

Environmental fate and behavior studies of a polymeric PFAS, polytetrafluoroethylene (PTFE) – results and application to risk assessment

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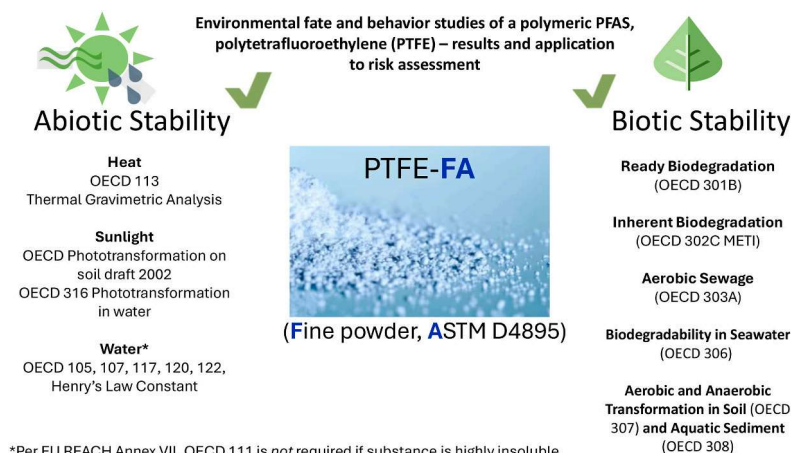
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HIGHLIGHTS

- Environmental fate and behavior (OECD) tests were done on a fine powder PTFE.
- No degradation was observed in air, sunlight, seawater, soil, sediment, or sludge.
- No transformation or subsequent release of (polymeric/non-polymeric) PFAS was observed.
- PTFE shows a low likelihood of adsorption to soil/sediment or movement with them.
- PTFE does not partition to air/water (as gas/vapor).

GRAPHICAL ABSTRACT



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ABSTRACT

The term per- and polyfluoroalkyl substances (PFAS) covers a wide and diverse array of chemistry often defined as containing at least one fully fluorinated carbon. PFAS may be non-polymeric (perfluoroalkyl substances or polyfluoroalkyl substances) or polymeric (fluoropolymers, perfluoropolyethers or side-chain fluorinated polymers). Although peer-reviewed publications have demonstrated that polytetrafluoroethylene (PTFE) has low toxicity, high stability, high chemical resistance, and is not bioaccumulative, the literature does not contain environmental fate and behavior testing. This paper presents environmental fate and behavior results for a well characterized PTFE-FA (high molecular weight, fine powder, microparticulate PTFE meeting the ASTM D4895 specification). Physicochemical properties, biotic and abiotic degradation (in air, water, soil and sediment), transformation, mobility, partitioning, long range transport potential, and application of this data to the state-of-the-science polymer risk assessment are discussed. This paper asks if PTFE-FA was found in the environment, would it degrade to and subsequently release substances of concern like non-polymeric PFAS. These results demonstrate PTFE-FA's absence of mobility, degradation, adsorption to soil/sediment, partitioning to air (as a gas or vapor) from water or organic matter, long-range transport in air (as a gas or vapor), water or soil,

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transformation to and subsequent release of non-polymeric PFAS. Therefore, the persistence of PTFE-FA does not imply future degradation, transformation and subsequent release of substances of concern. As the EU PFAS restriction proposal evolves, this data reduces uncertainty in this fluoropolymer risk assessment based on the lack of degradation, transformation and subsequent release of substances of concern. Evaluation of environmental fate for micro- and nanoparticles and fluoropolymer end-of-life was out of scope.

1. Introduction

The term per- and polyfluoroalkyl substances (PFAS) refers to a very broad chemical definition that includes thousands of substances with different physical, chemical and biological properties and environmental fate (Buck et al., 2011; OECD, 2021). PFAS includes non-polymers and polymers, gases, liquids, and solids. Polymeric PFAS include fluoropolymers, perfluoropolyethers, and side chain fluorinated polymers (Buck et al., 2011; Henry et al., 2018; OECD, 2013, 2021).

PFAS are the subject of growing interest by numerous local, national, and regional initiatives to minimize, remediate and limit their release into the environment (e.g., US EPA, 2006; UNEP Stockholm Convention 2009, 2019, 2022; US EPA, 2021; ECHA, 2023; Maine Legislative bills: LD1503-2021 & LD217-2023; Minnesota HF2310-2023; California Department of Toxic Substances Control, 2022). One of the primary concerns expressed by regulators for all PFAS and/or their degradation products is their shared characteristic of persistence (ECHA, 2023; Balan et al., 2021). Due to PFAS persistency, the authors of the EU PFAS Restriction Proposal believe continued use of PFAS will increase environmental concentrations of PFAS (through degradation, transformation, and subsequent release of substances of concern (EC, 2020)) which they consider equivalent to increased (bioavailable) exposure. They consider all PFAS to be non-threshold substances, regardless of hazard profile or properties, and PFAS emission to be a proxy for risk. Meeting the definition of persistent (P) or very persistent (vP) is not, however, in itself, sufficient to classify a substance as a “hazard” under EU REACH or the CLP (EC, 2011, 2023a,b) or the UNEP GHS. The UNEP and Stockholm Convention [and the US EPA] consider P or vP *only* in combination with Bioaccumulation (B) or Toxicity (T). The EU is now also using mobility (M) in combination with P or vP and T, but P *alone* is not currently a regulatory hazard criterion. The EU PFAS Restriction Proposal includes concerns about PFAS mobility, long range transport potential, accumulation in plants, bioaccumulation in biota, and (eco)toxicological effects.

Understanding environmental fate and transport is necessary to assess exposure potential and ultimately, when coupled with hazard assessment, potential risk. The key to exposure assessment is the generation of information on the physicochemical properties and fate of a substance using standard OECD test methods (Bunning et al., 2022). Physicochemical data describes the tendency of a substance to partition to or concentrate in a particular environmental compartment. Knowledge of partitioning and fate of PTFE-FA elucidates exposure assessment for humans and biota.

2. Materials and Methods

The following studies (see Table 1) were performed at an independent third party, GLP-accredited laboratory (Charles River Laboratories (CRL)-Hertogenbosch, the Netherlands). PTFE, a polymeric PFAS from the monomer tetrafluoroethylene (TFE), has three physical forms: granular, aqueous dispersion, and fine powder (Ebnesajjad, 2011). An ultra-high molecular weight, fine powder PTFE (Chemical Abstract Service, CAS, no. 9002-84-0) that met the ASTM D4895-18 (ASTM, 2018) specification for PTFE made from dispersion (prohibits the presence of additives or foreign material, colors, fillers, plasticizers, reprocessed or reground resin or any fabricated articles, and more than 1 % by weight of a non-TFE fluoromonomer), herein referred to as “PTFE-Fine powder ASTM”, or “PTFE-FA” was tested. Not all

commercially available PTFE meet this standard. PTFE-FA was >99.99 % pure. The certificate of analysis is provided with each study final report in the Supplement.

Radiolabeling of the PTFE-FA proved very challenging technically. As a homopolymer, PTFE has no obvious molecular moiety to guide radiolabel placement. Synthesis from the radiolabeled monomer would result in extremely high specific activity (due to high molecular weight), be problematic for worker safety, and contaminate the polymerization reactor and finishing equipment. Due to PTFE insolubility (Tuminello, 2002), liquid scintillation counting for isotope detection is impossible. Even if a ^{14}C label was present in PTFE-FA, its β particle would likely be captured by a surrounding fluorine atom and never reach the scintillation medium or be detected by the scintillation counter. If a per-fluorinated solvent were used, the β particle from the polymer would quickly be quenched by the solvent's fluorine atoms. The inherent electron emission of the ^{14}C isotope may induce covalent bond cleavage forming byproducts (Adeleh et al., 2024). Therefore, non-radiolabeled PTFE-FA was tested. Analysis of 33 PFAS (Table 2) was performed as a surrogate for degradation of PTFE-FA. These PFAS could be measured and quantified directly (See Analytical Methods and Table 2.).

The PTFE-FA average particle size (D_{50}) was 529 μm , meeting the definition of a microplastic (typically <5000 μm per UNEP, 2019). Although European Chemical Industry Council (CEFIC) ECO 052 (Hahn and Hennecke, 2022) notes that particle size for persistence assessment should be 250 μm or less, consistent with International Organization for Standardization (ISO) standard guidelines (ISO, 2017), because the test material particle size was within about 2x of the ISO standard recommended size and was commercially available, no further processing was performed to artificially decrease particle size (Hahn and Hennecke, 2022). The commercially relevant particle sized PTFE-FA was tested.

Studies were performed at CRL by OECD test guidelines (TG) utilizing validated analytical methods (See Guidelines for the Testing of Chemicals | OECD). These studies were performed with standard OECD durations since prolonged study duration is not generally accepted by regulatory authorities. The following OECD TG series were used.

- OECD TG 100 series: Physical chemical properties (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-1-physical-chemical-properties_20745753);
- OECD TG 300 series: Environmental fate and behaviour (https://www.oecd.org/en/publications/revised-introduction-to-the-oecd-guidelines-for-testing-of-chemicals-section-3_9789264030213-en.html)

Table 1 lists the studies performed, modifications made to the OECD TGs to accommodate the test material, the relevance of each study to hazard assessment and links to the OECD TGs. Reports and protocols for each experiment are provided in the Supplement.

3. Analytical methods

Analytical methods, based on ultra-performance liquid chromatography (Waters Acquity Premier; UPLC) with tandem mass spectrometry (Waters Xevo TQ-XS; MS/MS), were developed for the quantitative analysis of the PFAS in Table 2 in aqueous samples, natural sediment, natural soil, and activated sludge. Retention was achieved using a Waters Acquity Premier Ultra Performance Liquid Chromatography (UPLC (R)) Charged Surface Hybrid (CSH) Phenyl-Hexyl column (100 mm ×

Table 1
Environmental fate testing of PTFE by Charles River laboratories.

Test Title (OECD Test Guideline Designation)	Protocol Link	Protocol Modifications Made ^a	Relevance for PTFE
Melting Point/Melting Range (OECD 102)	https://doi.org/10.1787/9789264069527-en	None	To support thermal stability at environmentally relevant temperatures.
Vapor Pressure (OECD 104)	https://doi.org/10.1787/9789264069565-en	None	Volatility will help predict likelihood of partitioning to air and long-range transport potential.
Water Solubility (OECD 105)	https://doi.org/10.1787/9789264069589-en	The water solubility of the test item (1×10^{-5} g/L or 1×10^{-4} g/L) was lower than what can be tested with the Column Elution Method. Cryogrinding was performed to achieve a smaller fineness of the test item. However, these finer particles clumped, floated on the surface. Cryogrinding was discontinued for the remainder of tests in OECD TG 120.	Insoluble substances are not considered to be able to contaminate drinking, surface, and ground water
Adsorption - Desorption Using a Batch Equilibrium Method (OECD 106)	https://doi.org/10.1787/9789264069602-en	Performance of OECD 106 requires the test item to be completely dissolved in aqueous phase 0.01 M CaCl ₂ . The test item was insoluble in the test medium.	To determine the likelihood of the substance partitioning to soil and/or sediment.
Partition Coefficient (n-octanol/water): Shake Flask Method (OECD 107)	https://doi.org/10.1787/9789264069626-en	The test item was insoluble in conventional organic solvents and water; therefore, the test was not technically feasible.	N-octanol/water partition coefficient (K _{ow}) is a screening test for bioaccumulation. Substances that are more soluble in n-octanol are more likely to be fat soluble and bioaccumulative. Substances with very high K _{ow} (i.e., >4.5) 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.
Screening Test for Thermal Stability and Stability in Air (OECD 113)	https://doi.org/10.1787/9789264069749-en	As a safety precaution for the DSC cell a preliminary test was performed using a thermogravimetric analyzer (TGA).	Test for degradation from heat (relevant environmental temperatures)
Partition Coefficient (n-Octanol/Water), High Performance Liquid Chromatography (HPLC) Method (OECD 117)	https://doi.org/10.1787/9789264069824-en	The test item was insoluble in conventional organic solvents and water; therefore, the test was not technically feasible.	N-octanol/water partition coefficient (K _{ow}) is a screening test for bioaccumulation. Substances that are more soluble in n-octanol may be more likely to be fat soluble and bioaccumulative. Substances with very high K _{ow} (i.e., >4.5) 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.
Determination of the Number-Average Molecular Weight and the Molecular Weight Distribution of Polymers using Gel Permeation Chromatography (OECD 118)	https://doi.org/10.1787/9789264069848-en	After 19 h in solvents suitable for GPC analysis (dichloromethane, tetrahydrofuran, N,N-dimethylformamide, chloroform and N,N-dimethylacetamide), the test item did not dissolve. Therefore, the test was not technically feasible.	Molecular weight is a factor in determining bioavailability. Low molecular weight fractions may be available for migration out of the polymer.
Henry's Law Constant	HLC (k _H) k _H =P _{vp} /C _{ws} [atm x m ³ /mol] Where: P _{vp} = vapor pressure of the test item [atm] C _{ws} = water solubility of the test item [mol/m ³]	The test item was insoluble in water and had a vapor pressure of <1.3 x 10 ⁻⁸ Pa. It was not technically feasible to determine Henry's Law Constant.	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 (as a gas or vapor) from water. High HLC means likely to volatilize and have long range transport.
Solution/Extraction Behaviour of Polymers in Water (OECD 120)	https://doi.org/10.1787/9789264069886-en	Test item was ground to a particle size of 0.125–0.25 mm. Three 10 g samples were added to 1000 mL of water. Closed vessels were then agitated at 20 °C for 24 h, then centrifuged or filtered and polymer concentration determined.	The behavior of the test material in water is an important factor in aqueous fate and transport.
Adsorption Coefficient on Soil and Sludge using HPLC (OECD 121)	https://doi.org/10.1787/9789264069909-en	OECD 121 requires the analysis by reverse phase liquid chromatography which was not possible as PTFE-FA is insoluble in water polar organic solvent.	Soluble substances may sorb to soil or sludge, and then contaminate drinking, surface and ground water and move with the water.
Determination of pH, Acidity, and Alkalinity (OECD 122)	https://doi.org/10.1787/9789264203686-en	The guidance from OECD 122 as written could not be applied to PTFE-FA since it is not physically possible to obtain a stable dispersion of PTFE in aqueous media, because of the poor wettability. Therefore, modified methods were followed using mixtures of PTFE-FA and water, rather than solutions or dispersions of PTFE-FA. Therefore, the test material was cryoground to achieve a smaller particle size. However, the test material got lumpy and cryogrinding was	Soluble and ionizable substances may contaminate drinking, surface and ground water and move with the water.

(continued on next page)

2.1 mm i.d.; dp = 1.7 µm). Spike recovery was done in each matrix tested in these OECD test guidelines for all PFAS analytes listed in Table 2 resulting in acceptable values (except for sulfonated and amide compounds, though PTFE-FA has no sulfur or nitrogen to form such degradants) validating that these substances could be detected if they were

present above the detection limit in these matrices. Refer to the supplement for complete reports and analytical method development for each matrix tested.

These methods were validated with respect to specificity, calibration, accuracy and repeatability, limit of quantification, stability of

Table 1 (continued)

Test Title (OECD Test Guideline Designation)	Protocol Link	Protocol Modifications Made ^a	Relevance for PTFE
Octanol-air partition coefficient (log K_{oa})	Octanol:air partition coefficient (K_{OA}) $K_{OA} = C_O/C_A$ Where: C_O = concentration of the test item in octanol phase [g/m ³] C_A = concentration of the test item in air phase [g/m ³]	discontinued. Other modifications included stirring while adding PTFE-FA in incremental steps. The test item does not evaporate from nor dissolves in octanol. Vapor pressure of the test item was $<1.3 \times 10^{-8}$ Pa. It was not technically feasible to determine K_{oa} .	This test is useful for predicting partitioning behavior between various matrices (e.g., air and soil, vegetation)
Phototransformation of Chemicals on Soil Surfaces (OECD draft document July 2005)	https://www.regulations.gov/document/EPA-HQ-OPPT-2012-0450-0049 See Annex 6.	Due to insolubility, the test material could not be quantified directly by LC-MS. Therefore, a selection of 33 degradation products was measured down to the ng/kg level in all samples. Formation of these degradation products was evaluated as a proxy for the quantification of photolytic degradation.	Abiotic stability – test for degradation from soil surfaces in sunlight
Ready Biodegradability (OECD 301B and 301F)	https://doi.org/10.1787/9789264070349-en	Test item was dosed directly to medium. Additional replicates and control groups (e.g., negative control and negative control mixed with test item) were included. The test according to OECD TG 301F was performed with pre-adapted sludge that was obtained from the OECD 303A study.	Regulatory authorities use the test result to classify substances in terms of persistency. Biotic stability – test for biodegradability within 28 days
Inherent Biodegradability (OECD 302 C Modified MITI Test)	https://doi.org/10.1787/9789264070400-en	Test item was dosed directly to medium. Additional replicates and control groups (e.g., negative control and negative control mixed with test item) were included.	Biotic stability – test for biodegradability
Biodegradation of organic chemicals in Aerobic Sewage Treatment (OECD 303A)	https://doi.org/10.1787/9789264070424-en	The test item was added directly to the aeration vessel on a daily basis. The edges of relevant parts of the test setup were rinsed with medium to bring particulates back into suspension.	Biotic stability – test for biodegradation in the presence of aerobic bacteria in sewage treatment
Biodegradability in Seawater (OECD 306)	https://doi.org/10.1787/9789264070486-en	Test item in seawater was subjected to sonication (14 min) and stirring (83 min) but did not wettable by seawater. At 20 mg/L dilution, the test item was stirred for 75 min resulting in floating particles with precipitation. Due to insolubility the test was not technically feasible.	Biotic stability – test for biodegradation in seawater
Aerobic and Anaerobic Transformation in Soil (OECD 307)	https://doi.org/10.1787/9789264070509-en	Due to insolubility of the test item, spiking took place by direct addition of test material to bulk soil, which was then mixed and distributed over respective metabolism flasks. Due to direct addition to the soil, there was no dedicated equilibration period. Soil extracts were analyzed for the presence of 33 potential degradation products at each sampling interval, down to the ng/L level. Formation of these degradation products was evaluated as a proxy for quantitation of transformation.	Biotic stability – test for transformation in the presence of aerobic and anaerobic bacteria in soil
Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD 308)	https://doi.org/10.1787/9789264070523-en	Due to the insolubility and poor wettability of the test material, it was applied directly to the sediment before addition of the water layer. Due to direct addition to the sediment, there was no dedicated equilibration period. Sediment extracts were analyzed for the presence of 33 potential degradation products at each sampling interval, down to the ng/L level. Formation of these degradation products was evaluated as a proxy for quantitation of transformation.	Biotic stability – test for transformation in the presence of aerobic and anaerobic bacteria in sediment
Phototransformation of Chemicals in Water - Direct Photolysis (OECD 316)	https://doi.org/10.1787/9789264067585-en	A selection of 33 potential degradation products was measured down to the ng/L level in all samples. Formation of these degradation products was evaluated as a proxy for the quantification of photolytic degradation.	Abiotic stability – test for degradation in sunlight

^a See Supplement for full reports including protocols.

analytical system as well as solutions, and storage stability of samples. A linear calibration curve was obtained ranging from 2 to 50 ng/L (7.5–50 ng/L for selected PFAS). Stock solutions were determined to be stable for 41 to 74 days at room temperature. Details about the setup of the analytical method and associated parameters can be found in the Supplement.

Table 2 lists the PFAS analytes, their retention time, limit of quantitation and mass-to-charge ratios for parent and daughter. These analytes and analytical method development in the various matrices tested were determined based on best available analytical methods at the study start (2019), rigorous review, and adherence to scientific principles. Analyte selection was based on EPA Methods 533 and 537 and our knowledge of fluoropolymer chemistry. Ultrashort PFCAs were not in EPA 533 and 537 and are not in Table 2. Aleksandrov et al., 2019 demonstrated PTFE incineration would not result in degradation to ultrashort PFCAs. Although the EPA finalized Method 1633A which added ultrashort PFCAs to the PFAS of interest (USEPA, 2024), this experimental work was already completed with some analysis underway. Therefore, the same analyte list was used consistently for all studies, in keeping with standard scientific principles of testing.

For aqueous samples and samples from activated sludge, 2 mL of sample was transferred to a 7-mL glass vial and supplemented with 1 mL acetonitrile and 0.333 mL 1 % formic acid in methanol. This was left on a

roller-mixer for 30 min at 225 rpm, followed by filtering through a Whatman 0.2 µm Spartan 30/0.2 RC filter. If required, samples were diluted with a 60/30/10/0.1 (v/v/v/v) mixture of aqueous matrix, acetonitrile, methanol, and formic acid before filtration. All glassware, disposables, and equipment used were screened for background PFAS levels and items with negligible or lowest possible background PFAS levels were used throughout all procedures.

For soil samples, approximately 100 g of soil was weighed into a 500 mL test tube and extracted using 100 mL 0.1 % formic acid in methanol. Extraction was performed on a roller-mixer at 225 rpm for 30 min, followed by centrifugation at 3000 g for 5 min. A 5-mL subsample was filtered using a Whatman 0.45 µm Spartan 30/0.45 RC filter into a 14 mL test tube. This subsample was evaporated to dryness under nitrogen at a temperature of 55 °C (up to a maximum of 75 °C, if required to reach complete dryness). Dried extracts were redissolved in 1.6 mL water, 0.8 mL acetonitrile, and 0.266 mL 1 % formic acid in methanol. If required to ensure matrix-matched dilution, the resulting samples were further diluted using soil extracts (diluted and filtered) from the respective Quality Control (QC) sample. Due to the variable water content of soil samples, density of relevant solutions was determined throughout the analytical procedures. Introduction of water to the extraction solvent by soil moisture and/or pore water was corrected by measuring the total volume of extraction solution after the centrifugation step. (See the

Table 2
PFAS standards for degradation analyses.

PARENT MASS-TO-CHARGE RATIO (<i>m/z</i>)	DAUGHTER MASS-TO-CHARGE RATIO (<i>m/z</i>)	RETENTION TIME (MIN)	NAME	CRL REPORT ABBREVIATION	LITERATURE ABBREVIATION
313.1	119.0	4.7	Perfluoro- <i>n</i> -hexanoic acid	PFHA	PFHxA
363.0	169.0	5.4	Perfluoro- <i>n</i> -heptanoic acid	PFHOOH	PFHpA
413.1	169.1	6.1	Perfluoro- <i>n</i> -octanoic acid	PFOA	PFOA
463.1	219.1	6.6	Perfluoro- <i>n</i> -nonanoic acid	PFNA	PFNA
513.1	219.1	7.2	Perfluoro- <i>n</i> -decanoic acid	PFDA	PFDA
563.1	269.1	7.7	Perfluoro- <i>n</i> -undecanoic acid	PFUA	PFUnA
613.1	169.0	8.2	Perfluoro- <i>n</i> -dodecanoic acid	PFDDA	PFDoA
663.1	169.0	8.7	Perfluoro- <i>n</i> -tridecanoic acid	PFTDA	PFTTrDA
713.1	169.0	9.1	Perfluoro- <i>n</i> -tetradecanoic acid	PFtetrDA	PFTA
569.1	169.0	8.2	N-Methylperfluorooctanesulfonamidoacetic acid	MPFOSAA	NMeFOSSA
569.1	418.9	7.6	N-Ethylperfluorooctanesulfonamidoacetic acid	EPFOSAA	NEtFOSSA
212.9	169.0	2.9	Perfluoro- <i>n</i> -butanoic acid	PFBA	PFBA
262.9	218.9	3.9	Perfluoro- <i>n</i> -pentanoic acid	PFPA	PFPeA
299.1	79.9	4.2	Potassium perfluoro-1-butanedisulfonate	PFBS	PFBS-K
349.1	98.9	5.0	Sodium perfluoro-1-pentadisulfonate	SPFPS	PFPeS-Na
399.0	98.9	5.4	Potassium perfluoro-1-hexadisulfonate	PPFHS	PFHxS-K
449.0	80.0	6.2	Sodium perfluoro-1-heptadisulfonate	SPFHpts	PFHpS-Na
499.0	80.0	6.8	Potassium perfluoro-1-octadisulfonate	PPFOS	PFOS-K
549.0	80.0	7.3	Sodium perfluoro-1-nonadisulfonate	SPFNS	PFNS-Na
599.0	98.9	7.8	Sodium perfluoro-1-decadisulfonate	SPFDSulf	PFDS-Na
327.1	307.1	4.6	Sodium 1H, 1H, 2H, 2H-perfluoro-1-hexanesulfonate	SPFHS	4:2 FTS
427.1	407.1	6.0	Sodium 1H, 1H, 2H, 2H-perfluoro-1-octanesulfonate	SPFOS	6:2 FTS
527.1	407.1	7.2	Sodium 1H, 1H, 2H, 2H-perfluoro-1-decane-sulfonate	SPFDS	8:2 FTS
498.1	78.0	8.3	Perfluorooctane sulfonamide	PFSA	FOSA
511.9	218.9	9.6	N-Methyl-perfluorooctanesulfonamide-N-Me-FOSA	MPFOSA	N-MeFOSA
525.9	168.9	10.1	Sulfuramid	SA	–
569.9	418.9	7.6	N-Ethyl-Perfluorooctane-sulfamidoethanol N-Et-FOSE alcohol	EPFOSA	–
362.9	168.9	5.4	1H, 1H, 2H, 2H-Perfluoro-1-octanol	PF10	–
462.9	218.9	6.6	1H, 1H, 2H, 2H-Perfluoro-1-decanol	PF1D	–
562.8	268.9	7.7	1H, 1H, 2H, 2H-Perfluorododecan-1-ol 10:2 FTOH	FTOH	10:2 FTOH
513.9	168.9	9.7	Perfluoro-3-7-dimethyl octane carboxylate PF-3,7-DMOA	DMOA	–
344.8	280.9	4.7	7H-Perfluoroheptanoic acid	7PFHA	PFHpA
477.1	393.1	6.7	2H, 2H-Perfluoro decan carboxylate H2PFDA	H2PFDA	–

Note: the LOQ was 5 ppt for all except DMOA (N/A) and H2PFDA (15 ppt). DMOA, for this compound the method could, in the combination of compounds, not be developed sensitive enough to reach the desired LOQ. For this reason it was decided to screen all samples for DMOA and report if any signal was observed. No specific LOQ was given to the compound.

Note: analytes identified at the beginning of study were based on method capability at that time and had to be maintained for duration of study for consistency of output.

Supplement for more detail.)

For sediment samples, approximately 140 g or 200 g of sediment (depending on sediment type) was weighed into a 500-mL test tube and mixed with 140 or 200 mL, respectively, of 0.1 % formic acid in methanol. Extraction was performed on a roller-mixer at 225 rpm for 30 min, followed by centrifugation at 3000 g for 5 min. A 7- or 10-mL subsample (depending on sediment type) was filtered into a 14-mL test tube using a Whatman 0.45 μ m Spartan 30/0.45 regenerated cellulose (RC) filter. This subsample was evaporated to dryness under nitrogen at a temperature of 55 °C (up to a maximum of 75 °C, if required to reach complete dryness). Dried extracts were redissolved in 1.6 mL water, 0.8 mL acetonitrile, and 0.266 mL 1 % formic acid in methanol. If required, the resulting samples were further diluted using diluted and filtered sediment extracts from the respective QC sample to ensure matrix-matched dilution. Due to the variable water content of sediment samples, density of relevant solutions was determined throughout the analytical procedures. Introduction of water to the extraction solvent by sediment pore water was corrected by measuring the total volume of extraction solution after the centrifugation step. (See the Supplement for more detail.)

4. Results

The results are presented below in [Table 3](#). (See the Supplement for reports and protocols.)

5. Discussion

In parallel with the initiation of this testing, the EU was considering REACH registration of polymers ([Risk & Policy Analysts Limited, 2012](#); [Bougas et al., 2020](#); [BIO by Deloitte in collaboration with PIEP, 2015](#); [ECETOC, 2019](#)) and data requirements for polymer hazard assessment. Standard OECD environmental fate and behavior TGs needed to be adapted for polymers (See [Table 1](#) and the Supplement.). After this testing, [Brunning et al. \(2022\)](#) published a table showing relevant polymer tests and recommended new polymer properties to be assessed ([Table 4](#)). It is a reference to which regulators could be directed to avoid performance of tests of limited application to high molecular weight fluoropolymers.

Recent publications have suggested additional information potentially useful in polymer hazard assessment (see [Table 5](#)).

- Glass transition temperature, T_g (for additional information on sorption and desorption and polymer degradation) ([ECETOC, 2019](#)). T_g may have an indirect impact on health hazard ([OECD, 2021](#)).
- Particle size, shape, composition, hydrophobicity, distribution of functional groups and surface charge (to help characterize biological fate processes) ([ECETOC, 2019](#))
- Low molecular weight content ([ECETOC, 2019](#); [OECD, 2009](#)) influences potential polymer leachables
- Particle size distribution, surface properties and aggregation characteristics of solid polymers (useful for environmental fate) ([ECETOC, 2019](#))
- Granulometry, surface tension/surface activity ([Otte et al., 2023](#))

This additional information for PTFE-FA is provided in [Table 5](#) and demonstrates that even as the science of polymer risk assessment evolves, data continues to support the low hazard of PTFE-FA.

Based on the three ECETOC technical documents on polymers (TR 133-1, TR 133-2, and TR 133-3) a three-tiered approach for polymers was published ([Otte et al., 2023](#)). It highlights the prominent difference between polymers and many small molecules, limited bioavailability, which is a key consideration in the [Otte et al. \(2023\)](#) approach. Tier 1 information requirements depend on systemic bioavailability. Subsequent tiers incorporate properties, effects, use, and exposure considerations ([Otte et al., 2023](#)). See [Fig. 1](#). Explanatory test methods are

Table 3

Environmental fate testing of PTFE-FA by Charles River laboratories - results.

Test Title (OECD Test Guideline Designation)	Status/Results
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
Vapor Pressure (OECD 104)	<1 x 10 ⁻¹⁰ mm Hg @ 20 °C; indicating extremely low potential of PTFE to partition to the air as a gas or vapor. The vapor pressure of the PTFE was determined by the isothermal thermogravimetric effusion method.
Water Solubility (OECD 105) and Water Solution/Extraction Behavior of Polymers in Water (OECD 120)	PTFE-FA particle size >> the upper limit (250 μ m) defined in TG 120. Cryogenic milling was unsuccessful in reducing particle size. It was not possible to determine water solubility of PTFE-FA. Published literature supports insolubility of PTFE.
Adsorption - Desorption Using a Batch Equilibrium Method (OECD 106)	PTFE is not soluble in water or conventional organic solvents. Therefore, adsorption/desorption behavior determination was not possible.
Partition Coefficient (n-octanol/water): Shake Flask Method (OECD 107)	PTFE is not soluble in octanol or water. Therefore, no Partition Coefficient determination was possible.
Screening Test for Thermal Stability and Stability in Air (OECD 113)	Stable at continuous processing temperature 260 °C with 5 % loss in weight at 549 °C (1020 °F). PTFE is considered stable at room temperature. No decomposition or chemical reaction is observed <150 °C (302 °F).
Partition Coefficient (n-Octanol/Water), High Performance Liquid Chromatography (HPLC) Method (OECD 117)	PTFE is not soluble in octanol or water. Therefore, no Partition Coefficient determination was possible.
Determination of the Number-Average Molecular Weight and the Molecular Weight Distribution of Polymers using Gel Permeation Chromatography (OECD 118)	PTFE is not soluble in water nor was it sufficiently soluble to be evaluated by GPC even after sonication and stirring (19 h) in representative lab solvents. Therefore, standard MW methods have been replaced by standardized indirect methods that use specific gravity (Standard Specific Gravity) and melt flow index (melt flow rate) to determine fluoropolymer MW. By alternative methods, MW is > 500,000 Da.
Henry's Law Constant	Because PTFE is not soluble, this test could not be performed.
Adsorption Coefficient on Soil and Sludge using HPLC (OECD 121)	Because PTFE is not soluble in organic solvent, this test was not feasible.
Determination of pH, Acidity, and Alkalinity (OECD 122)	PTFE was not soluble in water, thus modified methods were followed. (See report in the Supplement for method modifications.) Test results demonstrated PTFE is not corrosive, caustic, or ionizable.
Octanol-air partition coefficient (log K _{oa})	PTFE is not soluble in octanol. Therefore, no Partition Coefficient determination was possible.
Phototransformation of Chemicals on Soil Surfaces (OECD draft document Jan 2002)	PTFE was completely photolytically stable in soil.
Ready Biodegradability (OECD 301B)	Did not reach 60 % degradation threshold at 28 days. Not readily biodegradable.
Inherent Biodegradability (OECD 302 C METI)	No inherent biodegradability. Did not reach biodegradation threshold in 28 days.
Biodegradation of organic chemicals in Aerobic Sewage Treatment (OECD 303A)	No biodegradation. PTFE does not have any inhibitory effects on activated

(continued on next page)

Table 3 (continued)

Test Title (OECD Test Guideline Designation)	Status/Results
Biodegradability in Seawater (OECD 306)	sludge. PTFE is stable and non-inhibitory. PTFE was not soluble for evaluation by guideline even after sonication (15 min) and stirring (83 min). PTFE does not degrade in seawater.
Aerobic and Anaerobic Transformation in Soil (OECD 307)	PTFE is completely stable and inert in soil under aerobic and anaerobic conditions. PTFE shows no signs of degradation or transformation in soil under aerobic or anaerobic conditions.
Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD 308)	No transformation or degradation of PTFE in natural water/sediment systems. PTFE is completely stable and inert under aerobic and anaerobic conditions in relevant environmental compartment.
Phototransformation of Chemicals in Water - Direct Photolysis (OECD 316)	PTFE is completely photolytically stable in water.

mentioned to cover recent developments (middle part of figure, “Additional tests”) but are not part of the ECETOC proposal (Otte et al., 2023).

The EU PFAS restriction draft questions mobility as a factor contributing to potential for: long range transport via water, drinking water contamination, and uptake in plants (ECHA, 2023). REACH defines a substance as mobile when the log K_{oc} is less than 3 or very mobile when less than 2 (EC, 2023a,b). These PTFE-FA studies address the lack of mobility and water solubility. The tendency for environmental transport of a substance depends on the transport properties of the medium into which it is released or partitions, and the lifetime of the

substance in the medium (Covaci, 2014). High water solubility, anionic ionizable form, and negligible vapor pressure combine to make low molecular weight perfluoroalkyl acids (PFAAs) candidates for high uptake and accumulation in crops (Gredelj et al., 2020). In contrast, PTFE-FA has negligible water solubility and would not move in solution through the plant via mechanisms such as transpiration, as would PFAAs. Furthermore, fluoropolymers like PTFE-FA are neutral and not anionic (see OECD TG 122 in the Supplement and Henry et al., 2018).

Another factor upon which environmental fate is based is the rate of transformation into other substances (Covaci, 2014). PTFE-FA demonstrated no potential for transformation, even at the 10 ng/L level.

5.1. Primary environmental fate

5.1.1. 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. The following tests confirmed the lack of volatility of PTFE-FA: OECD 104, OECD 113, Log K_{oa}, and Henry's Law.

5.1.2. Vapor pressure

Vapor pressure of PTFE-FA at 20 °C was estimated to be $< 1.3 \times 10^{-8}$ Pa ($< 1 \times 10^{-10}$ mm Hg at 20 °C) (OED 104) making it unlikely to volatilize and having very low potential to partition (as a vapor or gas) to air.

5.1.3. Water solubility

Water solubility is a critical environmental fate factor because undesirable water-soluble substances are available for migration between

Table 4

Summary of key parameters used in exposure assessment of low-molecular weight chemical compounds and their applicability to polymers

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Key Parameters	Information given	Relevance to dissolved polymers?	Relevance to bulk solid polymers?	Rationalization and comments
<i>Basic physicochemical properties</i>				
Water solubility	Extent of dissolution in water	Applicable	Applicable	Water solubility and dissociation constants give useful information on likely environmental compartment and reactivity and charge distribution; both have been applied to polymers. Vapor pressure of dissolved polymers will likely be driven by LMW content (oligomers and monomers). The high molecular weights of polymers mean most will decompose before a boiling point is reached.
pKa	Acidity (thus behavior at environmental pH)	Applicable	Applicable	
Tm	Whether substance will exist as solid or liquid in environment	Applicable	Applicable	
P	Partitioning between air and liquid/solid phase	Applicable	Not applicable	
Tb	Whether substance will exist as solid/liquid or gas in environment	Not applicable	Not applicable	
<i>Partition coefficients</i>				
Kd	Partitioning between soil and water	Applicable	Not applicable	Dissolved polymers will behave similarly to LMW chemicals, meaning Kd, Koc, and Kow can be applied (however, applicability should be assessed for those in the nano-size range). Equilibrium constants are not applicable to particulate matter or colloidal solutions, for which partitioning is controlled by kinetic factors and thermodynamic equilibrium is not reached, so application of thermodynamic parameters to bulk solids is not appropriate.
Koc		Applicable	Not applicable	
Kow	Partitioning between lipid (octanol) and water	Applicable	Not applicable	
<i>Bioconcentration and bioaccumulation</i>				
ku and kd	Uptake and depuration rates	Applicable	Applicable	The concept of BCF assumes passive diffusion and is thus not relevant for polymer molecules or particles (for which active processes will play a major role in organism uptake). In some soil/sediment systems, BAF may be applicable; however, specific parameters for polymer accumulation should be developed, and current tests should be interpreted to reflect uptake/depuration rates.
BCF	Partitioning into organisms	Not applicable	Not applicable	
BAF		Not applicable	Not applicable	
<i>Biotic and abiotic degradation</i>				
t1/2	Time taken for concentration to reduce by half	Applicable	Applicable	Rate constants and half-lives can be applied to both dissolved and solid polymers because they provide a simple measure of degradation rate.
kdeg	Rate constant for (bio)degradation	Applicable	Applicable	

pK_a = dissociation constant; T_m = melting point; P = vapor pressure; T_b = boiling point; K_d = soil-water partition coefficient; K_{oc} = soil organic carbon-water partition coefficient; K_{ow} = octanol-water partition coefficient; ku = uptake rate constant; kd = depuration rate constant; BCF = bioconcentration factor; BAF = bioaccumulation factor; t_{1/2} = half-life; kdeg = degradation rate constant; LMW = low molecular weight.

Table 5
Additional data elements suggested for polymer hazard assessment.

DATA ELEMENT FOR HAZARD ASSESSMENT	LITERATURE CITATION	REASON CITED IN LITERATURE	PTFE (FINE POWDER) DATA	SOURCE
Glass transition temperature, T _g	ECETOC (2019) Bunning et al. (2022)	for additional information on sorption and desorption and polymer impact found to influence sorption/desorption of organic contaminants and polymer degradation rate	130 °C	Puts et al. (2019)
Particle size distribution (Granulometry)	ECETOC (2019)	useful for environmental fate assessment	avg fine powder type 1: 500±200 µm	ASTM D4895-18, 2023 . Standard Specification for Polytetrafluoroethylene (PTFE) Resin Produced From Dispersion. supplier product quality control data
Particle size		to help characterize biological fate processes; ability to reach the deep lung on inhalation	529 µm	
Particle shape		When assessing particulate polymers, care should be taken e.g., regarding effects of size distribution and shape on biodegradability	round; spherical	Drobny and Ebnesajjad (2023)
Polymer composition		to help characterize biological fate processes; polymers with structures susceptible to degradation may yield transformation products of health and/or environmental hazard	PTFE meeting ASTM D4895	supplier SDS, certificate of analysis
Hydrophobicity		to help characterize fate processes; sorption to soil	extremely hydrophobic	Dalvi and Rossky, 2010 ; Puts et al. (2019)
Distribution of functional groups		Polymers with more RFG per mole have increased reactivity (chemically and biologically); to help characterize biological fate processes	CF ₃ or COOH are the most common terminal groups for PTFE ^a	Henry et al. (2018)
Surface charge		Cationic polymers associated with aquatic toxicity; polycationic associated with adverse human health	neutral; no surface charge	Puts et al. (2019)
Low molecular weight content	ECETOC 2019 ; OECD 2009	to identify potential substances to migrate out of polymer and impact health/environmental hazards	<1 ppm	Henry et al. (2018) and Supplement
Molecular weight (standard specific gravity)	OECD (2009)	impacts biocompatibility, health and environmental hazard	2.161	supplier product quality control data; ASTM D4895-18
Aggregation characteristics (solid polymers)		useful for environmental fate	In this body of work, no aggregation was observed after submersion, sonication, stirring, shaking, after weeks of incubation (OECD 303A) PTFE refloated.	Established in current body of work
Adsorption/desorption - depending on chemical composition and particle size	Otte et al. (2023)	physical-chemical properties and interactions relevant to bioavailability and hazard assessment	Not possible	PTFE is not soluble in water or conventional organic solvents. Re-established in this body of work.
Boiling Point - only for polymers liquid at 20 °C with low molecular weight oligomers			Not applicable	PTFE-FA was solid at 20 °C
Vapor pressure - only for polymers liquid at 20 °C with low molecular weight oligomers			<1 x 10 ⁻¹⁰ mm Hg	Established in current body of work
Water solubility via TOC - only if polar structural elements are present			Not water soluble	polar structural elements not present in PTFE-FA; Puts et al. (2019)
Hydrolysis - only for polymers with labile functional groups (e.g., esters)			Not applicable	PTFE has no labile functional groups
Granulometry (particle size distribution) - only for solid, granular, water insoluble products; aqueous dispersion			D10 was 311 µm, D50 was 559 µm, and the D90 was 888 µm; coefficient of variation <3 % (D50), <5 % (D10 and D90)	Established in current body of work
Surface tension/surface activity - only if surface active structural elements are present (e.g., polar apolar blocks)			no surface active structural elements present; 26.22 mN/m	Drobny and Ebnesajjad (2023) ; Established in current body of work
Flash point, Flammability			Not applicable supplier SDS	PTFE-FA was solid at 20 °C; Not identified GHS hazard on SDS
Explosiveness, spontaneous combustibility Oxidizing properties			supplier SDS	Not identified GHS hazard on SDS

ASTM [D4895-18, 2023](#). Standard Specification for Polytetrafluoroethylene (PTFE) Resin Produced From Dispersion.

^a Based on the calculated molecular weight in this work, the functional group equivalent weight (FGEW) be > 108 since there would be 2 terminal end groups per mole.

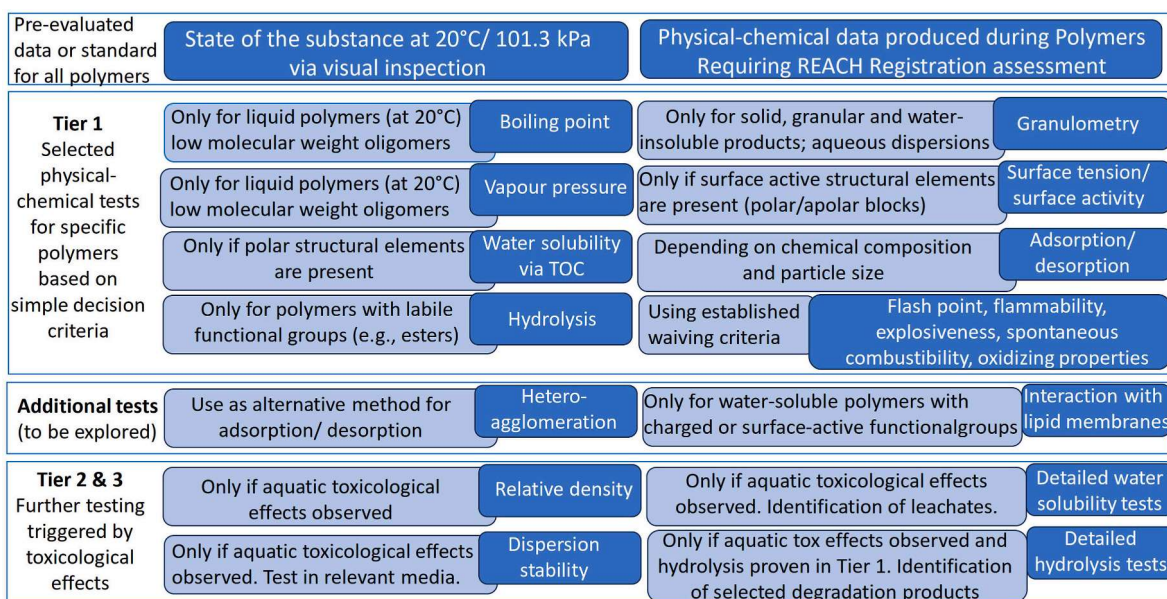


Fig. 1. Overview of physical-chemical data and appropriate trigger and dependencies for all Tiers, combining established and explanatory tests methods. Modified and reprinted from “Three-tiered approach for standard information requirements for polymers requiring registration under REACH,” by J.C. Otte et al., 2023, *Regulatory Toxicology and Pharmacology* 144, Article 105495. Copyright 2023 by Elsevier Inc. Modified and reprinted with permission. Abbreviations: TOC – total organic carbon.

environmental media and can contaminate water. The lower the water solubility, the lower the likelihood of partitioning to water or uptake by plants. The published literature and results of OECD TG 105 and 120 confirm PTFE is insoluble in water (Hanford and Joyce, 1946; Renfrew and Lewis, 1946; Puts et al., 2019; OECD TG 105 and 120 results). PTFE-FA is highly unlikely to be a water-soluble contaminant, or to move in solution with water.

5.1.4. Adsorption/desorption

Adsorption/desorption studies are useful for generating essential information on the mobility of chemicals, their binding capacity to soil/sludge and their distribution in soil, water, and air. OECD 106 and 121 evaluate a substance's binding capacity. Although the suitability of OECD 106 method was confirmed by Jop et al. (1997), ECETOC reported technical challenges, such as dispersing the polymer in water/soil/sediment and analytical method development (ECETOC, 2020). Additional work is needed to correlate available Koc data with different polymer types (ECETOC, 2020). Because 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, which PTFE-FA is not (Hanford and Joyce, 1946; Renfrew and Lewis, 1946; Puts et al., 2019; Madzarevic, 2020; Radisic, 2022), they were not technically feasible.

5.1.5. Partition coefficients

Partitioning of non-polymeric PFAS to solids and soils is thought to occur through two primary processes: sorption through electrostatic interactions and sorption to organic matter via hydrophobic interactions (Uriakhil et al., 2021). PTFE-FA is neutral and not ionic. While PTFE-FA is hydrophobic, published literature does not describe hydrophobic or electrostatic interactions of polymeric PFAS (like PTFE-FA) with soil or sediment. Electrostatic and hydrophobic interactions as discussed for non-polymeric PFAS are unlikely for PTFE-FA. Uptake and accumulation of PTFE-FA in plants is not expected based on the negligible water and octanol solubility, extremely low bioavailability, and the low likelihood of soil adsorption.

ECETOC (2020) states that octanol water partition coefficient (Kow) might not be needed if the molecular weight exceeds the threshold for

systemic bioavailability, stated to be 1000 Da by the OECD (2009). Also, ECETOC's technical report 133-3 (ECETOC, 2021) states that partition coefficients and dissociation constants are generally not relevant for solid, insoluble polymers (like PTFE-FA) since they do not dissociate and are not soluble in water. The results of OECD TG 107 and OECD TG 117 support that PTFE is not fat soluble nor bioaccumulative via adsorption to organic matter in soils or sediments.

5.1.6. Molecular weight

ECETOC (2021) notes that, due to the complexity of polymers, analytical methods cannot provide precise information on the entire molecular weight distribution (MWD). PTFE-FA was not sufficiently soluble to be evaluated by gel permeation chromatography (GPC) even after sonication and stirring (19 h) in representative lab solvents. Therefore, standard specific gravity (SSG), viscosity and/or melt flow index are typically used to characterize these insoluble polymers (Starkweather and Wu, 1989; Henry et al., 2018; ECETOC, 2021). SSG is inversely related to the polymer molecular weight, per ISO 12086-2. Suwa et al. (1973) explain this is because the rate of crystallization. Consequently, the crystallinity of melt-crystallized PTFE varies inversely with molecular weight in a certain range. Doban et al. (1956) found the following relationship: $SSG = 2.612 - 0.058 \times \log_{10} Mn$. Using this equation, the molecular weight of PTFE-FA was calculated to be 59,703, 529 g/mol. Therefore, although the molecular weight of PTFE-FA could not be characterized using GPC, the SSG-calculated molecular weight of PTFE-FA far exceeds that which is recognized as being too large to be bioavailable (DeMello, 1987; Beyer EC, 1993; Alberts B et al., 1994; Lipinski C.A. et al., 2001; Zhang and Wilkinson, 2007; OECD, 2009).

In addition to being too large for passive transport into the cell, PTFE-FA lacks lipid solubility to penetrate the cell membrane and functional groups involved in hydrogen bonding. PTFE-FA is highly hydrophobic and has no hydrogen bond donating potential because it has no hydrogen atoms. It is not structurally like steroids, peptides, natural compounds, etc., which are the only known exceptions to Lipinski's Rule of Five (Ganesan A, 2008).

Active transport into the cell is dependent on chemical and structural properties like molecular shape, volume/size, whether the atomic bonds can rotate, etc. As previously discussed, PTFE-FA is extremely large,

lacks rotational bonds and functional groups that can interact with the transporter proteins responsible for active transport. Therefore, PTFE-FA cannot be actively transported into cells.

Some substances can bind to the cell surface and signal events inside the cell. However, PTFE-FA does not fit into cell surface receptors. PTFE-FA is unlike the types of high molecular weight compounds that can impact organisms or tissues through active transport or cell surface binding/signaling like “natural compounds” (e.g., cyclosporine A, rapamycin, steroids, flavones, peptides, etc.) (Leeson, 2012).

5.1.7. Determination of pH, acidity, and alkalinity

Test results demonstrated that a 1 % (w/v) aqueous PTFE-FA dispersion 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 6.5–8.5 (Safe Drinking Water Foundation). These results demonstrated that PTFE-FA is not corrosive nor caustic, is not ionizable, and is further evidence that PTFE-FA is not soluble in water.

5.1.8. Henry's law constant (HLC)

Henry's law constant, calculated from vapor pressure and water solubility, is a measure of the concentration of a chemical in air over its concentration in water. HLC reflects volatility and likelihood to partition to air from water. A high HLC means a substance is likely to volatilize and have long range transport potential. (See ECHA, 2017) Due to the insolubility of PTFE-FA, HLC could not be determined. PTFE-FA was not soluble in octanol, and the vapor pressure of the test item at 20 °C was estimated to be $< 1.3 \times 10^{-8}$ Pa. It was not technically feasible to determine the octanol:air partition coefficient (Madzarevic, 2020; Henry et al., 2018). Considering the extremely low vapor pressure, PTFE-FA is unlikely to partition from water to air (as a gas or vapor) or from organic media to air.

5.2. Biodegradation testing

ECETOC (2020) noted that while biodegradation testing is a critical part of environmental fate and behavior testing, there are definite methodological limitations for the assessment of a polymer. Polymers can differ considerably with respect to molecular weight, residual monomers, residual starters, and intentionally or non-intentionally added substances. In combination with their high molecular weight and limited solubility, one protocol for all polymers is difficult which ECETOC concluded may necessitate protocol modifications like the modifications applied in this body of work (See Table 1.).

5.2.1. Biodegradability – ready, inherent and in aerobic sewage treatment

Results of OECD TGs 301B, 301F, 302C, and 303A tests demonstrated that PTFE-FA was not readily or inherently biodegradable. There was no indication of any biodegradation at all. While ECETOC (2020) advised that OECD TGs involving measuring dissolved oxygen may not be applicable to poorly soluble or sorptive materials, OECD 301B results were based on CO₂ production to counteract the relatively low organic content of PTFE-FA (See Table 1.). For OECD 301F and 302C the air pressure in each vessel was measured by respirometer and converted automatically into oxygen consumption (mg O₂/L). PTFE-FA does not biodegrade and to subsequently release substances of concern into the environment. The OECD TG 303A results in simulated sewage treatment demonstrate that PTFE-FA is not degradable. PTFE-FA is not inhibitory to sludge microbes. The absence of inhibitory effects on activated sludge and assorted microbiota is also apparent from the fact that response in PTFE-FA vessels was comparable with respective control groups for all biodegradation studies. If PTFE-FA had inhibitory effects, the response would have been considerably lower than corresponding control groups. Unsurprisingly, PTFE-FA was not sufficiently soluble for evaluation by TG 306 (biodegradability in seawater) even after sonication (15 min) and stirring (83 min).

Although ECETOC (2021) suggests biodegradation studies may need

extended duration, due to polymer stability, if no biodegradation is observed at all during the first 28 days of incubation, prolongation of the experiment is usually fruitless since microbial adaptation during the test is undesirable. The test according to OECD TG 301F was performed with pre-adapted sludge that was exposed to relatively high PTFE-FA concentrations for a duration of 28 days in the OECD 303A test. The complete lack of biodegradation of PTFE-FA even with pre-adapted sludge is indicative of the fact that no biodegradation would have been observed if the tests according to OECD TG 301B and OECD TG 302C had been extended.

5.2.2. Biodegradability in soil and aquatic sediment

No signs of PTFE-FA degradation or transformation were observed under aerobic and anaerobic conditions in soil or natural water/sediment systems (OECD TG 307). Therefore, PTFE-FA was considered stable and inert under aerobic and anaerobic conditions in relevant environmental compartments. ECETOC (2020) notes that OECD TG 307 is applicable for both water-soluble and insoluble polymers.

5.2.3. Direct phototransformation and phototransformation in aqueous medium and soil

PTFE-FA was completely photolytically stable under all test conditions with direct irradiation, irradiation in aqueous medium, and irradiation in soil thin-layers, per the results of OECD TG 316 and the OECD 2002 proposed guideline on phototransformation of chemicals on soil surfaces. Although a mass balance could not be constructed due to unlabeled PTFE-FA, according to OECD, because this test method is applicable to labelled and unlabeled test substances for which an analytical method with sufficient accuracy and sensitivity is available, this test is valid since analytical methods with sensitivity down to the ng/L level were used to quantify potential degradation products. The test method for photolysis in soil is applicable to water-insoluble compounds such as PTFE-FA (OECD, 2002).

Groh et al. (2023) analyzed the draft EU REACH proposal for registration of polymers and questioned the applicability of certain criteria to prediction of environmental and health hazards of polymers. The authors state that weathering or degradation of a polymer can lead to the formation of reactive functional groups (RFGs) not present in the virgin material (Groh et al., 2023). The work presented herein has demonstrated the lack of degradation under a variety of environmental conditions. Henry et al. (2018) noted the absence of RFGs, potentially predictive of hazard (USEPA, 2010).

This testing was performed on PTFE-FA, a fine microparticle-sized powder meeting the ASTM D4895 standard with high purity (see Materials and Methods). Extrapolation of these results to other forms of PTFE (granular, aqueous dispersion grades or those not meeting ASTM D4895, etc.) or other fluoropolymers is dependent upon physical and chemical characteristics. If there is evidence of material equivalence (specifications, certificate of analysis, regulatory compliance statements, etc.), then this data may apply. Consider tested articles identified as “PTFE1 Teflon semi-clear tubing” and “PTFE2 Teflon opaque black tubing” analyzed by Joudan et al. (2024). The supplier specification sheets for the PTFE1 and PTFE2 tubing stated they are not RoHS- (Restriction of Hazardous Substances) or REACH-compliant, respectively, meaning substances of concern could be present to confound and complicate interpretation and comparison with this data. Therefore, that tubing may be compositionally different from PTFE-FA. Test materials with comparable specifications to PTFE-FA would be anticipated to yield comparable results. These test results cannot be assumed to apply to test materials of undisclosed origin or composition. The purity of the test material, including low molecular weight leachables of substances used in manufacture and processing, may influence results.

6. Future work

6.1. Micro- and nanoparticles

PTFE-FA in microparticle form was tested using standard methodologies, which do not necessarily address microparticle-specific behaviors. Alignment on test methods for polymers, particularly insoluble microparticulate polymers was not available at the start of this project (and still is not). The environmental fate and behavior of microplastics was outside the scope of this manuscript. While questions relating to mobility and transport potential of microparticles and their associated risks are an emerging topic, these emerging concerns are not related to their chemical composition.

While this was not a comprehensive review of micro- and nanoparticles (MNPs) and further research is needed, some fundamental aspects of MNPs should be considered to assess potential risks and reduce uncertainty regarding secondary microplastics, their generation, bioavailability, and (eco)toxicological effects. This is to facilitate hazard and exposure assessment of plastic microparticles more definitively.

6.2. Micro- and nanoparticles defined

Microplastics are plastic particles less than 5 mm in size (Akdogan and Guven, 2019; EC, 2023b) and fiber-like particles below 15 mm in length (EC, 2023b). Nanoparticles are between 1 nm and 100 nm (ISO, 2017).

6.3. Primary and secondary microplastics defined

Primary microplastics are those manufactured to be less than 5 mm in size. Secondary microplastics are the result of environmental weathering and mechanical breakdown (fragmentation) of larger plastic pieces (GESAMP, 2015).

6.4. Mechanisms for secondary PTFE microplastic generation

Due to the inertness and inherent persistency of PTFE-FA, its lifetime in the environment is expected to be extremely long. Additional research is recommended to identify potential mechanisms for generation of secondary microplastics for PTFE and fluoropolymers in general. Today there are no harmonized methods to test polymers for potential environmental generation of secondary microplastics (MP). While GESAMP (2015) and Zhang et al. (2021) recognized weathering (via sunlight, oxidative degradation, hydrolysis, etc.) as a mechanism for generation of some polymer MP, it appears not to be a potential mechanism for PTFE-FA based on these results. Acknowledging that weathering in the environment is an integrative process involving all these mechanisms, the lack of PFAS analytes - even at the ng/L level - in PTFE-FA exposed to artificial sunlight continuously for 16 days suggests that weathering under the influence of UV-radiation and sunlight is unlikely. The data from biotic and abiotic degradation studies under aerobic and anaerobic conditions likewise suggest a lack of weathering.

Published data on PTFE submitted to ECHA (July 10, 2023) as part of public comments on the EU proposed universal PFAS restriction show that larger pieces of PTFE are not subject to weathering, meaning the potential for PTFE to form microplastics is low (see comment number 6167; reference number 50d3d582-d7e1-4877-bbf4-2101a2a07b1c). Though microbial action may weaken other plastics increasing susceptibility to fragmentation (Fleming, 1998) and (micro)particulation, published data of explanted PTFE hernia patches examined by scanning electron microscopy, attenuated total reflectance Fourier transform infrared spectroscopy, modulated differential scanning calorimetry, and optical microscope showed no degradation of PTFE (King et al., 2013; Henry et al., 2018). Results presented herein demonstrate that aerobic and anaerobic microbes do not degrade/weaken fluoropolymers (See also W. L. Gore submission to the firefighting foam proposed restriction

submitted July 12, 2022: comment number: 3582; Reference number: 3403a4cd-28bb-4397-b8ab-e013cb97f0fa.).

Real-world environmental ageing tests on an expanded PTFE (ePTFE), meeting the same specifications as PTFE-FA, were performed in Phoenix, AZ from January 1987 through June 1990 (1556 days). The humidity cycle was 16–45 %. The temperature cycle was 7.2°–40.6 °C (45°–105 °F). The ratio of sunlight to darkness was 44 %. Tests for tensile break strength and elongation% to failure showed the ePTFE thread was not affected by weathering. (See public comment submitted to ECHA on UPFAS restriction number 6167; reference number 50d3d582-d7e1-4877-bbf4-2101a2a07b1c.)

Groh et al. (2023) thought future work on polymer hazard assessment might include weathering the polymer, testing the polymer for changes, and then using the weathered polymer as the test material in (eco)toxicity tests. The toxicity testing previously published in Henry et al. (2018) and its Supplement was performed with articles made from a different but fully comparable batch of PTFE-FA. Because the results presented herein demonstrate no changes (or weathering) to the polymer as a result of light, water, heat, microbes, etc., (eco)toxicity data on the virgin polymer and articles derived from it appear to be fully appropriate for hazard assessment of PTFE.

GESAMP (2015) and Zhang et al. (2021) discuss the other mechanism for generation of secondary microplastics, mechanical forces such as wind, waves, abrasion, compaction, etc. These mechanical forces fragmented larger plastic pieces. Although microbial action may weaken some plastics thereby increasing susceptibility to fragmentation, this is unlikely for PTFE-FA as the data presented here and in King et al. (2013) show it is not subject to aerobic or anaerobic microbial degradation. While we look to the evolving data to assess whether the abrasion/shear forces in a landfill necessary to cause secondary microparticle generation with PTFE-FA are significantly different from other polymers, the US EPA recently noted "... the physical processes that lead to the development of microplastics are expected to be relatively low in landfills, the bulk of stable fluoropolymers would be expected to be retained for a long duration" (USEPA, 2024).

6.5. Additional microplastic research needs

Micro- and nanoplastic research on all polymers is currently very active, which will be helpful to.

- reduce uncertainty regarding secondary microplastic generation
- understand their bioavailability
- ascertain likelihood of (eco)toxicological effects (existing PTFE MP low (eco)toxicity data includes Lee et al. (2022), Feng et al. (2022), Sfriso et al. (2020), Dewan et al. (1995), and Geiser et al. (2003))
- facilitate hazard and exposure assessment of plastic microparticles to more definitively address potential risks
- develop/validate standardized laboratory models or guidelines for predicting nano- and microparticle generation and long-range transport.

When studying the potential risk of secondary microplastics, consider the volumes of the specific plastic manufactured globally, as well as persistence and susceptibility to weathering and biotic fragmentation. PTFE and other fluoropolymers constitute about 0.1 % of the total plastics processing demand in the EU (Conversio Market & Strategy GmbH, 2022), which informs the relative contribution and potential risk impacts of microplastic PTFE from microplastics generally. More insight into the factors influencing formation of microplastics and the potential risk from exposure to (weathered) microplastics is needed to adequately assess the cumulative risk for the total expected residence time of PTFE in the environment.

6.6. Future work – End-of-Life and main receiving environmental compartment of PTFE

The purpose of this study was not to address PTFE discharge into the environment or to specify the main receiving environmental compartment. Defining the main exposure path for PTFE-FA was not the intent of this body of work, though data was provided on the degradation, partitioning and mobility of the test material in each environmental compartment which will be useful in environmental risk assessment. End-of-life considerations of PTFE-FA, such as incineration, were also out of scope of this work.

7. Conclusions

The tests discussed here were the validated, internationally recognized environmental fate and behavior test methods available in 2019 when this project began. Recognizing that the science of risk assessment is constantly evolving as this work was progressing, we sought out state-of-the-art science tests for polymer assessment emerging since project initiation in 2019, as shown in Table 5 and discussed in the text. Note that existing PTFE-FA data were presented for every current parameter needed for polymer assessment on Table 5. Therefore, this data addresses current validated environmental fate and behavior testing, as well as current and future polymer assessment criteria. Data from validated methods and their methodological limitations for application to polymers were discussed as were state-of-the-science approaches to polymer risk assessment.

These results highlight the differences between PTFE and other PFAS. PTFE-FA has an extremely high molecular weight, low bioavailability, and lacks the characteristics of molecules subject to passive or active transport into the cell or binding with cell surface receptors to signal changes within the cell. The OECD environmental fate tests confirm the lack of biotic, abiotic, photolytic, and (simulated) sewage treatment degradation of PTFE-FA. The findings demonstrate that PTFE-FA, even as a microparticle, does not contribute to elevated PFAS concentrations in wastewater treatment plant discharges or solids, nor is it inhibitory to sludge microbes.

This data also demonstrates the low likelihood of the PTFE-FA to partition to or concentrate in any environmental compartment or to be translocated into or accumulate within plants due to its negligible volatility and solubility and low likelihood of soil adsorption. This data, in conjunction with the data presented in the Supplement to Henry et al. (2018) showing very low levels of residual monomer, oligomers, and low molecular weight leachables, reinforces the low leachability of PTFE-FA in the environment and low hazard. This knowledge of environmental fate, transport and partitioning reduces uncertainty in PTFE exposure assessment for humans and biota. While it is not possible to eliminate all uncertainty in any risk assessment, this data demonstrates the absence of the tested PTFE-FA degradation, transformation and subsequent release of substances of concern.

Persistence is an inherent characteristic of a substance that indicates its degree of resistance to degradation or environmental transformation. Persistence alone does not predict toxicity, bioaccumulation, long-range transport potential, mobility, water solubility or ability to partition to an environmental compartment (air, water, soil, sediment).

CRedit authorship contribution statement

Barbara J. Henry: Writing – original draft, Conceptualization, Writing – review & editing, Resources, Visualization. **Niels Timmer:** Supervision, Writing – review & editing, Project administration.

Disclaimer

Barbara Henry is a (retired) employee of W. L. Gore & Associates, Inc. Niels Timmer is an employee of Charles River Laboratories, Den

Bosch BV, 's Hertogenbosch.

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Declaration of competing interest

The authors declare they have no competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix B. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.chemosphere.2025.144569>.

Data availability

All data and information used in this manuscript have been made available in tabulated form (Tables 1–3) by the authors and are included in the paper and the Supplementary data.

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