning of PFAAs between soil and water by adsorption/ desorption experiments. To determine the likelihood of PTFE to partition and adsorb to soil via OECD 106 and 121, a sample of the fine powder PTFE was provided to Charles River Labs in Den Bosch (Netherlands). However, it is not possible to obtain information regarding the mobility and distribution of PTFE in soil, water and air using OECD 106 and OECD 121, as OECD 106 requires the test substance to be completely soluble in water and OECD 121 requires the test substance to be completely soluble in conventional organic solvents or in solvent/water mixtures. As commented above, PTFE is insoluble in water, and is insoluble in octanol.

The challenges of conducting these two OECD tests, has motivated the initiation of other related soil/water/air studies that do not require water-soluble or organic solvent-soluble compounds, namely OECD 303A, 307, and 308. Nonetheless, there remain analytical challenges to adapt this guidance to fine powder PTFE. Separate submissions will be made when final results are received. As stated previously, because of the negligible water and octanol solubility of PTFE, the likelihood of soil adsorption is low so

bioavailability, uptake, and accumulation in plants would not occur, which these study results are expected to confirm.

4. Bioavailability and Bioaccumulation

In this section we provide information and references which demonstrate high molecular weight fluoropolymers have not been observed to be bioavailable or bioaccumulate.

Bioavailability means the extent to which a substance is taken up by living cells. In mammals the substance crosses the cell walls of the respiratory or intestinal tracts via inhalation or ingestion, respectively, or crosses cell walls in the skin via dermal contact. Bioaccumulation is the process of build-up of substances in an organism that takes place if the rate of intake exceeds the rate of elimination.

Substances not capable of being bioavailable or bioaccumulative do not penetrate cell membranes or do so only poorly (see Leeson 2012; ECETOC Special Report No.18. Brussels, July 2014.; Zhang and Wilkinson, 2007). There are two processes for passage into a cell membrane: passive and active transport.

Passive transport means the movement of a molecule across a cell membrane without expending energy, such as by diffusion from an area of high concentration to one of low concentration, or, facilitated diffusion, in which diffusion is aided by a transport protein in the cell membrane.

The conditions for passive transport of a molecule into a cell membrane, are defined by the so-called Lipinski's Rules or "rule of 5" (Leeson, 2012) which state that a molecular compound is more likely to be membrane permeable and easily absorbed by the body, if:

1. Its molecular weight is less than 500 Dalton (Da)
2. The molecule's lipophilicity, expressed as a quantity known as logP (the logarithm of the partition coefficient between water and 1-octanol), is less than 5
3. The number of groups in the molecule that can donate hydrogen atoms to hydrogen bonds (usually the sum of hydroxyl and amine groups in a drug molecule) is less than 5
4. The number of groups that can accept hydrogen atoms to form hydrogen bonds (estimated by the sum of oxygen and nitrogen atoms) is less than 10.

There are exceptions to Lipinski's rules most notably for "natural products", such as cyclosporine A, rapamycin, steroids, flavones, peptides, etc. (Zhang and Wilkinson, 2007). Those substances that meet these criteria are likely to be bioavailable, and there is evidence that "violating" more than 1 of these diminishes bioactivity (e.g., oral activity of a drug).

Applying Lipinski's Rules to fluoropolymers, when considering their molecular composition, they have *not* been observed in the literature to transport passively into cells because they do not meet any of the criteria:

1. of their size well above 500 Dalton ranging from 7.000 to millions of Da
2. of the lack of lipid solubility to penetrate the cell membrane
3. of the lack of oxygen and nitrogen atoms estimating groups accepting hydrogen atoms

4. they are highly hydrophobic and have little or no hydrogen bond donating potential because they have few or no hydrogen bonds
5. They are not structurally similar to steroids, peptides, natural compounds, etc., that are exceptions to Lipinski's Rules.

Active transport means moving molecules across a cell membrane using energy.

Active transport and cell surface binding/signaling require interaction with the cell surface and are dependent on physical characteristics of the molecule such as shape, volume/size, etc. However, the types of high molecular weight compounds that can be bioavailable through active transport or cell surface binding/signaling are "natural compounds" like cyclosporine A, rapamycin, steroids, flavones, peptides, etc. (Zhang and Wilkinson, 2007). When considering their molecular composition, fluoropolymers are not subject to active transport because they do not bind to cell surface receptors to trigger events within the cell and are very different from steroids, peptides, cyclosporine, and other "natural compounds".

The accuracy of the understanding of active and passive cell membrane transport has been questioned with regard to polystyrene micro- and nanoparticles that have been used to deliver chemotherapeutic drugs to cancer cells (Lohmann et al., 2020, p. D).

Active or passive transport of polymer micro- and nanoparticles into cell membranes, are dependent upon many variables that extend beyond the molecular composition of the polymer. These variables include size, shape, charge, crystallinity, surface reactivity, particle concentration, and dissolution into intracellular compartments. No single particle property can be identified as the most important for bioavailability and bioaccumulation. However, it is hypothesized that surface reactivity may be the best predictor for transport, and particle surface reactivity has been proposed for classifying into hazard groupings (Braakhuis et al., 2014; Maocai et al., 2019).

Using the surface reactivity of a micro- or nanoparticle to predict its potential for bioavailability and bioaccumulation is not inconsistent with Lipinski's Rule. Micro- and nanoparticles do not behave universally, and the behavior of one particle type can not necessarily extrapolate to other particle types.

As an example, it is informative to compare transport across the gut wall of a high surface reactive polymer particle (polystyrene, "PS") to a low surface reactive polymer particle (high molecular weight PTFE). Studies (Lu L. et al., 2016; Kashiwada, 2006; Jin et al., 2022; Deng et al., 2017; Lu Y. et al., 2018; Hayati et al., 2022; Gaspar et al., 2018) have demonstrated, across a variety of species, that PS micro- and nanoparticles are bioavailable via ingestion across the gut wall, and bioaccumulate in various cells and organs, including stem cells, Leydig cells, spermatogenic cells, hepatopancreas cells, hepatocytes, liver, gills, testes, and the blood-brain barrier. PS microparticles have been identified in human blood, also speculated from ingestion (Leslie et al., 2022). Intracellular bioaccumulation of PS micro- and nanoparticles can disrupt numerous cellular processes and enzymatic pathways. Numerous mechanisms have been proposed for PS particle-induced intracellular disruptions, which involve the chemical reactivity of PS's molecular composition and/or PS particles' surface reactivity.

In comparison, studies examining the transport of PTFE particles across the gut wall demonstrate absent bioaccumulation, which implies low or absent bioavailability.

Rodents fed large quantities of PTFE nanoparticles did not show bioaccumulation in the blood, brain, heart, kidney, lung, spleen, testes, or ovaries (Lee et al., 2022).

Other studies permit direct comparison of the biological response to particles comprising PS and PTFE, at the scale of the organ wall and at the scale of the whole body. At the organ wall scale, inhaled particles of PS and PTFE were both found (Geiser et al., 2003) submersed in the hamster respiratory wall's aqueous lining layer and adjacent to epithelial cells; however, only PS particles were found phagocytosed within resident macrophages. At the whole-body scale, inflammatory bowel disease (IBD) status was correlated to the total concentration of polymer particles found in human feces (Yan et al., 2021). For healthy vs. IBD patients, the approximate median concentration of PS particles was 1.1 vs. 1.4 particles/g (dry weight) respectively, whereas for PTFE the approximate median concentration was 1.1 vs. 0.4 particles/g (dry weight) respectively. These data suggest that there is a positive correlation between PS particle concentration and IBD, but a poor correlation between PTFE particle concentration and IBD.

As IBD is an inflammatory disease significantly mediated by activated T cells, these data further suggest that the bioavailability and bioaccumulation of PS particles is greater than that of PTFE particles. This suggestion is consistent with the importance of particle surface reactivity and is not inconsistent with Lipinski's rule.

In conclusion, the data from all these studies demonstrate, in terms of bioavailability and bioaccumulation, that particle properties do not necessarily extrapolate from one polymer composition to another. High molecular weight fluoropolymer particles comprise low surface reactivity, contributing to their observed absent bioavailability and bioaccumulation.

5. (Eco)Toxicological Effects

The discussion about environmental and health effects in the Restriction Proposal demonstrates that the group of PFAS substances is too broad to be assessed together. Even though the Dossier Submitters acknowledged that experimental data is limited for many PFAS, they conclude that there is sufficient evidence that demonstrates the risks of PFAS exposure and regard the importance of the uncertainty as low (See Annex F, page 5).

In this section we would like to demonstrate that – at least for fluoropolymers like PTFE – this risk assessment is not correct since fluoropolymers are not hazardous/toxic. They have demonstrated neither environmental effects nor effects on human health.

a) Environmental Effects

Due to insolubility in water and low bioavailability (see above) aquatic toxicity of fluoropolymers is very unlikely. Because they are insoluble in water, there is no route of exposure to aquatic organisms. Even if there were an exposure pathway, the demonstrated low bioavailability and low surface activity are further indication of low risk. This is recognized by exemptions for testing in REACH Regulation: According to Annex VII entry 9.1.1, 9.1.2 and Annex VIII entry 9.1.3 and 9.1.4 REACH Regulation, short-term toxicity testing on invertebrates, algae, fish and activated sludge is not required *if mitigating factors indicate that aquatic toxicity is unlikely to occur, as for instance, if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes*.

Due to stability (see Section IV.1. below), degradation to substances with potential of aquatic toxicity is also not to be expected.

In the Restriction Proposal no information to the contrary can be found. With regard to the ecotoxicity of fluoropolymers, it is primarily referred to possible hazards from microplastics. However, this is not a substance-inherent hazard and should be handled separately (see already Section II in main document).

b) Human Health Effects

Based on a large body of data, human health effects are not to be expected from fluoropolymers like PTFE.

aa) Information Provided in Restriction Proposal

With regard to fluoropolymers, very little information is provided in the Restriction Proposal. Section B.5. of Annex B, references a few studies and the Dossier Submitters acknowledge the gaps in some of these studies.

As an additional point of reference, we would ask the DS to note that pre-clinical studies with various animal models over extended implantation durations have not demonstrated systemic toxicity of PTFE. PTFE-containing implantable medical devices have been on the market since 1975. It is estimated that there are now over 45 million PTFE-based Gore medical implants in patients worldwide and that number grows annually as new configurations are developed to serve new applications or supplant or improve upon existing technologies. Examinations of devices over protracted clinical implantation durations continue to affirm the biological safety of ePTFE as a biomaterial. The clinical history of the safe implantation of PTFE medical devices over 45 years, toxicity data, preclinical data, and chemical extractable testing confirm that fluoropolymers are not bioavailable and safe to use in their intended uses in implantable medical devices.

bb) Low Risk Potential

In general, fluoropolymers have a low hazard and low bioavailable exposure, and therefore, low-risk potential. This is mainly based on their molecular size and the resulting non-bioavailability (see Section 4 above). To be capable of producing systemic toxicity including carcinogenicity a substance needs to be bioavailable.

There are several publications speaking to the low human hazard as well. For example, Ebnesajjad (2013) stated that, “This family of plastics (fluoropolymers) has low toxicity and almost no toxicological activity. Fluoropolymers have not been known to cause skin sensitivity or irritation in humans.”

With respect to chronic toxicity in humans with PTFE implants, Brand and Brand (1980) investigated the incidence of foreign-body cancers associated with implantations and concluded that “*low number actually observed permits the prediction that the incidence of cancer at implantation sites will remain low*.” Similarly, Radulovic and Wojcinski (2014) conclude that “The lack of toxicity (of PTFE) is most likely due to the following: gastrointestinal absorption of PTFE is negligible given its extremely high molecular weight (1,000,000 – 10,000,000 for PTFE fine powder)” and that “PTFE is chemically inert under physiologic conditions, and PTFE is not metabolized.”

Also, the World Health Organization's International Agency for Research on Cancer concluded that "Organic polymeric materials (like fluoropolymers) as a group are not classifiable as to their carcinogenicity to humans (Group 3)," (WHO IARC, 1999).

cc) Data on PTFE, FEP and PFA

The understanding outlined above is confirmed by evidence in experimental animals proving proof of biocompatibility and lack of toxicity.

The biocompatibility is largely due to its relative inertness in physiologic environments (Ebnesajjad, 2013). A key component of the chemical structure of the polytetrafluoroethylene molecule is the presence of many carbon-fluorine bonds, one of the strongest chemical bonds known among organic compounds. Because the carbon backbone is protected by a fully fluorinated envelope, fluoropolymers resist attack by even the most highly corrosive chemicals and solvents precluding the possibility of chemical cleavage of the polymer chains *in vivo.* This effectively eliminates the possibility of chemical degradation *in vivo* to produce potentially toxic leachables. The resistance of PTFE to microbial degradation was documented in Guidoin et al., 1993 who noted that "PTFE was proven to have sufficient resistance to *in vivo* degradation…" (Guidoin et al., 2013).

For certain applications such as food, pharmaceutical, and medical devices, there are country-specific data requirements for fluoropolymers. For example, formal biocompatibility evaluations are required by the USFDA and other global regulatory authorities to support submissions for approval of medical devices and pharmaceuticals (e.g., combination products, such as drug-eluting stents or prefilled single-dose syringes). The *International Organization for Standardization (ISO) 10993 Biocompatibility of Medical Devices standards* describe a broad array of biocompatibility tests that require consideration for each new device or significant changes to existing devices (ISO 2009). Over the years, medical devices containing PTFE have been evaluated using ISO 10993 and US Pharmacopeia (USP) Class VI standards (USP 2016), and have been determined to be biocompatible in their intended uses.

The ISO 10993 standards are globally accepted standards which provide guidance for evaluation of the biological response to a medical device. The USFDA and most international regulatory agencies, recognize and use ISO 10993 standards to guide safety evaluations of medical devices submitted for their approval. Biocompatibility and regulatory authority-specific requirements of medical devices are set forth in ISO 10993-1, (e.g., PMDA 2003; USFDA 2016). See Henry *et al.*, 2018 for more details.

In the Supplement to Henry *et al.*, 2018 we first published the following tables of PTFE data from ISO 10993 and OECD guideline toxicity studies.

Table 2 Summary of GLP toxicological studies that confirm the non-toxic nature of PTFE, FEP and PFA

Study	Standard/Guideline	Result
In vitro Cytotoxicity	ISO 10993-5	Non-cytotoxic
In vivo skin sensitization	ISO 10993-10; OECD 406	Non-sensitizing
In vivo irritation	ISO 10993-23	Non-irritating
In vivo acute toxicity	ISO 10993-11	Not acutely toxic
In vivo subchronic toxicity	ISO 10993-6, ISO 10993-11	No adverse effects observed
In vivo and *in vitro* genotoxicity assays	ISO 10993-3	Non-genotoxic
In vivo implantation	ISO 10993-4, ISO 10993-6	No adverse effects observed
In vitro hemocompatibility assays	ISO 10993-4	Hemocompatible

Note: 90-Day Subchronic Toxicity Studies included hematology, urinalysis, clinical chemistry, gross pathology, microscopic histopathology, organ weights, clinical observations. Histopathology performed on: ovaries, testes, brain, heart, liver, kidneys, spleen, thymus, adrenal glands, lymph nodes.

PTFE

Fine powder PTFE, meeting the ASTM D4895 and OECD polymer of low concern criteria, in three physical forms (sheet (form A), fiber (form B), tube (form C)) was subjected to the ISO 10993-1 (Biological evaluation of medical devices – Part 1: Evaluation and testing) testing in compliance with Good Laboratory Practices (GLPs, 21 CFR, Part 58) at an accredited contract laboratory, NAMSA (Northwood, OH), in accordance with current ISO 10993 guidelines. All three physical forms of PTFE were manufactured, sterilized, and packaged using methods intended for commercial product. **The test results demonstrate the low toxicity and *in vivo* biocompatibility of PTFE.**

Final reports for these GLP studies from accredited contract laboratories have been provided in full to the fire-fighting foam restriction process in 2022 (see Annex VI)

Table A.3. PTFE Form A

Test Performed (Lab Report No.) (Date Completed) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article and Control(s)	Conclusions
In Vitro Cytotoxicity *MEM Elution Test* (12T_29147_03) (May/2012) ISO 10993-5 ISO 10993-12	Extraction: Minimum Essential Medium with 5% fetal bovine serum, 2% antibiotics, 1% L-glutamine. Conditions: 37 ºC, 24 hours. Extraction Ratio: 6 cm^2/mL Test system: Mouse fibroblast L-929 cells.	PTFE fiber, Code: SMR108316 Neg. Control = High density polyethylene (HDPE) Pos. Control = Powder-Free Latex Gloves	**PASS** – non cytotoxic Test article was not cytotoxic.
Delayed-Type Hypersensitivity *Kligman Maximization Test in Guinea Pigs* (12T_29147_06, 12T_29147_07) (June/2012) ISO 10993-10	Extraction: 0.9% NaCl; sesame oil. Conditions: 50 ºC, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE fiber, Code: SMR108316 Neg. Control = 0.9% NaCl, sesame oil Periodic Pos. Control = 1-chloro-2,4-dinitrobenzene (DNCB)	**PASS** - non-sensitizing All animals increased in weight, no signs of systemic toxicity, no reaction to challenge.
Irritation *Intracutaneous Irritation Study in Rabbits* (12T_29147_04, 12T_29147_05) (May/2012) ISO 10993-10	Extraction: 0.9% NaCl; sesame oil. Conditions: 50 ºC, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE fiber, Code: SMR108316 Neg. Control = 0.9% NaCl, sesame oil Pos. Control: N/A.	**PASS** – non-irritating No treatment-related signs of toxicity. The difference in the mean score for both test and control was ≤ 1 for both the NaCl and sesame oil test.
Systemic Toxicity *Acute Systemic Toxicity Study in Mice* (12T_29147_08, 12T_29147_09) (May/2012) ISO 10993-11	Extraction: 0.9% NaCl; sesame oil. Conditions: 50 ºC, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE fiber, Code: SMR108316 Neg. Control = 0.9% NaCl, sesame oil Pos. Control: N/A	**PASS** – not systemically toxic No treatment-related signs of toxicity or loss of body weight in any group.

Rabbit Pyrogen Study (Material Mediated) (12T_29147_10) (May/2012) ISO 10993-11 USP 151	Extraction: 0.9% NaCl. Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE fiber, Code: SMR108316 Neg. Control = 0.9% NaCl. Pos. Control: N/A	**PASS** – non-pyrogenic Body temperature increases were ‹ 0.5 °C for individual test animals and ‹ 3.3 °C for all treated animals.
<u>Genotoxicity</u> ***Bacterial Reverse Mutation Assay*** (12T_31264_03, 12T_31264_04) (May/2012) OECD Test No. 471 ISO 10993-3 ISO 10993-12	Extraction: 0.9% NaCl, dimethyl sulfoxide Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL Test system: *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537; *Escherichia coli* strain WP2uvrA.	PTFE fiber, Code: SMR108316 Neg. Control = vehicle only Pos. Control = Sodium azide, Methyl Methanesulfonate, Benzo[a]pyrene, 2-aminoanthracene, 2-Nitrofluorene, ICR-191	**PASS** – non mutagenic The test article extracts were not considered to be mutagenic.
Mouse Lymphoma Assay (12T_31264_05, 12T_31264_06) (July/2012) OECD Test No. 476 ISO 10993-3 ISO 10993-12	Extraction: RPMI culture medium, dimethyl sulfoxide Conditions: RPMI: 37 °C, 72 hours dimethyl sulfoxide: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL Test system: Mouse Lymphoma L5178Y/$TK^{+/-}$ cells	PTFE fiber, Code: SMR108316 Neg. Control = vehicle only Pos. Control = 3-Methylchol-anthrene, Methyl Methanesulfonate	**PASS** – non mutagenic The test article extracts did not induce gene mutations or chromosomal damage.
Mouse Peripheral Blood Micronucleus Study (12T_31264_07, 12T_31264_08) (June/2012) OECD Test No. 474 ISO 10993-3 ISO 10993-12	Extraction: 0.9% NaCl, Sesame Oil Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE fiber, Code: SMR108316 Neg. Control = 0.9% NaCl, Sesame Oil Pos. Control = Methyl methanesulfonate, 50 mg/kg	**PASS** – non mutagenic The test article extracts did not induce micronuclei formation.
<u>Local Effects after Implantation</u> ***Muscle Implantation Study in Rabbits (4 weeks)*** (12T_29147_11) (June/2012) ISO 10993-6	N/A	PTFE fiber, Code: SMR108316 Four 1×1×10 mm sections were implanted/rabbit. Neg. Control = HDPE. Four 1×1×10 mm sections were implanted/rabbit.	**PASS** - Non adverse No adverse effects were observed micro- or macroscopically. The test article was a non-irritant.

Hemocompatibility **Hemolysis Study** **Direct Contact and Indirect Contact** (12T_29147_13) (May/2012) ISO 10993-4 ISO 10993-12 ASTM F756 **Partial Thromboplastin Time, Direct Contact** (12T_29147_14) (May/2012) ASTM F2382 ISO 10993-12	Direct contact: The test article was introduced directly to test system at 6 cm^2/mL Indirect contact: Extraction: PBS Conditions: 50 °C for 72 hours. Test Article: extracted at 6 cm^2/mL No extraction. The test article was introduced directly to human plasma at 4 cm^2/mL	PTFE fiber, Code: SMR108316 Negative Control = HDPE Positive control = sterile water for injection PTFE fiber, Code: SMR108316 Negative Control = Polypropylene tube Positive Control = soda lime glass beads	**PASS** – Non-hemolytic. Direct contact: ≤ 2% hemolysis. Indirect contact: ≤ 2% hemolysis. **PASS** – No effect on coagulation. The average Partial Thromboplastin Time was 94% of the negative control.
Complement Activation **C3a Complement Activation Assay (Direct Contact)** (12T_29147_15) (May/2012) ISO 10993-4	No extraction. Test article was directly exposed to test system at a ratio of 6 cm^2/mL at 37 °C for 60 minutes.	PTFE fiber, Code: SMR108316 Negative Control = HDPE Negative Control = LDPE; Positive Controls = latex gloves, Cobra Venom Factor (CVF)	**PASS** – No activation of complement. The test article sample was not statistically higher ($p<0.05$) than both the activated human serum and negative controls.
SC5b-9 Complement Activation Assay (Direct Contact) (12T_29147_16) (May/2012) ISO 10993-4	No extraction. Test article was directly exposed to test system at a ratio of 6 cm^2/mL at 37 °C for 60 minutes.	PTFE fiber, Code: SMR108316 Negative Control = HDPE Negative Control = LDPE; Positive Controls = latex gloves, CVF	**PASS** – No activation of complement. The test article sample was not statistically higher ($p<0.05$) than both the activated human serum and negative controls.
Subchronic toxicity ***13-Week Systemic Toxicity Study in Rats*** (12T_29147_12) (September /2012) OECD Test No. 408 ISO 10993-11	N/A	PTFE fiber, Code: SMR108316 Test Article Dose: 90 linear cm/rat. Based upon an average male 250 g rat (i.e., 360 cm/kg), which is equivalent to a 70 kg patient receiving 25,200 linear cm. Neg. Control = HDPE	**PASS** – There were no clinical or systemic signs of toxicity (including gross-, microscopic-, and clinical-pathology evaluations). The test article was considered a non-irritant.

Table A.4. PTFE Form B

Test Performed (Lab Report #) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article and Control(s)	Conclusions
***In Vitro* Cytotoxicity** **L929 MEM Elution Test** Completed April4/2012 12T_28380_03 ISO 10993-5 ISO 10993-12	Test article was extracted at a ratio of 6cm^2/ml in 1X MEM media + 5% FBS + 2% antibiotics at 37 °C for 24 hours. Test system: Mouse fibroblast L-929 cells	Test article name: VT6 Lot: SMR108669 Negative Controls = HDPE, 1X MEM Positive Control = Powder-free latex gloves	**PASS** – non cytotoxic Test article was not cytotoxic.
Delayed-Type Hypersensitivity **Kligman Maximization Test in Guinea Pigs** Completed June/2012 12T_28380_06 12T_28380_07 ISO 10993-10	Test article was extracted at a ratio of 6cm^2/ml in 0.9% USP NaCl and sesame oil at 50 °C for 72 hours.	Test article name: VT6 Lot: SMR108669 Negative Controls = 0.9% USP NaCl, sesame oil; Positive Control = Dinitrochlorobenzene.	**PASS –** non-sensitizing All animals increased in weight, no signs of systemic toxicity, no reaction to challenge.
Irritation **ISO Intracutaneous Study in Rabbits** Completed May/2012 12T_28380_04 12T_28380_05 ISO 10993-10	Test article was extracted at a ratio of 6cm^2/ml in 0.9% USP NaCl and sesame oil at 50 °C for 72 hours.	Test article name: VT6 Lot: SMR108669 Negative Controls = 0.9% USP NaCl, sesame oil; Positive Control: N/A.	**PASS** – non-irritating No treatment-related signs of toxicity. The difference in the mean score for both test and control was ≤ 1 for both the NaCl and sesame oil test.

Test Performed (Lab Report #) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article and Control(s)	Conclusions
Systemic Toxicity **Acute Systemic Toxicity Study in Mice** Completed May/2012 12T_28380_08 12T_28380_09 ISO 10993-11	Test article was extracted at a ratio of 6cm^2/ml in 0.9% USP NaCl and sesame oil at 50 °C for 72 hours.	Test article name: VT6 Lot: SMR108669 Negative Control = 0.9% USP NaCl, sesame oil; Positive Control: N/A	**PASS** – not systemically toxic No treatment-related signs of toxicity or loss of body weight in any group.
Rabbit Pyrogen Study (Material-Mediated) Completed April/2012 12T_28380_10 ISO 10993-11 USP 151	Test article was extracted at a ratio of 6cm^2/ml in 0.9% USP NaCl at 50 °C for 72 hours.	Test article name: VT6 Lot: SMR108669 Negative Control = 0.9% USP NaCl; Positive Control: N/A.	**PASS** – non-pyrogenic Body temperature increases were < 0.5 °C for individual test animals and < 3.3 °C for all treated animals.

Test Performed (Lab Report #) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article and Control(s)	Conclusions
Subchronic Toxicity **13-Week Systemic Toxicity Study in Rats via subcutaneous implantation** Completed September/2012 12T_28380_12 ISO 10993-11 OECD 408	No extraction: Test article was directly implanted in each animal as 1cm x 2cm sections (0.07g each) at 6 sites (corresponding to 1.68g material/kg body weight). This corresponds to approximately 87% of what occurs in a worst-case clinical scenario; implantation of more material was not surgically practical.	Test article name: VT6 Lot: SMR108669 Neg. Control = HDPE Pos. Control = N/A	**PASS** – There were no clinical or systemic signs of toxicity (including gross-, microscopic-, and clinical-pathology evaluations). The test article was considered a non-irritant.
Genotoxicity **Bacterial Reverse Mutation Assay** Completed May/2012 12T_30064_02 12T_30064_03 OECD 471 ISO 10993-3 ISO 10993-12	Test article was extracted at a ratio of $6cm^2$/ml in 0.9% USP NaCl and dimethyl sulfoxide (DMSO) at 50 ºC for 72 hours. A dose range finding study was also performed that used test article extracted at a ratio of $6cm^2$/ml in DMSO at 50 ºC for 72 hours. Test systems: *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537; *Escherichia coli* strain WP2uvrA.	Test article name: VT6 Lot: SMR108669 Negative Controls = 0.9% USP NaCl, DMSO; Positive Controls = Sodium azide, methyl methanesulfonate (MMS), 2-aminoanthracene, benzo[a]pyrene, 2-nitrofluorene, ICR-191.	**PASS** – non mutagenic The test article extracts were not considered to be mutagenic.
Mouse Lymphoma Assay Completed June/2012 12T_30064_04 12T_30064_05 OECD 476 ISO 10993-3 ISO 10993-12	Test article was extracted at a ratio of $6cm^2$/ml in serum free cell culture media ($RPMI_0$) at 37 ºC for 72 hours; test article was extracted at a ratio of $6cm^2$/ml in DMSO at 50 ºC for 72 hours. Test system: Mouse Lymphoma L5178Y/$TK^{+/-}$ cells	Test article name: VT6 Lot: SMR108669 Negative Controls = DMSO, $RPMI_0$. Positive Controls = MMS, 3-methylcholanthrene.	**PASS** – non mutagenic The test article extracts did not induce gene mutations or chromosomal damage.

Test Performed (Lab Report #) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article and Control(s)	Conclusions
Mouse Peripheral Blood Micronucleus Study Completed May/2012 12T_30064_06 12T_30064_07 OECD 474 ISO 10993-3 ISO 10993-12	Test article was extracted at a ratio of 6cm^2/ml in 0.9% USP NaCl and sesame oil at 50 °C for 72 hours.	Test article name: VT6 Lot: SMR108669 Negative Control = 0.9% USP NaCl, sesame oil; Positive Control =MMS, 50mg/kg	**PASS** – non mutagenic The test article extracts did not induce micronuclei formation.
Local Effects after Implantation **Muscle Implantation Study in Rabbits, 4 weeks** Completed June/2012 12T_28380_11 ISO 10993-6	No extraction. 10mm x 1mm x 1mm sections of the test article representative of all materials in the device were implanted directly into the test system.	Test article name: VT6 Lot: SMR108669 Negative Control = HDPE; Positive Control = N/A	**PASS –** Non adverse No adverse effects were observed micro- or macroscopically. The test article was a non-irritant.
Hemocompatibility **Hemolysis-Rabbit Blood (Direct and Indirect Contact)** Completed April/2012 12T_28380_13 ISO 10993-4 ISO 10993-12 ASTM F756	Test article was directly exposed to test system at a ratio of 6cm^2/ml for the direct contact test; for the indirect contact test, test article was extracted at a ratio of 6cm^2/ml in Ca- and Mg-free phosphate buffered saline at 50 °C for 72 hours.	Test article name: VT6 Lot: SMR108669 Negative Control = High density polyethylene. Positive control = Sterile H_2O for injection	**PASS** – Non-hemolytic. Direct contact: ≤ 2% hemolysis. Indirect contact: ≤ 2% hemolysis.

Test Performed (Lab Report #) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article and Control(s)	Conclusions
Partial Thromboplastin Time Assay **(Direct Contact)** Completed April/2012 12T_28380_14 ISO 10993-4 ISO 10993-12 ASTM F2382	No extraction. Test article was directly exposed to human plasma at a ratio of 4.0cm^2/ml at 37 °C for 15 minutes.	Test article name: VT6 Lot: SMR108669 Negative Control = Polypropylene tube Positive Controls = Soda lime glass beads	**PASS** – No effect on coagulation. The average Partial Thromboplastin Time was 84% of the negative control.
C3a Complement Activation Assay **(Direct Contact)** Completed April/2012 12T_28380_15 ISO 10993-4	No extraction. Test article was directly exposed to test system at a ratio of 6cm^2/ml at 37 °C for 60 minutes.	Test article name: VT6 Lot: SMR108669 Negative Control = LDPE; Positive Controls = latex gloves, Cobra Venom Factor (CVF)	**PASS** – No activation of complement. The test article sample was not statistically higher ($p<0.05$) than both the activated human serum and negative controls.
SC5b-9 Complement Activation Assay **(Direct Contact)** Completed April/2012 12T_28380_16 ISO 10993-4	No extraction. Test article was directly exposed to test system at a ratio of 6cm^2/ml at 37 °C for 60 minutes.	Test article name: VT6 Lot: SMR108669 Negative Control = LDPE; Positive Controls = latex gloves, CVF	**PASS** – No activation of complement. The test article sample was not statistically higher ($p<0.05$) than both the activated human serum and negative controls.

Note: VT6 = PTFE tube

Table A.5. PTFE Form C

Test Performed (Lab Report No.) (Date Completed) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article[a] and Control(s)	Conclusions
In Vitro Cytotoxicity ***MEM Elution Test*** (12T_2724_03) (April/2012) ISO 10993-5 ISO 10993-12	Extraction: Minimum Essential Medium with 5% fetal bovine serum, 2% antibiotics, 1% L-glutamine. Conditions: 37 °C, 24 hours. Extraction Ratio: 6 cm^2/mL Test system: Mouse fibroblast L-929 cells.	PTFE patch, Code: SMR108314 Neg. Control = High density polyethylene (HDPE) Pos. Control = Powder-Free Latex Gloves	**PASS** – non cytotoxic Test article was not cytotoxic.
Delayed-Type Hypersensitivity ***Kligman Maximization Test in Guinea Pigs*** (12T_2724_13, 12T_2724_14) (June/2012) ISO 10993-10	Extraction: 0.9% NaCl; sesame oil. Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE patch, Code: SMR108314 Neg. Control = 0.9% NaCl, sesame oil Pos. Control = 1-chloro-2,4-dinitrobenzene (DNCB)	**PASS –** non-sensitizing All animals increased in weight, no signs of systemic toxicity, no reaction to challenge. One (sesame oil, Test group) animal (#6256) was euthanized on day 26. Necropsy revealed a broken left rear leg. No evidence of sensitization was observed in the sesame oil group; therefore, the loss of this animal did not impact the conclusion.

Irritation ***Intracutaneous Irritation Study in Rabbits*** (12T_2724_06, 12T_2724_07) (May/2012) ISO 10993-2 ISO 10993-10 ISO 10993-12	Extraction: 0.9% NaCl; sesame oil. Conditions: 50 ºC, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE patch, Code: SMR108314 Neg. Control = 0.9% NaCl, sesame oil Pos. Control: N/A.	**PASS** – non-irritating No treatment-related signs of toxicity. The difference in the mean score for both test and control was ≤ 1 for both the NaCl and sesame oil test.
Systemic Toxicity ***Acute Systemic Toxicity Study in Mice*** (12T_2724_04, 12T_2724_05) (May/2012) ISO 10993-2 ISO 10993-11 ISO 10993-12	Extraction: 0.9% NaCl; sesame oil. Conditions: 50 ºC, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE patch, Code: SMR108314 Neg. Control = 0.9% NaCl, sesame oil Pos. Control: N/A	**PASS** – not systemically toxic No treatment-related signs of toxicity or loss of body weight in any group.
Rabbit Pyrogen Study (Material Mediated) (12T_2724_12) (May/2012) ISO 10993-11 USP 151	Extraction: 0.9% NaCl. Conditions: 50 ºC, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE patch, Code: SMR108314 Neg. Control = 0.9% NaCl. Pos. Control: N/A	**PASS** – non-pyrogenic Body temperature increases were ‹ 0.5 ºC for individual test animals and ‹ 3.3 ºC for all treated animals.
Genotoxicity ***Bacterial Reverse Mutation Assay*** (12T_30255_03, 12T_30255_04) (May/2012) OECD Test No. 471 ISO 10993-3 ISO 10993-12	Extraction: 0.9% NaCl, dimethyl sulfoxide Conditions: 50 ºC, 72 hours. Extraction Ratio: 6 cm^2/mL Test system: *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537; *Escherichia coli* strain WP2uvrA.	PTFE patch, Code: SMR108314 Neg. Control = vehicle only Pos. Control = Sodium azide, Methyl Methanesulfonate, Benzo[a]pyrene, 2-aminoanthracene, 2-Nitrofluorene, ICR-191	**PASS** – non mutagenic The test article extracts were not considered to be mutagenic.

Mouse Lymphoma Assay (12T_30255_05, 12T_30255_06) (June/2012) OECD Test No. 476 ASTM E1280 ISO 10993-3 ISO 10993-12 ***Mouse Peripheral Blood Micronucleus Study*** (12T_30255_07, 12T_30255_08) (June/2012) OECD Test No. 474 ISO 10993-3 ISO 10993-12	Extraction: RPMI culture medium, dimethyl sulfoxide Conditions: RPMI: 37 °C, 72 hours dimethyl sulfoxide: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL Test system: Mouse Lymphoma L5178Y/$TK^{+/-}$ cells Extraction: 0.9% NaCl, Sesame Oil Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE patch, Code: SMR108314 Neg. Control = vehicle only Pos. Control = 3-Methylchol-anthrene, Methyl Methanesulfonate PTFE patch, Code: SMR108314 Neg. Control = 0.9% NaCl, Sesame Oil Pos. Control = Methyl methanesulfonate, 50 mg/kg	**PASS** – non mutagenic The test article extracts did not induce gene mutations or chromosomal damage. **PASS** – non mutagenic The test article extracts did not induce micronuclei formation.
<u>Local Effects after Implantation</u> ***Muscle Implantation Study in Rabbits (4 weeks)*** (12T_2724_15) (June/2012) ISO 10993-6	N/A	PTFE patch, Code: SMR108314 Four 1×1×10 mm sections were implanted/rabbit. Neg. Control = HDPE. Four 1×1×10 mm sections were implanted/rabbit. Pos. Control: N/A	**PASS** – Non adverse No adverse effects were observed micro- or macroscopically. The test article was a non-irritant.
<u>Hemocompatibility</u> **Hemolysis Study Direct Contact and Indirect Contact** (12T_2724_11) (April/2012) ISO 10993-4 ISO 10993-12 ASTM F756	Direct contact: The test article was introduced directly to test system at 6 cm^2/mL Indirect contact: Extraction: PBS Conditions: 50 °C for 72 hours.	PTFE patch, Code: SMR108314 Negative Control = HDPE Positive control = sterile water for injection	**PASS** – Non-hemolytic. Direct contact: ≤ 2% hemolysis. Indirect contact: ≤ 2% hemolysis.

	Test Article: extracted at 6 cm^2/mL		
Partial Thromboplastin Time, Direct Contact (12T_2724_08) (May/2012) ASTM F2382 ISO 10993-12	No extraction. The test article was introduced directly to human plasma at 4 cm^2/mL	PTFE patch, Code: SMR108314 Negative Control = Polypropylene tube Positive Control = soda lime glass beads	**PASS** – No effect on coagulation. The average Partial Thromboplastin Time (PTT) was 75% of the negative control.
Complement Activation **C3a Complement Activation Assay (Direct Contact)** (12T_2724_09) (May/2012) ISO 10993-4	No extraction. Test article was directly exposed to test system at a ratio of 6 cm^2/mL at 37 °C for 60 minutes.	PTFE patch, Code: SMR108314 Negative Control = HDPE, LDPE Positive Controls = latex gloves, Cobra Venom Factor (CVF)	**PASS** – No activation of complement. The test article sample was not statistically higher ($p<0.05$) than both the activated human serum and negative controls.
SC5b-9 Complement Activation Assay (Direct Contact) (12T_2724_10) (May/2012) ISO 10993-4	No extraction. Test article was directly exposed to test system at a ratio of 6 cm^2/mL at 37 °C for 60 minutes.	PTFE patch, Code: SMR108314 Negative Control = HDPE, LDPE Positive Controls = latex gloves, CVF	**PASS** – No activation of complement. The test article sample was not statistically higher ($p<0.05$) than both the activated human serum and negative controls.
Subchronic toxicity ***13-Week Systemic Toxicity Study in Rats*** (12T_2724_16) (October/2012) ISO 10993-6 ISO 10993-11	N/A	PTFE patch, Code: SMR108314 Test Article Dose: 6, 1 mm x 1 cm x 2cm pieces per animal was the maximum implant in this subcutaneous rat model. Neg. Control = HDPE Pos. Control = N/A	**PASS** – There were no clinical or systemic signs of toxicity (including gross-, microscopic-, and clinical-pathology evaluations). The test article was considered a non-irritant.

FEP

The tests were also conducted for fluorinated ethylene propylene (FEP). The results which also demonstrate the low toxicity and biocompatibility, are presented in the table below and have also been provided to the fire-fighting foam restriction process in 2022 (see Annex VI).

Table A.6. Biocompatibility Tests, Conditions, and Conclusions for FEP

Test Performed (Lab Report No.) (Date Completed) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article* And Control(s)	Conclusions
In Vitro* Cytotoxicity** ***Cytotoxicity Study Using ISO Elution Method (12T-49383-03) (November/2012) ISO 10993-5	Extraction: Minimum Essential Medium with 5% fetal bovine serum, 2% antibiotics (penicillin, streptomycin, amphotericin B) and 1% (2mM) L-glutamine Conditions: 37 °C, 48 hrs. Extraction Ratio: 6 cm^2/mL Test System: Mouse Fibroblast L-929 Cells	PTFE, FEP, silicone Neg Control = High density polyethylene (HDPE) Pos. Control = Powder-free Latex Gloves	**PASS** – non cytotoxic Test article was not cytotoxic
Delayed-Type Hypersensitivity ***Kligman Maximization Test in Guinea Pigs*** (12T-49383-14, 12T-49383-15 (January/2013) ISO 10993-10	Extraction: 0.9% NaCl, Sesame oil Conditions: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL	PTFE, FEP, silicone Neg. Control = 0.9% NaCl, Cottonseed Oil Pos. Control = Dinitrochlorobenzene (DNCB)	**PASS** – non-sensitizing All animals increased weight, with no signs of systemic toxicity, nor reaction on challenge were observed.

Irritation ***Intracutaneous Rabbit Study*** (12T-49383-06, 12T-49383-07) (November/2012) ISO 10993-10	Extraction: 0.9% NaCl, Sesame Oil Conditions: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL	PTFE, FEP, silicone Neg. Control = 0.9% NaCl, Sesame Oil Pos. Control =N/A	**PASS** – No difference between the test extract overall mean score and the corresponding control overall mean score was observed for both NaCl and Sesame Oil extracts
Systemic Toxicity ***Acute Systemic toxicity in Mice*** (12T-49383-04, 12T-49383-05) (October/2012) ISO 10993-11	Extraction: 0.9% NaCl, Sesame oil Conditions: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL	PTFE, FEP, silicone Neg. Control = 0.9% NaCl, Sesame Oil Pos. Control = N/A	**PASS –** None of the animals treated with the test extract exhibited a significantly greater reaction than the control animals.
Rabbit Pyrogen Test (Material Mediated) (97G-2330) (December/1997) ISO 19003-11	Extraction: 0.9% NaCl Conditions: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL	PTFE, FEP, silicone Neg. Control = 0.9% NaCl Pos. Control = N/A	**PASS –** non-pyrogenic Body temperature increases were <0.5 °C and summed <3.3 °C for all treated animals
Subchronic Toxicity ***13-Week Systemic Toxicity Study in Rats Following Subcutaneous Implantation*** (12T-49383-16) (March/2013) ISO 10993-11 ISO 10993-6	N/A	PTFE, FEP, silicone 15x3x1mm Neg. Control = High density polyethylene 20x10x1mm 15x3x1mm 10x1mm discs Pos. Control = N/A	**PASS** – No evidence of systemic toxicity, including gross, microscopic, and clinical pathology evaluations. The test article was considered a non-irritant.

Genotoxicity ***Mouse Lymphoma Assay*** (12T-52351-03, 12T-52351-04) (January/2013) ISO 10993-3	Extraction: Serum-free culture medium ($RPMI_0$), Dimethylsulfoxide (DMSO) Conditions: 37 °C, 72 hours ($RPMI_0$) 50 °C, 72 hours (DMSO) Extraction Ratio: 6 cm^2/mL Test system: Mouse Lymphoma L5178Y ($TK^{+/-}$) cells	PTFE, FEP, Silicone Neg. Control = $RPMI_0$ medium, Dimethylsulfoxide (DMSO) Pos. Control = Methylmethane sulfonate (MMS), 3-methylcholanthrene (3-MCA)	**PASS** – non-mutagenic The test article extract was not considered mutagenic
Bacterial Reverse Mutation Study (12T-52351-01, 12T-52351-02) (December/2012) ISO 10993-3	Extraction: DMSO, 0.9% NaCl Conditions: 50 °C, 72 hours Extraction Ratio: 6cm^2/mL	PTFE, FEP, silicone Neg. Control = Dimethylsulfoxide (DMSO) Pos. Control = sodium azide, methyl methanesulfonate, 2-aminoeanthracene, benzo[a]pyrene, 2-nitrofluorene, ICR-191	**PASS** – non-mutagenic The test article extract was not considered mutagenic.
Local Effects after Implantation ***Muscle Implantation Study in Rabbits (4 Weeks)*** (12T-49383-13) (January/2013) ISO 10993-4 ISO 10993-6	N/A	PTFE, FEP, Silicone Neg Control = USP High density polyethylene 1x1x10mm sections were implanted in rabbit Pos Control = N/A	**PASS** – No adverse effects were observed micro or macroscopically. The test article was a non-irritant. The difference between the average scores for all categories of biological reaction for the test article and control article implants sites were <1, and the difference between mean scores for test article and control article sites was <1.

Hemocompatibility ***Partial Thromboplastin Time*** (12T-49383-11) (November/2012) ISO 10993-4	Extraction: Human plasma Conditions: 37 °C, 15 minutes Extraction Ratio: 4 cm^2/mL	PTFE, FEP, silicone Neg Control = Human plasma Pos Control = Glass beads	**PASS –** Test article was considered a minimal activator
Hemolysis Study ***Direct Contact and Indirect Contact*** (12T-49383-12) (November/2012) ISO 10993-4	Extraction: Calcium and magnesium-free phosphate buffered saline (CMF-PBS) Conditions: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL	PTFE, FEP, silicone Neg. Control = High density polyethylene (HDPE) Pos Control = Sterile Water for Injection (SWFI)	**PASS –** Both the test article in direct contact with blood and the test article extract were non-hemolytic (0.0%)
Complement Activation ***C3a Complement Activation Assay*** (12T-20497-05) (February/2012) ISO 10993-4	Extraction: Normal Human Serum (NHS) Conditions: 37 °C, 1 hour Extraction Ratio: 6 cm^2/mL	PTFE, FEP, silicone Neg Control: LDPE, Inactivated Normal Human Serum Control Pos Control: Cobra Venom Factor (CVF)	**PASS** – Overall, the C3a concentrations obtained for the test article were within the historic range of the activated NHS control and negative control, although the C3a concentrations obtained for the test article were statistically higher than both the activated NHS and negative controls in this experiment.

SC5b-9 Complement Activation Assay (12T-49383-09) (November/2012) ISO 10993-4	Extraction: Normal Human Serum Conditions: 37 °C, 1 hour Extraction Ratio: 6 cm^2/mL	PTFE, FEP, Silicone Neg Control: Normal Human Serum, Low Density Polyethylene Pos Control: Cobra Venom Factor	**PASS –** Overall, although the SC5b-9 in the test sample was statistically higher than both the activated NHS and negative controls in this study, the concentration of SC5b-9 in the test article sample was less than the historical range of activated NHS and negative controls. Therefore, the test article was considered a low potential activator of the complement system.

PFA

The tests were also conducted for a tetrafluoroethylene copolymer with perfluoroalkyl vinyl ethers known as a perfluoroalkoxy polymer, or PFA. The results which also demonstrate the low toxicity and biocompatibility of PFA, are presented in the table below with final reports also provided as comments to the fire-fighting foam restriction process in 2022 (see Annex VI). Note that PFA is labeled as PATT in this table and in the final reports also provided in the Non-confidential Attachment.

Table A.7. Biocompatibility Tests, Conditions, and Conclusions for PFA

Test Performed (Lab Report No.) (Date Completed) Testing Guideline(s)	**Extraction Vehicle(s)** **Conditions**	**Test Article* And Control(s)**	**Conclusions**
***In Vitro* Cytotoxicity** **MEM Elution Test**	Extraction: Minimum Essential Medium with 10% serum, 292 mg/l L-glutamine, 2.3 g/l	PATT	**PASS –** non cytotoxic Test article was not cytotoxic

(MEM97-342-21, A097-342-20, MEM99-193-2) (December/1997) (A099-193-3) (September/1999) ISO 10993-5 (MEM99-193-2) (July/1999) ISO 10993-5	sodium bicarbonate, 3.6 g/l HEPES and gentamycin 100 ug/m Conditions: 37 °C, 24-30hrs Extraction Ratio: 6 cm^2/mL Test System: Mouse Fibroblast L-929 Cells Extraction: Minimum Essential Medium with 10% serum, 292 mg/l L-glutamine, 2.3 g/l sodium bicarbonate, 3.6 g/l HEPES and gentamycin 100 ug/m Conditions: 37 °C, 72-75 hours Extraction Ratio: 6 cm^2/mL Test System: Mouse Fibroblast L-929 Cells	Neg Control = Minimum Essential Medium Test Media Pos. Control = Thermolite in PTFE	
Delayed-Type Hypersensitivity ***Kligman Maximization Test in Guinea Pigs*** (00-4477-G1, 00-4477-G2 00-4478-G1, 00-4478-G2) (November/2000) ISO 10993-10 (97G-2331) (January/1998) ISO 10993-10	Extraction: 0.9% NaCl, Cottonseed oil Conditions: 70 °C, 24 hours Extraction Ratio: 6 cm^2/mL	Name: PATT Neg. Control = 0.9% NaCl, Cottonseed Oil Pos. Control = 0.1% Dinitrochlorobenzene (DNCB)	**PASS** – non-sensitizing All animals increased weight, with no signs of systemic toxicity, nor reaction on challenge were observed**.**

Irritation ***Intracutaneous Irritation Study in Rabbits*** (99-2325-G1, 99-2327-G1) (December/1999) ISO 10993-23 (97G-2384) (January 1998) ISO 10993-23 (96-0692) March/1996 ISO 10993-23	Extraction: 0.9% NaCl, Cottonseed Oil, 1:20 Ethanol in NaCl and Polyethylene Glycol Conditions: 70 °C, 24 hours Extraction Ratio: 6 cm^2/mL	PATT Neg. Control = 0.9% NaCl, Cottonseed Oil, 1 in 20 Ethanol 0.9% NaCl; Polyethylene Glycol 400 (PEG) Pos. Control = N/A	**PASS –** No significant signs of erythema or edema were observed at any of the test or control article sites. All animals increased weight. The difference in mean reaction scores (erythema/edema) was <1 for all extracts.
Systemic Toxicity ***Acute Systemic Toxicity Study in Mice*** (99-2325-G1, 99-2327-G1) (December/1999) ISO 10993-11 (96-0692) March/1996 ISO 10993-11 (97G-2383) January/1998 ISO 10993-11	Extraction: 0.9% NaCl, Cottonseed Oil, 1:20 Ethanol in NaCl and Polyethylene Glycol Conditions: 70 °C, 24 hours Extraction Ratio: 6 cm^2/mL	PATT Neg. Control = 0.9% NaCl, Cottonseed Oil, 1 in 20 Ethanol 0.9% NaCl; Polyethylene Glycol 400 (PEG) Pos. Control = N/A	**PASS –** No animals showed overt signs of toxicity at any observation point. No significantly greater biological reaction in the animals treated with control articles was observed. All animals increased in weight.

Rabbit Pyrogen Test (Material Mediated) (97G-2330) December 1997 ISO 10993-11	Extraction: 0.9% NaCl Conditions: 37 °C, 72 hours Extraction Ratio: 1 g/5 mL	PATT Neg. Control = 0.9% NaCl Pos. Control = N/A	**PASS –** non-pyrogenic Body temperature increases were <0.5 °C and summed <3.3 °C for all treated animals
Subchronic Toxicity **13-Week Systemic Toxicity Study in Rats; Subcutaneous Implantation** (12T-20497-03) (June/2012) ISO 10993-6 ISO 10993-11	N/A	PATT Test article = 1.2 cm sections, implanted Neg. Control = High Density Polyethylene (HDPE) 1 x 1 x 12 mm sections	**PASS** – No evidence of systemic toxicity, including gross, microscopic, and clinical pathology evaluations). The test article was considered a non-irritant.
Chronic Toxicity **2 Year Systemic Toxicity Study in Rabbits; Subcutaneous Implantation** (June/1997)	N/A	PATT (0.25 mm thick), silicone rubber (0.25 mm thick)	**PASS** – No evidence of systemic toxicity, minimal foreign-body tissue response, no evidence of inflammation or calcification
Genotoxicity ***Mouse Bone Marrow Micronucleus Assay*** (97G-2367, 97G-2368) (May/1998) ISO 10993-3	Extraction: Cottonseed Oil, 0.9% NaCl Conditions: 37 °C, 72 hours Extraction Ratio: 6cm^2/mL	PATT Neg. Control = Cottonseed Oil Pos. Control = Mitomycin C	**PASS –** Non-mutagenic The test article extract did not induce gene mutations

(00-2092-G2, 00-2093-G2) (July/2000) ISO 10993-3			
Bacteria Reverse Mutation Assay (97G-2365) (December/1997) ISO 10993-3 (99G-0681) (April/1999) ISO 10993-3 (00-2091-G1, 00-2093-G1) (July/2000) ISO 10993-3	Extraction: DMSO, 0.9% NaCl Conditions: 37 °C, 72 hours Extraction Ratio: 6cm^2/mL	PATT Neg. Control = Dimethylsulfoxide (DMSO) Pos. Control = 2-Aminoanthracene, Sodium Azide, 2-Nitrofluorene, 9-Aminoacridine, 1-Ethyl-3-Nitro-1-Nitrosoguanidine (ENNG)	**PASS** – non-mutagenic The test article extract was not considered mutagenic.
Mouse Lymphoma Mutagenesis Assay (00-2093-G3, 00-2092-G3) (July/2000) ISO 10993-3 (97G-2369, 97G-2370) (March/1998) ISO 10993-3	Extraction: Fischer's Cell Culture Medium, Dimethylsulfoxide (DMSO) Conditions: 37 °C, 72 hours Extraction Ratio: 6cm^2/mL Test system: Mouse Lymphoma L5178Y ($TK^{+/-}$) cells	PATT Neg. Control = Fischer's Cell culture medium, or Dimethylsulfoxide (DMSO) Pos. Control = Dimethyl benzanthracene (DMBA), Ethylmethane sulfonate (EMS)	**PASS** – non-mutagenic The test article extract was not considered mutagenic

Local Effects after Implantation ***Intramuscular implantation in rabbits (2 weeks)*** (99-2325-G1, 99-2327-G1) (December/1999) ISO 10993-4 ISO 10993-6 96-0693 (Apr/1996) USP 23, NF 18, 1995 ISO 10993-4 ISO 10993-6 (07-5345-G1) (February/2008) ISO 10993-4 ISO 10993-6 ***(1 week)*** (96-0692) (March/1996) ISO 10993-4 ISO 10993-6	N/A	Four 1 x 1 x 10 mm PATT sections were implanted/rabbit Neg. control = Negative Control Plastic, or Negative Control High Density Polyethylene (1 x 1 x 10 mm sections) were implanted/rabbit Pos. Control: N/A	**PASS** – No adverse effects were observed micro or macroscopically. The test article was a non-irritant. The difference between the average scores for all categories of biological reaction for the test article and control article implants sites were <1, and the difference between mean scores for test article and control article sites was <1.

Subchronic Subcutaneous implantation in rabbits (2 weeks, 1 month, 3 months, 6 months, 12 months) ISO 10993-6	N/A	PATT (92-122 µm thick), PTFE (80-211 µm thick) silicone rubber (85-166 µm thick)	**PASS** – no adverse effects were observed. No evidence of foreign-body tissue response. Inflammation associated with healing was observed at 2 weeks but subsided with minimal fibrosis. Calcification observed at 12-months.
Chronic Subcutaneous Implantation in rabbits (3, 6, 12 months) ISO 10993-6	N/A	PATT (205-282 µm thick), silicone rubber (208-362 µm thick)	**PASS –** no adverse effects were observed. Minimal foreign-body tissue response, with no evidence of inflammation. No evidence of calcification was observed.
Prothrombin Time Assay (99-2326-G1, 99-2327-G4, 99-2325-G4) (October/1999) ISO 10993-4	Extraction: 0.9% NaCl Conditions: 70 °C, 24 hours Extraction Ratio: 6 cm^2/mL	PATT Neg Control = 0.9% NaCl, Negative Control Plastic Pos Control = Oxalic Acid	**PASS** – There was no significant difference in Prothrombin Time relative to the untreated and negative control
Hemolysis – Rabbit Blood (97G-2329) (December/1997) ISO 10993-4 (12T-20497-04) (February/2012) ASTM F756 ISO 10993-4	N/A	PATT Neg. Control = 0.9% NaCl Pos Control = Water for Injection, USP PTAU (PATT+Gold) Neg Control = High density polyethylene (HDPE) Pos Control = Sterile Water for Injection, USP	**PASS –** The test article demonstrated ≤5% hemolysis.

Complement Activation ***SC5b-9 Complement Activation Assay*** (99-2327-G2, 99-2325-G2) (October/1999) ISO 10993-4 (97-G-2371) (January/1998) ISO 10993-4 (12T-20497-06) (February/2012) ISO 10993-4	Extraction: 0.9% NaCl, Normal Human Serum Conditions: 70 °C, 24 hours, 37 °C, 1 hour Extraction Ratio: 6 cm^2/mL	PATT Neg Control = Negative Control Plasma, Untreated Plasma, Low Density Polyethylene Pos. Control = Cellulose Acetate, Cobra Venom Factor	**PASS –** No increased in C3a or SC5b-9was observed when compared to the untreated plasma and the negative control.

Note the chronic duration of the implantation studies with PFA resulted in no evidence of systemic toxicity, minimal foreign-body tissue response, and no evidence of inflammation or calcification.

IV. RESISTANCE TO DEGRADATION

In this section, we would like provide data to demonstrate that fluoropolymers like PTFE do not degrade under relevant environmental conditions.

1. Environmental Fate Testing of PTFE by Charles River Laboratories

The standard environmental fate studies performed on PTFE by Charles River Laboratories demonstrate lack of degradation/transformation to low molecular weight substances, e.g., perfluoroalkyl substances. PTFE does not degrade in oxygen[47], UV light (unaudited preliminary report, OECD 316), water and seawater (OECD 105, 306), or under relevant environmental temperatures (OECD 102, 113). The resistance of PTFE to microbial degradation was already documented in Guidoin et al., 1993 who noted that "PTFE was proven to have sufficient resistance to *in vivo* degradation [...]," (Guidoin et al., 2013). Biotic stability was confirmed by Charles River Laboratories (OECD 301B,302C). Non-biodegradability, inertness, and non-inhibition in activated sludge was also confirmed by Charles River Laboratories (unaudited preliminary report, OECD301F).

2. Data on GORE® TENARA® Sewing Thread

To further support the stability of PTFE, we would like to share simulation of environmental conditions and real-world ageing of our product GORE® TENARA® Sewing Thread.

TENARA® Sewing Thread is made of expanded polytetrafluorethylene (ePTFE) which is used in outdoor, marine, and other applications. The use applications of the product are such that the thread needs to resist UV sunlight, chemicals, saltwater, extreme weather, and acid rain, while allowing it to maintain its strength, flexibility, and appearance for an extended period of time. The information presented below compares these key application properties of PTFE to other materials after long term exposure to outdoor environmental conditions.

a) Simulation of Environmental Conditions

Accelerated weather (UV & Acid Rain) tests on several commercial sewing threads were conducted at Denkendorf Research Institute (Denkendorf, Germany) using the protocol in the following table. The climates of Southern Europe and the Southern United States were simulated via accelerated climate testing. Two simulated weather periods were tested: 9 days (equating to 2-3 years), and 18 days (equating to ~5 years). An acid rain mixture of sulfuric and nitric acids was used at a pH of 2.85. Humidity cycles were 20-100%, while temperature cycles were 0°-80 °C. Ultraviolet light Energy was set at 60 W/m².

[47] Pro-K Fluoropolymergroup, Technical brochure 3.1 Application of PTFE-polymers in oxygen systems, Sept. 2020, available at https://www.pro-kunststoff.de/assets/Merkbl%C3%A4tter%20und%20Co/TM%203.1%20Application%20of%20PTFE-polymers%20in%20oxygen%20systems.pdf.

The performance of the thread after cycles was determined through the following tests:

- Stress-Strain DIN EN ISO 2062
  Gauge Length: 250mm
  Crosshead Speed: 250mm/min
  Pretension: 0.5 cN/tex
- Titer DIN EN ISO 2060
- Number N at least 3 per condition

Stress-strain measures mechanical strength of the yarn. Titer is density (mass per unit length). Titer is needed to calculate tenacity, breaking force divided by the liner density, i.e., a strength measurement normalized for size. Elongation at yield and elongation at break are direct out puts from stress strain testing with tenacity, a calculated output

The materials tested were: GORE® TENARA® Sewing Thread M1000 KTR, GORE® TENARA® Sewing Thread M1000 TR- white, GORE® TENARA® Sewing Thread M1000 TR- black, Dabond® V92 polyester multifilament bonded natural white made from polyester, and NOMEX® NC- Tech 34 filament raw white made from M-aramid. The results of these tests which are presented in Figures 1 to 4 below demonstrate that PTFE thread performance in strength (tenacity) and elongation was unaffected by exposure to simulated environmental conditions. This confirms that the polymer did not degrade.

- **Figure 1** GORE® TENARA® Sewing Thread – shows retention of Tenacity after simulated UV & Acid Rain Exposure
- **Figure 2** Compares retention of Tenacity of GORE® TENARA® Sewing Thread with a NOMEX® NC- Tech 34 and Dabond® V92 polyester
- **Figure 3** Compares retention of Elongation at Yield of GORE® TENARA® Sewing Thread with a NOMEX® NC- Tech 34 and Dabond® V92 polyester
- **Figure 4** Compares retention of Elongation at Break of GORE® TENARA® Sewing Thread with a NOMEX® NC- Tech 34 and Dabond® V92 polyester

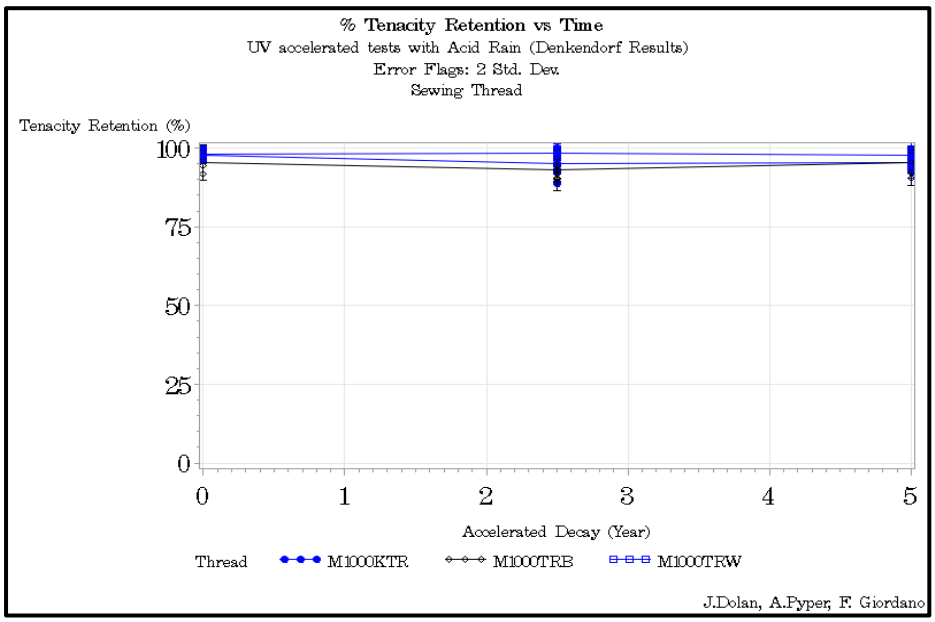


Figure 1 GORE® TENARA® Sewing Thread - Retention of Tenacity of UV & Acid Rain Exposure

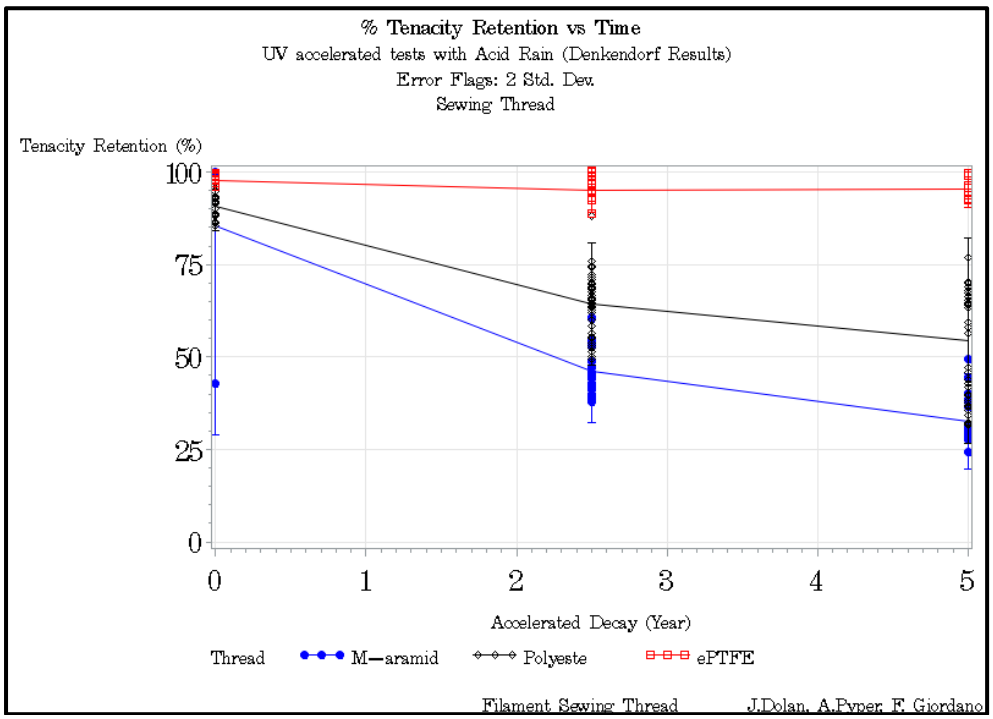


Figure 2 Retention of Tenacity: NOMEX® NC Tech 34 sewing thread, Polyester DABOND® V92 natural sewing thread, GORE® TENARA® Sewing Thread M1000KTR

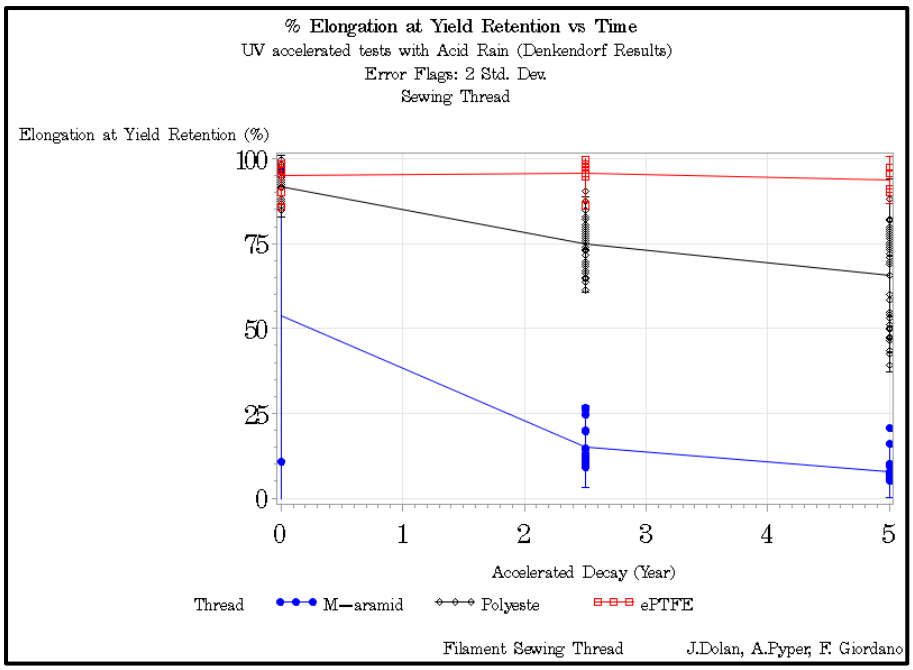


Figure 3 Retention of Elongation at Yield: NOMEX® NC Tech 34 sewing thread, Polyester DABOND® V92 natural sewing thread, GORE® TENARA® Sewing Thread M1000KTR

Elongation at yield is another output of stress strain testing (along with break strength). Tenacity (breaking force of yarn divided by linear density) is a calculated output and is a standard way of measuring strength of textile products such as yarn.

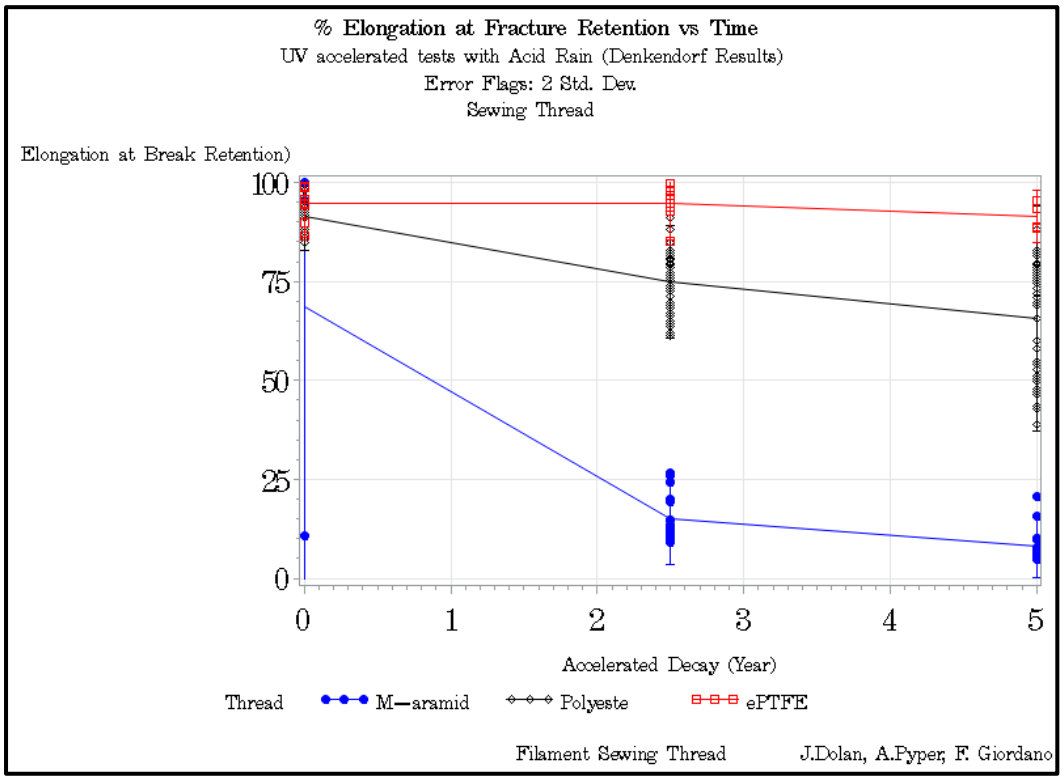


Figure 4 Retention of Elongation at Break: NOMEX® NC Tech 34 sewing thread, Polyester DABOND® V92 natural sewing thread, GORE® TENARA® Sewing Thread M1000KTR

b) Real-World Aging

The break strength of polyester (DACRON® thread) and natural/synthetic threads such as Eddcore thread made from cotton/polyester is reduced over time when exposed to sunlight and environmental elements such as rain, humidity as well as warm/cold temperature fluctuations. In particular, photons in sunlight break the bonds of the molecular chains resulting in the reduction of the thread's break strength. As sunlight duration increases, the loss of the thread's break strength increases.

Expanded polytetrafluorethylene (ePTFE) which is chemically the same as PTFE and has been mechanically expanded to increase porosity and strength, is not affected by photon damage therefore the break strength of an ePTFE thread is not compromised.

Figure 5 is a graph showing break strength retention of the three different threads that had been exposed to natural sunlight and environmental elements (>900 days) in Phoenix, Arizona. The results from the thread consisting of expanded polytetrafluorethylene, TENARA® Sewing Thread, maintained its break strength over a duration of >1250 days, indicating the polymer was not degraded by sunlight, rain, humidity, warm/cold temperature exposure confirming the polymer did not degrade.

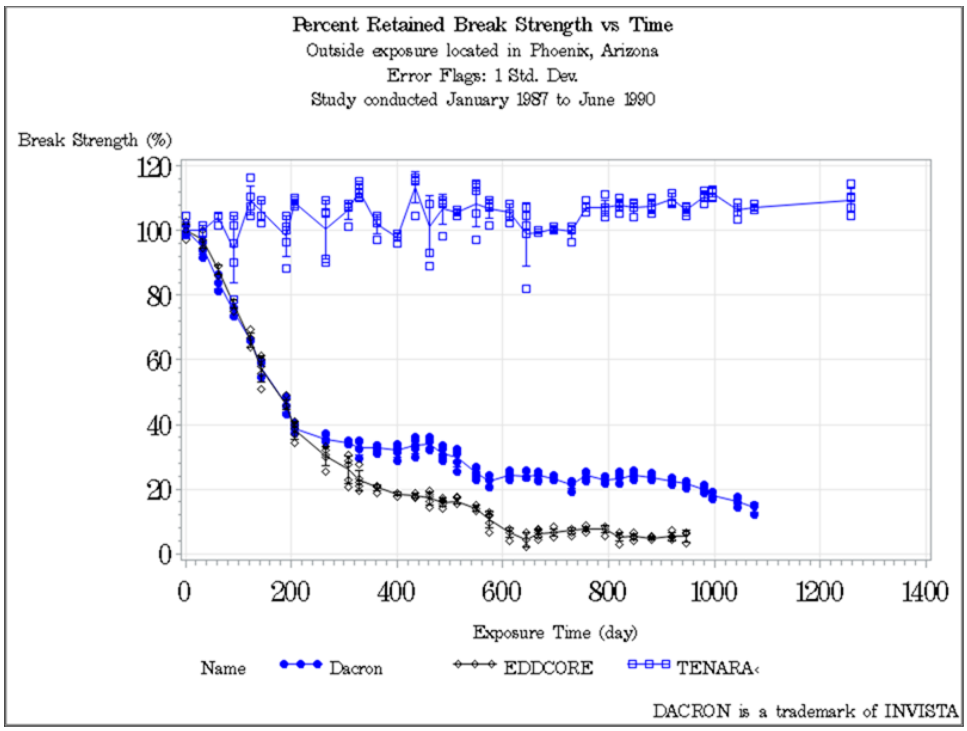


Figure 5 Break Strength Retention over Natural Sunlight & Environmental Exposure (Note: GORE® TENARA® Sewing Thread is a trademark of W. L. GORE & Associates)

The equation to calculate Break Strength Retention percent is:
$Break\ Strength\ Retention\% = 100*(Break\_Strength_{Non\ Exposed} - Break\_Strength_{Exposed}) / (Break\_Strength_{Non\ Exposed}$

The following real-world tests were performed in Phoenix, AZ (-112.01° Longitude, 33.43° Latitude) from January 1987 through June 1990. This test lasted 1,556 days. The humidity cycle was 16-45%. The temperature cycle was 7°-40° C. The ratio of sunlight to darkness was 44%. Threads were subjected to tensile tests for break strength and elongation% to failure. See Figures 6, 7, and 8.

Similar to lab testing, PTFE thread properties were demonstrated to be unaffected by exposure to challenging environmental conditions. In contrast, other polymers were significantly degraded under relevant environmental conditions. Additional data and analyses can be found in the submission made to the fire-fighting foam restriction process in 2022 (see Annex VI).

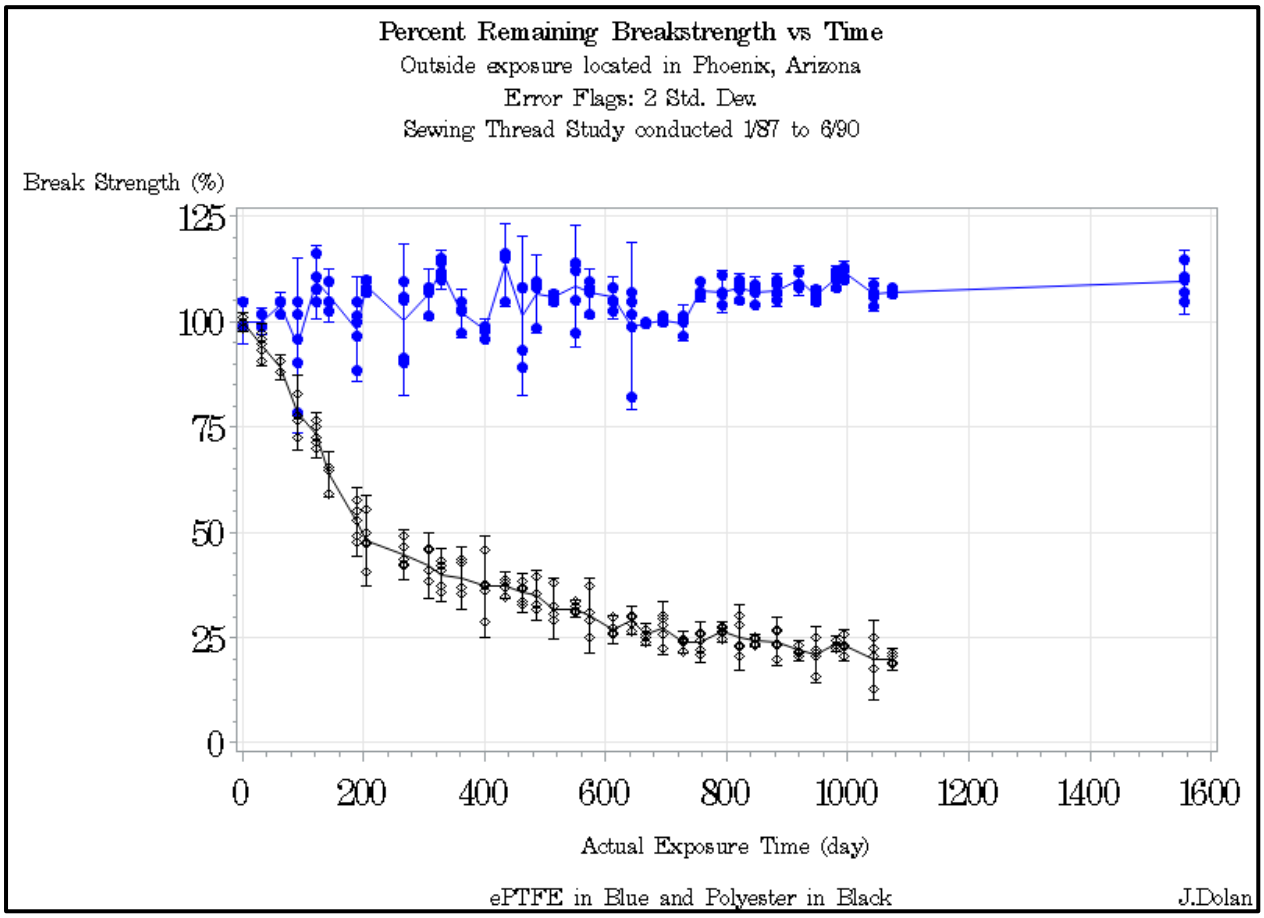


Figure 6 Retention% of Break- strength: Polyester DABOND® V92 natural sewing thread, GORE® TENARA® Sewing Thread M1000

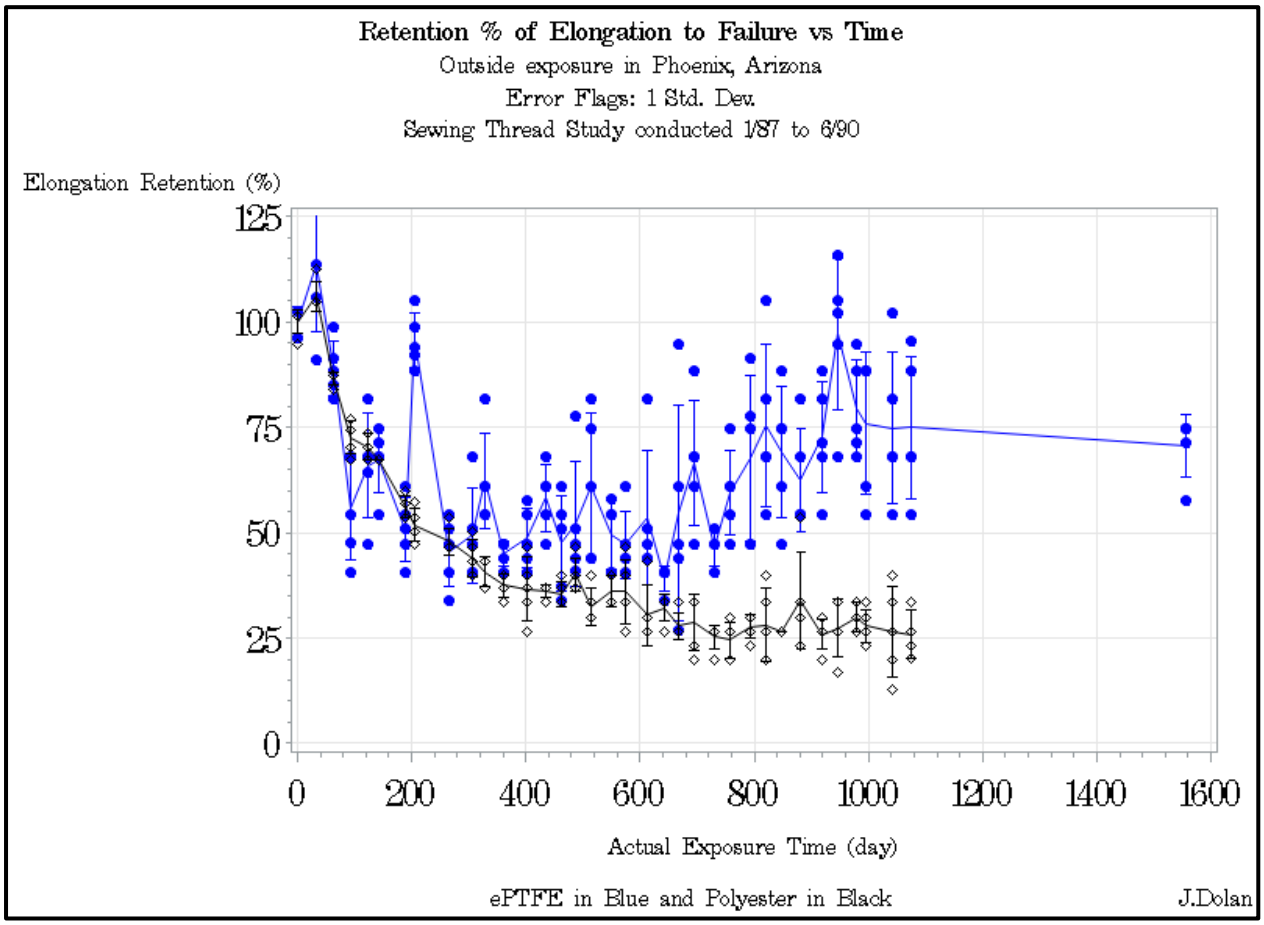


Figure 7 Retention% of Elongation to Break: Polyester DABOND® V92 natural sewing thread, GORE® TENARA® Sewing Thread M1000

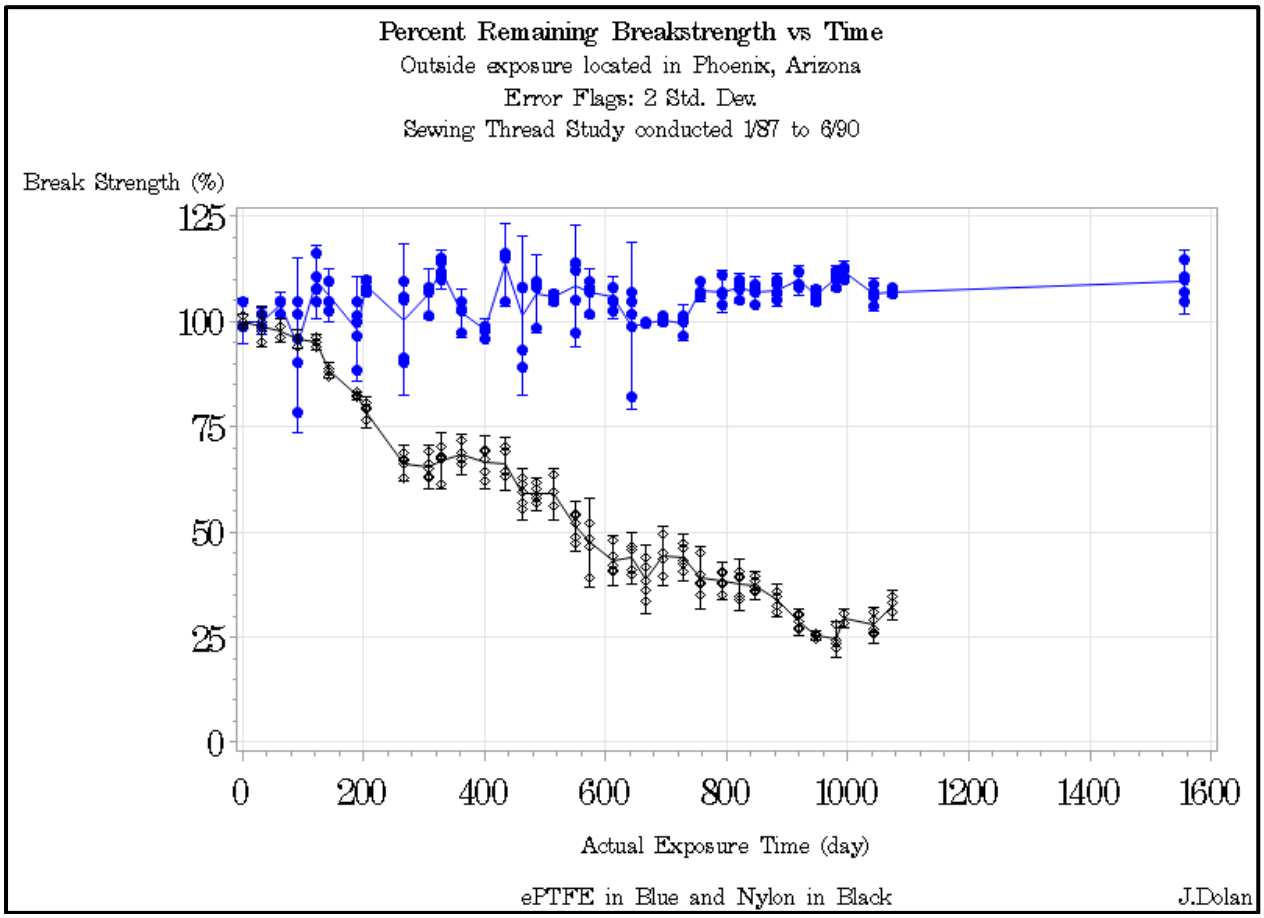


Figure 8 Retention% of Break- strength: Nylon BTS bonded, 1500 D sewing thread, GORE® TENARA® Sewing Thread M1000

Annex III – Overview of technically demanding applications where Gore intends to submit derogation requests

- Medical Devices
- Professional Apparel
- Aerospace and Defence Applications
- Semiconductor Manufacturing
- Chemical Manufacturing
- PEM Fuel Cells and PEM Electrolysers
- Specialty Wires and Cables
- Petroleum and Mining Industry
- Pollution Control and Dust Collection
- Heat Exchange Laminates
- Membranes Used for Venting of Medical Devices
- Products Used for the Processing and Delivery of Human and Veterinary Medicinal Products
- Technical Textiles
- Ingress Protection Vents for Vehicles and Vehicle Components
- Packaging Vents Used in Transport and Storage of Decomposing Chemicals
- Ingress Protection Vents for Communication Devices
- Ingress Protection Vents for Outdoor Electronic Applications
- Gas and Physical Sensors
- Battery Applications

Annex IV – Information on Gore's small-scale Polymerization Facility in Burgkirchen, Germany

I. OVERVIEW OF EMISSION CONTROL TECHNOLOGIES

Gore's site is equipped with state-of-the-art environmental controls including:

- Capture and recycling of monomers.
- A regenerative thermal oxidizer (RTO) with a caustic scrubber for air emissions.
- Activated carbon adsorption beds to treat water effluent.

II. MONITORING

Wastewater samples are collected and analyzed for traces of the used polymer processing aid daily in the on-site laboratory and a bi-weekly report is sent to the chemical park central wastewater treatment plant and to the local authorities.

In addition, the permit requires testing of the exhaust air and the soil to verify capture efficiency with regard to the processing aid.

III. OVERVIEW OF WORST-CASE EMISSION OF POLYMER PROCESSING AID

A summary of the annual emissions of the polymer processing aid of Gore fluoropolymer manufacturing facility in 2022 is shown in the Table below. **These emissions reflect worst-case scenario emissions calculated by Gore.** Monitoring of on-site emissions are often below analytical detection limits; the worst-case scenario emissions as used here represents a conservative estimation based on an assumption that emissions are just below detection limit. **Actual emissions of the polymer processing aid are expected to be significantly lower**. Additionally, further water treatment is carried out in the central wastewater treatment plant of the chemical park where the manufacturing site of Gore is located, which has not been accounted for in the emission estimates.

Worst-case annual emissions of fluorinated substances from Gore's fluoropolymer manufacturing facility in 2022	**Volume (tonnes)– worst-case**	**Control Device**	**Monitoring**
Air	‹ 0.0005	RTO, Scrubber	Temperature > 1000 °C
Water	‹ 0.00095	Activated carbon filters & site wastewater plant	Routine lab analysis
Annual total	**‹ 0.001**	-	-

Notes: Volumes given in tonnes and rounded to the first significant decimal. Total may therefore not sum up.

IV. WASTE HANDLING

The spent activated carbon beds are collected and thermally treated in a certified facility to regenerate the media. The facility continuously performs air monitoring with specialized maintenance restart leak testing, pursuant to a documented leak detection program.

The fluoropolymer scrap materials are shipped for thermal destruction at a certified treatment facility.

Annex V – Results of PFAS Measured: Incineration of PTFE and Wood (Paired t-testing)

Table 3
Results of all PFAS measured (ng/m3) and *P*-values for statistical comparison.

Abbrev.	Setting S1 (870 °C & 4 s)										
	Pair 1		Pair 2		Pair 3		Pair 4		Pair 5		p - value
	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	
PFHxA [PFC C6]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	163[b]	< LOQ	< LOQ
PFHpA [PFC C7]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	153[b]	156[b]	< LOQ
PFOA [PFC C8]	189[a]	194[c]	169[c]	179[c]	232[a]	302[c]	270[a]	354[c]	723[c]	184[a]	0.564
PFNA [PFC C9]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
PFDA [PFC C10]	< LOQ	128[a]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	153[b]	< LOQ	< LOQ
PFUdA [PFC C11]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	152[b]	< LOQ	< LOQ
PFDoA [PFC C12]	< LOQ	124[c]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	152[b]	< LOQ	< LOQ
PFTrDA [PFC C13]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
PFTeDA [PFC C14]	< LOQ	102[b]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	154[b]	< LOQ	< LOQ
PFBS [PFS C4]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
N-Me-FOSE alcohol	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ

Abbrev.	Setting S2 (1020 °C & 2.7 s)											
	Pair 6		Pair 7		Pair 8		Pair 9		Pair 10		Pair 11		p - value
	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	
PFHxA [PFC C6]	154[b]	< LOQ	< LOQ	136[b]	< LOQ	< LOQ	138[a]	< LOQ	< LOQ	< LOQ	118[b]	< LOQ	0.368
PFHpA [PFC C7]	< LOQ	< LOQ	< LOQ	135[b]	< LOQ	< LOQ	138[b]	< LOQ	< LOQ	< LOQ	116[b]	< LOQ	0.424
PFOA [PFC C8]	258[c]	189[c]	< LOQ	644[c]	< LOQ	137[b]	2743[c]	143[b]	143[b]	175[c]	413[c]	141[b]	0.407
PFNA [PFC C9]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	128[b]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
PFDA [PFC C10]	< LOQ	145[b]	< LOQ	133[b]	< LOQ	< LOQ	130[b]	< LOQ	< LOQ	< LOQ	117[b]	< LOQ	0.536
PFUdA [PFC C11]	< LOQ	< LOQ	< LOQ	133[b]	< LOQ	< LOQ	128[b]	< LOQ	< LOQ	< LOQ	115[b]	< LOQ	0.571
PFDoA [PFC C12]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	128[b]	< LOQ	< LOQ	< LOQ	115[b]	< LOQ	< LOQ
PFTrDA [PFC C13]	< LOQ	< LOQ	< LOQ	134[b]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
PFTeDA [PFC C14]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	131[b]	< LOQ	< LOQ	< LOQ	115[b]	< LOQ	< LOQ
PFBS [PFS C4]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	141[b]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
N-Me-FOSE alcohol	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	136[b]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	140[b]	< LOQ

[a] Only found in MeOH, all other concentrations were assumed as 1/2 LOQ.
[b] Only found on Filter, all other concentrations were assumed as 1/2 LOQ.
[c] Only found in MeOH & on Filter, all other concentrations were assumed as 1/2 LOQ.

Annex VI – Reference Number of submission to PFAS in Fire Fighting Foams Restriction Process

W. L. Gore GmbH has submitted hazards data on a set of fluoropolymers as part of the restriction process on PFAS in firefighting foams

Due to the file size limitation (20MB), documents had to be submitted through another file sharing and in batches. Gore believes the batches have been collected together for analysis. We list below the submission reference number and the date of each batch below to help retrieve those documents:

- 0da1b4d6-ff38-48db-abb8-daa7272aba92 (11.10.2022)
- f7aaf9e2-b710-4147-8824-68eb9b8d1fea (11.10.2022)
- 0b657618-993a-4fa2-8957-f3d477553a25 (11.10.2022)
- fbc86444-23a2-4c0c-ac0e-572502b2ddfc (11.10.2022)
- 667b597b-ca23-409d-b080-a56d54991c69 (11.10.2022)
- 4387a1bf-0535-4553-80cc-c87f2799d328 (11.10.2022)
- c9894726-45be-4048-82ee-b3955bcae4bc (11.10.2022)
- a0386a43-432e-4abd-9a6b-639023146980 (11.10.2022)
- 30682982-3a26-4fc3-bc11-285322004444 (11.10.2022)
- 32ba7e12-cb62-4418-951a-e4d0b2d53747 (20.10.2022)
- 6f025cfd-2156-4f57-a526-578a9bca8fda (20.10.2022)
- d2edbba2-999b-4c85-a6e8-758d597f0313 (20.10.2022)
- 758a2012-3659-418b-aa53-a1b82b518d91 (20.10.2022)
- 965759e2-4d7c-4672-9cc0-0f2a441e036e (20.10.2022)
- 08cf87e4-c1e3-4e1b-bc0d-88697ddfb612 (20.10.2022)
- e3a8c695-bc73-439e-b1cd-803594d344b4 (17.11.2022)

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NON-CONFIDENTIAL ATTACHMENT – pdfs of all references and reports are available on request.