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Review

A critical review of the application of polymer of low concern and regulatory criteria to perfluoropolyethers

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ABSTRACT

Perfluoropolyethers (PFPEs) are a class of per- and polyfluoroalkyl substances (PFAS) that are widely used as synthetic oils in various industries including space, health, semiconductor, electronics and automotive, due to their unique physical and chemical properties. To the best of our knowledge, PFPEs have not yet been evaluated using the Polymers of Low Concern (PLC) criteria. The objective of this study is to provide a brief overview of four commercially available PFPEs including their synthesis, typical applications, and evaluate them using PLC criteria. PFPEs are large molecular weight polymers with a narrow molecular weight distribution that makes them markedly different than non-polymeric PFAS. They are highly insoluble in water and octanol which enables the properties of immobility, non-bioaccumulativity and non-bioavailability in the environment. PFPEs also do not contain any significant amounts of residual monomer or low molecular weight oligomeric leachables as these are removed during the manufacturing processes. They also demonstrate excellent chemical, oxidative, biological, photolytic, and thermal stability under conditions of foreseeable use, and in the environment. Additionally, the life cycle impacts of PFPEs are also briefly discussed and found not to pose any significant risk. Overall, the unique properties of PFPEs as well as life cycle considerations demonstrate that PFPEs are of low concern from human health and environmental impact perspective, and that there is no scientific basis to group them with other non-polymeric PFAS. This study corroborates that PFPEs, like fluoropolymers, need to be evaluated as a separate, distinct class for regulatory risk assessment purposes.

1. Introduction

Per- and polyfluoroalkyl substances (PFAS) encompass a broad and diverse family of chemicals, exhibiting a wide range of varying chemical and physical properties [1]. There is no universally agreed upon definition of PFAS, rather PFAS have been defined differently by various organizations based on differences in structural composition [2]. PFAS were first defined by Buck et al. in 2011 as “highly fluorinated aliphatic substances that contain 1 or more C atoms on which all the H substituents (present in the nonfluorinated analogues from which they are notionally derived) have been replaced by F atoms, in such a manner that they contain the perfluoroalkyl moiety $C_nF_{2n+1}-$ ” [3]. In 2021, Organization for

Economic Co-operation and Development (OECD) and United Nations Environment Program (UNEP) proposed a revised and broader definition of PFAS where “PFASs are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group ($-CF_3$) or a perfluorinated methylene group ($-CF_2-$) is a PFAS” [4]. However, OECD in its report stated; “It should be noted that “PFASs” is a broad, general, non-specific term, which should only be used when talking about all the substances included in the PFAS definition described here (or the user should clearly define the scope of which substances are being referred to as PFASs in the documents they prepare)”. United States Environmental Protection

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Agency (US EPA) uses a narrower definition for reporting and record-keeping requirements under the Toxic Substances Control Act (TSCA) [5]. Under this structural definition, PFAS are defined as including one of the following three structures: " $R-(CF_2)_n-CF(R')R''$ ", where both the CF_2 and CF moieties are saturated carbons; $R-CF_2OCF_2-R'$, where R and R' can either be F , O , or saturated carbons; or $CF_3C(CF_3)R'R''$, where R' and R'' can either be F or saturated carbons".

The number of compounds that may be categorized as PFAS can vary widely based on which definition is followed. For example, under OECD revised broad PFAS definition, >6 million compounds can be classified as PFAS [6]. Given that a large number of compounds with diverse structures and chemical and physical attributes fall under the definition of PFAS, there is no one-size-fits-all solution to PFAS regulatory risk assessment. Unfortunately, there is considerable confusion in public and media leading to misunderstanding regarding PFAS where the various groups within PFAS are not clearly differentiated and all PFAS are generalized to exhibit adverse health and environmental impacts. However, there is no scientific basis for this generalization, and it is based solely on perception and inference from select non-polymeric PFAS compounds. The evaluation of PFAS should be based on their distinctions in chemical, physical, thermal, and biological properties, as well as their respective applications [2,7–9]. This has been recognized by US EPA which began "conducting new research to better understand the similar and different characteristics of specific PFAS and whether and how to address groups and categories of PFAS" [10]. Furthermore, in recognition of the diverse characteristics across the many PFAS, US EPA is implementing a categorical grouping strategy that relies on data pertaining to similarities in structure, physical and chemical characteristics, and available toxicity test results [2,11].

PFAS can be broadly divided into two groups: non-polymers and polymers [1]. PFAS such as perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) are examples of non-polymeric PFAS. Polymeric PFAS encompass fluoropolymers, perfluoropolyethers (PFPEs) and side-chain fluorinated polymers. Unlike non-polymeric compounds, which typically consist of small molecules with a defined chemical structure, polymers are made up of long chains of repeating subunits. Due to their large size and complex structure, polymers can behave very differently than small molecules when they are released into the environment or when they interact with biological systems. In fact, various countries recognize the major differences that exist between polymeric and non-polymeric compounds, and have developed criteria by which polymers can be classified as polymers of low concern (PLC) [12]. PLC are polymers that are expected to have "insignificant environmental and human health impacts" [13]. PLC criteria was developed based on the early work done by US EPA regulatory scientists [8, 14,15] and is based upon several polymer properties that have been identified to accurately predict adverse effects on human health and environment [12]. In previous work, Henry et al. and Korzeniowski et al. have used PLC criteria to evaluate 18 fluoropolymers [2,8]. Henry et al. and Korzeniowski et al. recognized that fluoropolymers are photochemically, oxidatively, chemically, thermally, and biologically stable, insoluble in water, environmentally immobile, and non-bioaccumulative, and they demonstrated that fluoropolymers satisfied the PLC criteria and do not pose any significant environmental or human health risks. These properties of fluoropolymers highlight the need to recognize fluoropolymers as a distinct and special subclass of PFAS, separate from non-polymeric PFAS [16]. This PLC criteria approach to polymer risk assessment was supported in 2019 by industry-led Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) who specifically supported the findings of Henry et al. [2,17]. Furthermore, a 2020 study contracted by the European Commission for identifying polymers requiring registration under REACH, also supported the PLC criteria recommendations set forth by Henry et al. [18].

PFPEs are another type of polymeric PFAS which are differentiated from fluoropolymers by the presence of ether linkages in the polymer backbone. Like fluoropolymers, PFPEs also possess unique properties

that make them ideally suited for several niche commercial applications. To the best of our knowledge, PFPEs have not yet been evaluated using the PLC criteria. The objective of this study is to provide a brief overview of four commercially available PFPEs including their synthesis, typical applications, and evaluate them using PLC criteria. Additionally, the life cycle impacts of PFPEs were also considered to supplement the PLC criteria evaluation. This study involved cooperation among three PFPE manufacturers with a global presence, originating from the USA, Europe, and Asia. The joint effort was focused on collecting and presenting data to support the PLC assessment and life cycle considerations. The aim is to help differentiate PFPEs from non-polymeric PFAS and facilitate fact-based risk assessment.

2. Commercially available PFPEs

While many attempts have been made to synthesize fluorinated lubricants that possess the significant heat and chemical resistance characteristic of fluorinated compounds, only a few have met the desired lubrication properties. Perfluoroalkanes, which have all hydrogen atoms replaced by fluorine, display excellent heat and chemical resistance [19]. However, due to the low intermolecular cohesion and lack of polarity typical of perfluoro compounds, they exhibit significant changes in viscosity with temperature and demonstrate poor durability under extreme pressure, making them unsuitable for use as lubricants.

In contrast, PFPEs containing an ether bond in their carbon backbone exhibit superior heat and chemical resistance and maintain a relatively stable viscosity across a wide range of operating temperatures [19,20]. Moreover, they possess excellent shear and compression resistance, making them suitable for use under high loads and pressures [21]. These properties give PFPE oils an advantage over other lubricants like mineral and synthetic oils, and have enabled PFPE oils to find numerous applications in various industries including military, aerospace, automotive, energy, semiconductor, medical, food and beverage, and metal production, among others.

PFPE fluids were first synthesized by DuPont in 1959 and disclosed in 1963 [21–23]. Subsequently, collaboration between U.S. military, NASA and DuPont led to further developments to utilize the high temperature lubricating properties of PFPE oils. Since then, four different types of PFPE oils have entered the commercial market, i.e., PFPE K, PFPE Y, PFPE Z and PFPE D (Table 1) [20,21,24–26].

All of these PFPE oils are composed entirely of carbon, fluorine, and oxygen in their non-functionalized inert forms. PFPE-Y and PFPE-Z are two families of PFPE oils that are both manufactured using a photo-oxypolymerization process. The PFPE-Y is "branched" PFPE, since it contains units bearing a pendant CF_3 -moiety while the PFPE-Z is "linear", or more precisely C_2-C_1 linear PFPE. PFPE-K is a series of fluorine end-capped, homopolymers of hexafluoropropylene oxide and like PFPE-Y is branched. PFPE-D is a structural isomer of PFPE-K but does not contain the CF_3 branching moiety so it is a linear PFPE. Details on the synthesis of these four types of PFPE oils are provided in the subsequent section.

3. Synthesis of PFPE oils

3.1. PFPE-D

PFPE-D was developed in the 1980s. The oligomer is obtained by ring-opening polymerization of 2,2,3,3-tetrafluorooxetane as a monomer with fluoride ion catalyst in a solvent (Fig. 1) [20,21]. It is then fluorinated directly with fluorine gas and synthesized in a way that stabilizes the end groups.

The resulting compound is purified and fractionated by distillation into products. PFPE-D is a structural isomer of PFPE-K, with the same repeating units. Unlike PFPE-K, the PFPE-D does not contain the pendant trifluoromethyl ($-CF_3$) group, so it is a linear chain polymer. The PFPE-D does not contain the oxydifluoromethylene group ($-CF_2O-$) in the chain

Table 1
Structures of commercially available PFPE oils.

Acronym	Name	CAS	Structure ^a	Linear/ Branched
PFPE D	Oxetane, 2,2,3,3-tetrafluoro-, homopolymer, fluorinated	113,114–19–5	F-(CF ₂ CF ₂ CF ₂ O) _n -CF ₂ CF ₃ <i>n</i> = 10 to 100	Linear
PFPE Z	Ethene, tetrafluoro-, oxidized, polymd	69,991–61–3	CF ₃ O-[CF ₂ CF ₂ O] _p -[CF ₂ O] _q CF ₃ <i>p/q</i> = 1	Linear
PFPE K	Poly[oxy(trifluoro(trifluoromethyl)-1,2-ethanediyl)], α-(1,1,2,2,2-pentafluoroethyl)-ω-[tetrafluoro(trifluoromethyl)ethoxy]-	60,164–51–4	CF ₃ CF ₂ CF ₂ O-[CF(CF ₃)CF ₂ O] _n -CF ₂ CF ₃ <i>n</i> = 6 to 100	Branched
PFPE Y	1-Propene, 1,1,2,3,3,3-hexafluoro-, oxidized, polymd.	69,991–67–9	CF ₃ -[(OCF(CF ₃)CF ₂) _m -(OCF ₂) _n]-OCF ₃ <i>m</i> + <i>n</i> = 8 to 45	Branched

Notes:.

a) The table shows the most abundant structures for the non-functionalized PFPEs in the commercial products. However, other end-groups can be present in the non-functionalized PFPE formulations as well such as: F-(CF₂CF₂CF₂O)_n-CF₃ for PFPE-D; CF₃CF₂CF₂O-[CF(CF₃)CF₂O]_n-CF(CF₃)₂ for PFPE-K; and CF₃-[(OCF(CF₃)CF₂)_m-(OCF₂)_n]-OCF₂F₅ and CF₃-[(OCF(CF₃)CF₂)_m-(OCF₂)_n]-OCF₂F₇ for PFPE-Y [27,28].

either, like PFPE-Y and PFPE-Z do.

3.2. PFPE-Z

PFPE-Z is obtained by a photo-oxypolymerization process, which

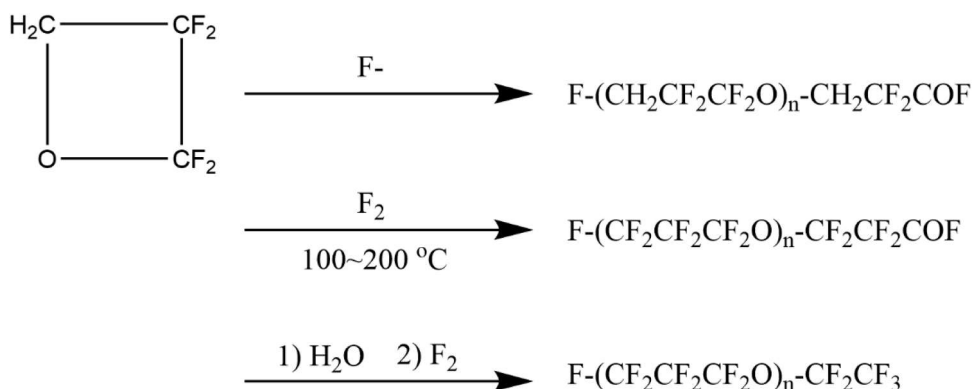


Fig. 1. Synthesis scheme for PFPE-D.

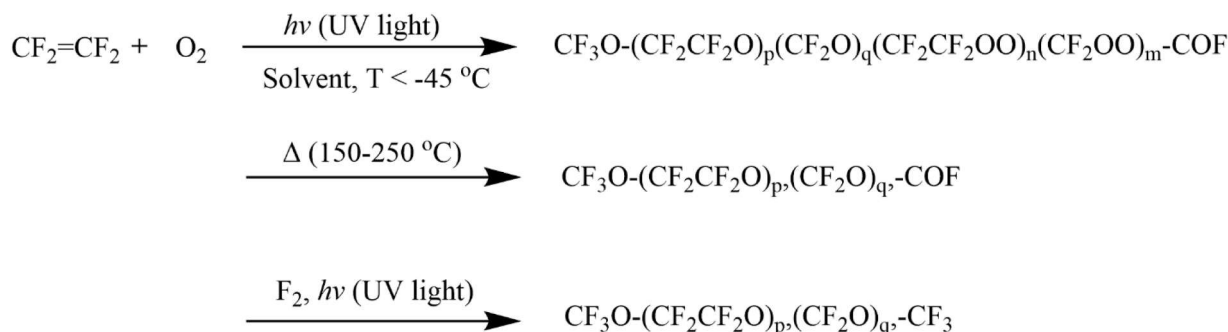


Fig. 2. Synthesis scheme for PFPE-Z.

involves the reaction between tetrafluoroethylene (TFE) and molecular oxygen (O₂) at low temperature (below –45 °C), in an appropriate solvent and UV light (Fig. 2) [29]. The oxypolymerization is a radical reaction, in practice applicable only to perfluorinated monomers, which gives a perfluoropolyether-polyperoxide intermediate, containing C₂ and C₁ units both in the ether form (-CF₂CF₂O-; -CF₂O-) and in the peroxide form (-CF₂CF₂OO-; -CF₂OO-). The ratio between the C₂ and C₁ units is not far from unity, whereas the amount of peroxidic units is generally kept around 10 % (molar fraction %). The very low temperature of the process is required to maximize the polymer yield.

The perfluoropolyether-polyperoxide intermediate, which also contains reactive acyl fluoride chain ends, can be stabilized by thermal treatment to eliminate the peroxides and then by fluorination with elemental fluorine to transform the acyl fluoride chain ends into more stable perfluorinated chain ends [29]. The resulting polymer contains -C₂F₄O- and -CF₂O- units randomly distributed along the chain in a ratio close to unity.

The raw polymer is then submitted to thin film distillation to get the commercial grades, having viscosity between 30 cSt and 1000 cSt (at 20 °C), and molecular weight between 3500 and 25,000 Da, respectively.

3.3. PFPE-Y

PFPE-Y, similar to PFPE-Z, is obtained by a photo-oxypolymerization process, which involves the reaction between hexafluoropropylene (HFP) and molecular oxygen (O₂) at low temperature (below –45 °C) and activated by UV light (Fig. 3) [29]. The oxypolymerization reaction gives a perfluoropolyether-polyperoxide intermediate, containing “branched” -C₃F₆O- units (-CF₂CF(CF₃)O-), but also in much lower amount -CF₂O- units, together with a few molar % of peroxidic units – all these units are randomly distributed along the polymer chain. The relatively complex composition comes from the intrinsic mechanism of the oxypolymerization process. The low temperature of the process is required to have the HFP in liquid form, but also to maximize the

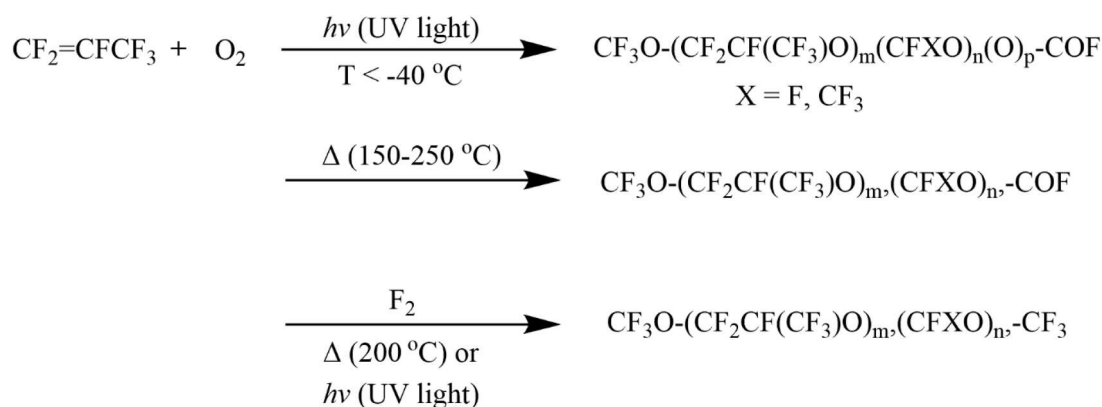


Fig. 3. Synthesis scheme for PFPE-Y.

polymer yield.

The perfluoropolyether-polyperoxide intermediate needs to be stabilized, since it contains both reactive peroxidic units and reactive acyl fluoride chain ends. The stabilization consists in two steps, the first one is a thermal treatment to eliminate the peroxides and the second one a fluorination with elemental fluorine (at high temperature) to transform the acyl fluoride chain ends into more stable perfluorinated chain ends [29].

The oil is finally distilled to get the commercial grades, with viscosity between 40 cSt and 2300 cSt (at 20 °C) - and molecular weight between 2000 Da and 10,000 Da, respectively. The lighter grades are obtained as distillates, while the heaviest ones as still bottoms.

The chemical structure of the commercial PFPE Y oils reflect the “copolymer” nature of the intermediate: the major part of the structure is composed by the branched C₃ units, the remaining minor part being the shorter C₁ units.

3.4. PFPE-K

PFPE-K is prepared by low temperature anionic polymerizations of hexafluoropropylene oxide (HFPO) (Fig. 4) [21,30,31]. HFPO can undergo polymerization in solvents like aliphatic hydrocarbon polyethers or nitriles, with CsF serving as the fluoride ion source. The reaction occurs at a temperature of −28 °C, which corresponds to the boiling point of HFPO [32–34]. The interim polymer possesses an acid fluoride terminal group, which is excessively reactive for lubricant applications. To enhance stability, the polymer undergoes a two-step reaction process: firstly, with water, resulting in a carboxylic acid formation, followed by treatment with elemental fluorine. The resultant polymer exhibits molecular weight variations within the range of approximately 1000 to 13,500 Da [21,35].

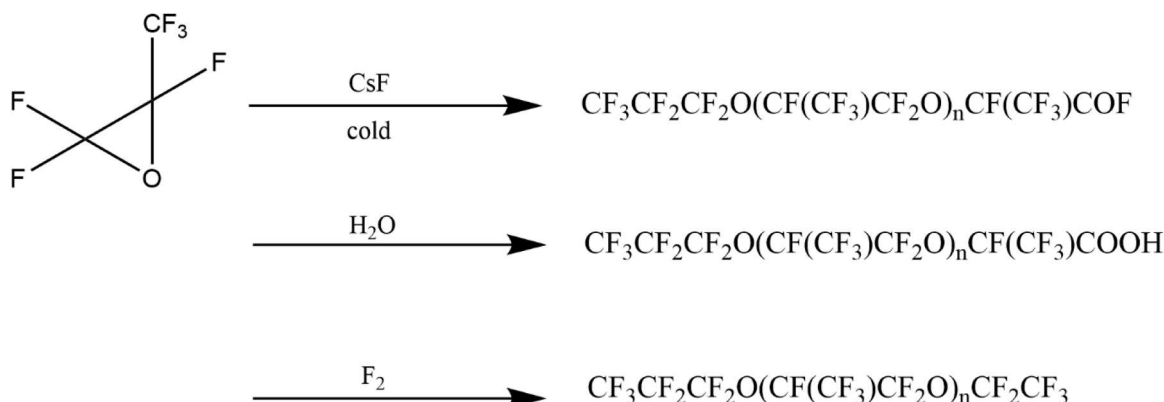


Fig. 4. Synthesis scheme for PFPE-K.

The crude PFPE-K oils typically undergo purification using absorbent materials, such as charcoal, alumina or soda lime, that serve to eliminate polar substances [21,36]. Subsequently, they are distilled under reduced pressure where the reaction mixture is fractionated into specific molecular weight and viscosity ranges, which relate to various grades available in the market.

4. General properties and uses of PFPEs

Synthetic lubricants encompass a wide range of substances that are artificially made through chemical synthesis, as opposed to being derived from crude oil [37]. Synthetic lubricants were developed to fulfill one or more of the following application needs: high-temperature stability; fire resistance; long service life; low-temperature performance; operation over a broad temperature range; high viscosity index; high lubricity; chemical inertness (reactivity safety) and radiation resistance [32,38].

As a class of synthetic lubricants, PFPE oils offer the advantages of the other classes of synthetics such as esters, polyglycols, and silicones without having their associated disadvantages. For example, esters are susceptible to hydrolysis and can break down in presence of water. Polyglycols are hygroscopic and water ingress into the lubricant sometimes may cause equipment corrosion. Silicones may be incompatible with some plastics and elastomers, and may have limited thermal stability [39]. Properties of PFPE oils that make them well suited for specialized applications as lubricants include [40]: increased non-flammability; excellent chemical, oxidative and thermal stability; high biological inertness; good dielectric properties that facilitate excellent electrical resistance; significant compatibility with metals, plastics, elastomers and rubbers; high inertness to liquid and gaseous oxygen; excellent radiation resistance; good viscosity index; low

evaporation loss due to low vapor pressures with respect to their molecular weights; excellent rheological and tribological properties; good lubricity in a wide temperature range; and easy formulation into greases.

One of the disadvantages of using PFPE oils as lubricants over other synthetic lubricants is the high cost. In fact, if a non-PFPE-based product could meet the lubrication requirements, it would almost certainly be used in place of PFPE based solely on cost [38]. Due to a unique combination of the above-mentioned properties, PFPE oils can serve applications under extreme conditions (e.g., very high or very low temperature, or presence of aggressive chemicals) and/or applications where they are “lubricants for life” (meaning no need for re-lubrication for the entire life of the equipment) [41]. Lubrication for life is of strategic importance for components in the aerospace, military, and automotive industry sectors. Other applications where these oils are essential for lubrication include liquid/high pressure oxygen (Federal Institute for Materials Research and Testing (BAM) and National Aeronautics and Space Administration (NASA) approved), oils and lubricants for vacuum pumps in the semiconductor industry, and lubrication of components in the nuclear industry [26].

Table 2 presents a summary of several industries that utilize PFPE oils, categorized based on the primary and secondary PFPE characteristics required for the respective applications.

Some of the applications of PFPE oils in these industries are discussed in more detail below.

4.1. Semiconductor industry

Nowadays semiconductor wafer fabrication has become increasingly complex, relying on harsh and reactive environments [42]. Vacuum pumps are essential for maintaining clean, low-pressure conditions by removing residual gases and by-products. To operate reliably, these

pumps require specialized oils that ensure lubrication, sealing, cooling, and corrosion protection; in addition, they must guarantee a very clean environment to avoid contamination of the lithographic and etching processes and they need to be extremely stable due to the very diversified and highly reactive chemicals used in these processes. For example, in the vacuum pump of semiconductor manufacturing equipment, chemically active substances such as silane gas and dry etching gas are inhaled into the pump which can cause the lubricant to decompose [19, 20]. PFPE oils with their superior thermal and electrical resistance, intrinsic chemical inertness, high non-flammability, and low evaporation loss meet the safety, reliability and durability standards required for this high-tech application [43].

PFPE oils and greases are also utilized in the semiconductor industry as lubricants for moving parts, such as robots used in lithographic processes [44]. Just like with vacuum pumps, these applications require lubricants that are very clean, stable, long-lasting, and produce minimal outgassing.

Furthermore, PFPE oils are used as a low-dust-emitting grease and sealant for clean rooms because of their low vapor pressure and low dust-emitting performance during sliding, making them essential in semiconductor manufacturing to improve yield [20].

4.2. Breathing & oxygen apparatus (for military, medical, & emergency services)

High compatibility with oxygen is a characteristic of PFPE lubricants which leads to their use in oxygen-enriched environments in medical, sub-sea, industrial processes and aerospace applications [45]. PFPE-Y, PFPE-Z and PFPE-K are certified by the BAM for safe use in oxygen environments (Table S17).

Medical ventilators, which were so desperately needed to battle

Table 2
PFPE functionality and commercial applications.

Commercial Application	PFPE Characteristics													
	Durable	Inert			Functional					Stable				
	Long-Life	Non-Toxic & Biologically Inert	Non-Flammable	Non-Oxidizing	Lubricity	Material Compatibility	Reactive Gas Safety	Non-Conducting	Recyclable (oil)	Hydrolytic & Chemical Stability	Wide Functional Temperature Range	Low Outgassing, Vapor Pressure, & Volatility	High Thermal Stability	Insoluble
Automotive Industry														
Breathing & Oxygen Apparatus (for Military, Medical, & Emergency Services)														
Chemical Process Industry														
Civilian & Military Aviation														
Copper Clad Laminate Manufacture - Belt Press														
Drinking Water Treatment - Chlorine Compatibility														
Energy Production & Storage														
Food and Beverage Production														
Industrial Gas manufacture, storage & distribution														
Metal production & processing														
Paper & Paperboard Manufacture (Corrugator)														
Semiconductor Industry														
Space Exploration & Satellites														

Notes:

Primary characteristics required for a particular application are highlighted Green.

Secondary characteristics required for a particular application are highlighted Purple.

Compiled based on input from the manufacturers.

COVID-19, demand oxygen-safe fluids and greases for ventilator components. Brian Lasiuk, Chief Technology Officer for Anesthesia and Respiratory Care at GE Healthcare, has also emphasized the essential requirement for ventilators to use lubricants that are compatible with environments rich in oxygen. “*We only use a lubricant approved for O₂ environments [in our ventilators], as unapproved lubricants may burn or explode in high O₂ concentrations*” [45].

Conventional synthetic lubricants are incompatible with oxidizing substances including oxygen [46]. Oxygen can vigorously react with traditional lubricants, potentially resulting in explosions, lubricant degradation, and equipment malfunction. Additionally, oxygen accelerates the decomposition of hydrocarbon lubricants, forming tar/varnish, which can potentially cause the failure of lubricated equipment. Oxygen can also trigger degradation reactions with conventional additives in the lubricants, resulting in decreased lubricant longevity and a necessity for more frequent lubricant application.

4.3. Space industry

The properties of PFPE lubricants also make them ideally suited to prevent friction and wear of components on satellites [47–50]. The lubrication required for satellites is a great example of “lubrication for life” since it must have long-lasting performance to help ensure the reliability of the entire mission [51]. Any failure, even of the smallest component, can halt critical functions and compromise the success of the mission.

The top requirements for these applications are high-load carrying capacity, wide temperature performance (typically from –90 to 250 °C), very low outgassing, low particle generation, and overall long-lasting performance (i.e., lube for life) [52]. For example, in reaction wheels, a small amount of lubricant must operate continuously 24/7 in the wheel’s bearing. Malfunction of the lubricant could culminate in the failure of the bearing, consequently causing a loss of satellite control. Similarly, improper outgassing of a lubricant near the camera lens can cause lens fogging and compromise the data.

4.4. Civilian & military aviation

For several decades, PFPE oils and greases have been extensively used in the aviation industry due to their wide temperature range and high stability, which are critical properties for maintaining top-level safety standards [53]. Effectively applying specialized lubricants made for high-speed and broad-range temperature conditions to airframe components is essential for maintaining the prolonged functionality and trouble-free operation of vital flight systems. PFPE lubricants meet the crucial attributes for lubricants used in engine components as they operate effectively across a wide temperature spectrum, exhibit compatibility with aviation fuels, and resist the corrosive vapors present in fuel systems.

PFPE are also essential to the defense industry and military aviation. For example, PFPE oils are used as lubricants for engine thrust actuators in some military jet aircrafts. These actuators redirect jet propulsion and necessitate a lubricant that can endure the intense heat of the engine’s exhaust, withstand exposure to hydrocarbon fuel, and remain unaffected by liquid oxygen [54]. Both PFPE-K and PFPE-Y meet the U.S. Department of Defense (DoD) MIL-PRF-27,617 specification (Table S17). MIL-PRF-27,617 covers the “*requirements for greases resistant to hydrocarbon fuel and liquid oxygen and for use as lubricants in aircraft, aerospace vehicles, and supporting equipment*” [55].

4.5. Food and beverage production

A secure food supply requires keeping food processing machinery running and preventing food contamination from unsafe substances. While many edible products, like vegetable oils and animal fats, can act as lubricants, their typical deficiencies are oxidation/polymerization,

low temperature freezing, viscosity limitations and rancidity. Due to their long lifespan, broad temperature range, and high compatibility with various materials, PFPE oils and PFPE-based greases that have been registered as achieving H1 category code status for incidental food contact according to NSF International registration guidelines for nonfood compounds are an ideal choice for lubricating machinery components used in the food industry [56]. Many grades of PFPE-K, PFPE-Y and PFPE-Z are NSF H1 accredited (Table S17). Furthermore, many grades of PFPE-K and PFPE-K-based greases are also Halal and Kosher certified, while PFPE-Z and PFPE-Y are used as raw materials for finished grease products that carry Halal and Kosher certification (Table S17). The machinery components in the food industry that are lubricated with PFPEs include various drive mechanisms such as conveyor belts, slicers, extruders, gearboxes, bearings, and pumps that are critical to maintaining the safe and efficient operation of our food supply [56].

4.6. Paper & paperboard manufacture (Corrugator)

One of the largest PFPE applications today is in the lubricating corrugator machinery. With the surge in e-commerce during the COVID-19 pandemic, there was an increased demand for the efficient production of corrugated cardboard boxes. In 2020, the corrugated cardboard industry shipped a record-breaking 407 billion square feet (BSF), surpassing its previous high of 405 BSF in 1999 [57]. Corrugated board production is a complex process that involves exposing paper to heat to create flutes, which are then joined with flat sheets of paper. The use of PFPE lubricants in this process can prolong maintenance intervals and equipment lifespan, resulting in greater operational efficiency and reduced environmental impact of cardboard manufacturing [58].

4.7. Automotive industry

Automotive lubricants must be capable of withstanding high temperatures and be compatible with a variety of materials to produce more efficient and powerful vehicles. PFPE oils and greases can satisfy both these requirements by being compatible with most plastics and elastomers, while also providing the ability to endure harsh chemicals such as brake fluid and exhaust fumes [54,54,59]. Their substantial high-temperature stability helps to extend the service life by fighting against wear and arcing conditions. Specific examples of PFPE oil applications include lubricants for Anti-Lock brake bearings and pistons, exhaust gas recirculation valves, sensors, and switches [54,60–62].

PFPE oils and greases are now also being developed as strategic materials to support the green transition towards electric vehicles. They are being researched for use in high-speed bearings for electric cars and various processes involved in the production of electric engines and batteries [63,64].

5. Polymers of low concern assessment

An OECD Expert Group has defined polymers of low concern (PLC) as those polymers that are “...deemed to have insignificant environmental and human health impacts” [13].

The criteria for defining PLC were first developed by US EPA for the US polymer exemption rule under TSCA [12,65,66]. The objective was to develop a framework that could identify polymers that posed minimal risk. The criteria were developed using extensive insights acquired by regulatory scientists at the US EPA through the examination of numerous data sets. These data sets were used to evaluate the overall physical-chemical characteristics of chemicals and their connection to potential hazards [8,14,15,67]. In 1993, an OECD Expert Group on polymers also concluded that ample data was available to define the essential properties that would classify a polymer as a PLC [68]. Several countries, such as Canada, China, Australia, USA, Taiwan, South Korea, and Japan, have implemented the PLC approach, and their criteria for

identifying PLCs are largely similar to one another [12]. A report commissioned by the European Commission identified several polymer properties that could be used to predict potential negative effects on human health and the environment, which were agreed upon by multiple member countries [12]. The report delineated the criteria that must be met for a polymer to be classified as a PLC. Henry et al. and Korzeniowski et al. incorporated these criteria in their assessments of fluoropolymers to demonstrate that they satisfy the conditions to be classified as PLC [2,8]. These PLC eligibility criteria are summarized in Table 3 and briefly discussed below. Additional details can be found in prior work [2,8].

5.1. Polymer composition

The polymer composition criterion requires that the polymer's structure and elemental composition are known and adequately described and identified, such as using Chemical Abstracts Service (CAS)

Table 3
PLC assessment criteria [2,8].

PLC Criteria	Compliance Metric
Polymer composition	Structure is adequately identified and has C, H, O, Si, S, F, Cl, Br, or I covalently bound to C
Number average molecular weight (M_n)	> 1000 Da
Molecular weight distribution (MWD)	1–3
Wt % oligomer	Not >5 % for <1000 Da and >2 % for <500 Da
Ionic character	Should not be cationic and must not be expected to become cationic in a natural aquatic environment. If cationic or expected to become cationic, should satisfy the following exception conditions: 1) Solid polymers, not dispersible or soluble in water, not dispersible in air (i.e. not sprayed or processed into powders) and only intended to be used in a solid phase; 2) Polymers with a low cationic density, i.e. a polymer whose cationic group has a combined equivalent weight greater than 5000 Da.
Reactive functional groups (RFGs)	Should not contain RFGs or contain RFGs of low concern. If moderate and/or high concern RFGs are present, FGEW needs to be considered.
Functional group equivalent weight (FGEW)	If polymer only contains moderate concern RFGs, these groups should have a FGEW above 1000 Da each and a combined FGEW over 1000 Da. If the polymer contains high-concern and moderate-concern groups (or high-concern groups only), the combined FGEW of these groups should be over 5000 Da. Furthermore, each high-concern group should have a FGEW over 5000 Da and each moderate-concern group should have a FGEW over 1000 Da
Structural similarities to RFGs of concern	For non-categorized RFGs, similarities to RFGs of concern should be evaluated to assess risk
Low M_w leachables	No concentration specifically required for PLC compliance.
Residual monomers	No concentration specifically required for PLC compliance.
Ratio of residual monomers to M_w	No specifically defined PLC criteria
Particle size	MMAD > 5 μ m
Water solubility	< 10 mg/L
Octanol–water partition coefficient (K_{ow})	K_{ow} < 5000 or Log K_{ow} < 5
Hydrolytic Stability	Stable and should not breakdown into fragments with M_n < 1000 Da
Photochemical Stability	Stable and should not breakdown into fragments with M_n < 1000 Da
Oxidation Stability	Stable and should not breakdown into fragments with M_n < 1000 Da
Biotic Stability	Stable and should not breakdown into fragments with M_n < 1000 Da
Thermal Stability	Stable at foreseeable use temperature and should not breakdown into fragments with M_n < 1000 Da

number.

The elemental composition requirements differ among various countries. For example, the REACH regulation in the EU states that polymers which contain elements like hydrogen, nitrogen, oxygen, silicon, sulfur, fluorine, chlorine, bromine, or iodine that are covalently bonded to C are considered less hazardous than those which do not contain the aforementioned elements [8,12,17]. Conversely, according to the Polymer Exemption Rule of the US EPA, a polymer may be subject to reduced agency review if it contains a minimum of two elements among carbon, hydrogen, oxygen, nitrogen, sulfur, or silicon [2,8,69].

In this study, a polymer is considered to satisfy the polymer composition PLC criteria, if its structure is adequately identified and it has carbon, hydrogen, oxygen, silicon, sulfur, fluorine, chlorine, bromine, or iodine covalently bound to carbon. This assessment is consistent with prior studies [2,8] with the exception of oxygen which was not of relevance to the polymers studied by Henry et al. and Korzeniowski et al. Oxygen is relevant to PFPE oils and presence of oxygen is taken to satisfy the PLC criteria based on provisions in US EPA Polymer Exemption Rule and REACH regulations.

5.2. Molecular weight, number average molecular weight, molecular weight distribution, and % oligomer < 1000 Da

The number average molecular weight (M_n), molecular weight distribution (MWD) and oligomeric content are important characteristics that determine the eligibility of a polymer as a PLC. Polymers are made up of a distribution of different sized polymer chains, therefore, they do not have a singular molecular weight. M_n represents the statistical mean molecular weight of all polymer chains within the sample, which is calculated as the summation of the product of each molecular weight (M_i) and its respective number fraction (n_i) [70]. Polymers with higher oligomeric content (>1 %) and lower M_n (<1000 Da) are considered to have higher potential health concern [12]. Oligomers can consist of various units such as dimers, trimers, and tetramers, indicating the presence of 2-, 3-, and 4-monomer units, respectively. According to OECD, polymers with oligomeric content >5 % for <1000 Da and >2 % for <500 Da are associated with greater potential health risks [13]. M_n is an important predictor of whether a chemical will not have adverse biological effects as molecules larger than 1000–10,000 Da are too large to enter cell membranes [8,71]. OECD has also noted that “as the M_n of a polymer increases, a reduced incidence of potential health concern effects might be expected” [13].

Furthermore, MWD, also known as polydispersity index, is another useful parameter to evaluate polymers as PLC because even if polymers have a large M_n , they may have low molecular weight oligomers that could penetrate the cell and potentially incur adverse biological effects. MWD measures the breadth of the size distribution of polymer molecules and is calculated by the ratio of weight average molecular weight (M_w) to M_n [8]. M_w differs from M_n as it takes into account the weight fraction of polymer chains, rather than the number fraction, when determining the average molecular weight. M_w is obtained by summing the product of each weight fraction (w_i) multiplied by its corresponding molecular weight (M_i). The PLC criteria do not specify a precise value for MWD (molecular weight distribution), but typically a MWD within the range of 1–3 is regarded as satisfactory.

5.3. Ionic character

Polymers can be nonionic, anionic, cationic, or amphoteric. Cationic polymers are of concern as they can be harmful to aquatic life [14,65], and water-soluble polycationic polymers can disperse and cause negative effects on human health if inhaled [72]. To satisfy PLC criteria, a polymer should not be cationic and should not potentially become cationic in an aquatic environment [12,18]. A cationic polymer is a polymer that possesses net positive charges on its atom(s) or associated group(s) of atoms, which are covalently attached to its polymer

molecule; examples of such groups include ammonium, phosphonium, and sulfonium cations [12]. Few exceptions that may still qualify a polymer as a PLC even if it is cationic or has propensity to become cationic include: 1) Solid polymers, insoluble or non-dispersible in water, not aerosolized or converted into powders, and exclusively meant for solid phase applications.; 2) Polymers characterized by a low cationic density, where the combined equivalent weight of their cationic moiety exceeds 5000 Da.

5.4. Reactive functional groups, functional group equivalent weight and structural similarities to reactive functional groups of concern

A reactive functional group (RFG) is defined as “an atom or associated group of atoms in a chemical substance that is intended or can be reasonably anticipated to undergo facile chemical reaction” [73]. RFG can be categorized as low-, moderate- and high-concern groups based on their toxicity potential (BIO by Deloitte, 2015; US EPA, 1997b). These are listed in Table S18 in the supporting information.

If polymers don't contain any RFG or contain RFG of low concern, they satisfy the RFG criterion for PLC. However, if a polymer contains RFGs of moderate and/or high concern, an additional parameter i.e. functional group equivalent weight (FGEW), needs to be evaluated to assess whether the polymer can qualify as a PLC. FGEW represents the ratio of M_n to the number of functional groups in the polymer, and it indicates whether the RFGs present in the polymer are adequately diluted to eliminate any potential risks [2,8,73]. A polymer with a lower FGEW indicates a higher degree of reactivity and an increased risk of adverse effects on human health and the environment [13]. If a polymer exclusively comprises of moderate concern RFGs, these groups must exhibit FGEWs exceeding 1000 Da each, with a cumulative FGEW exceeding 1000 Da, to meet the PLC criteria [12]. In the case of a polymer containing both high-concern and moderate-concern groups (or exclusively high-concern groups), the combined FGEW of these groups should surpass 5000 Da to fulfill the PLC requirements. Additionally, each high-concern group should possess a FGEW exceeding 5000 Da, while each moderate-concern group should have a FGEW exceeding 1000 Da.

When RFGs that are not part of the established categories are present, structural similarity to the RFGs of concern needs to be considered during PLC assessment.

5.5. Low molecular weight leachables, residual monomers and ratio of residual monomers to molecular weight

Low molecular weight leachables are a significant consideration for the PLC criteria due to their potential to migrate out of the polymer matrix and adversely affect human health and the environment. These low molecular weight leachables may consist of both organic and inorganic molecules that arise from various sources. These sources include incomplete polymerization processes, surface residues, or additional chemicals employed in the manufacturing process, such as initiators, catalysts, chain transfer agents, and surfactants [8].

Residual monomers resulting from incomplete polymerization reactions are low molecular weight organic leachables that are of particular concern. According to the OECD Expert Group on polymers and regulatory bodies [12,13], the residual monomer content of a polymer is a crucial factor in determining whether it meets the requirements for classification as a PLC. Since these monomers possess much lower molecular weight than the polymer, they are more toxicologically relevant and may potentially cause adverse effects by reacting with biomolecules. The ratio of residual monomer to molecular weight is a metric used in conjunction with leachable residual monomer concentration to evaluate whether a polymer meets the PLC criteria. A greater proportion of low molecular weight monomers per mole of polymer can increase the bioavailability and hazard potential, thereby reducing the likelihood of qualifying as a PLC.

It should be highlighted that when considering low molecular weight leachables and residual monomers, the PLC criteria do not stipulate specific concentration thresholds. Instead, these two factors are typically examined to confirm that they do not present any notable concern, as a precautionary measure.

5.6. Particle size

The particle size of a polymer is typically evaluated using the median mass aerodynamic diameter (MMAD). To meet the PLC criteria, the MMAD should exceed 5 μm as smaller particle size polymers may result in adverse health effects if inhaled.

5.7. Water solubility and octanol–water partition coefficient

Water solubility is another metric that needs to be considered when evaluating whether a polymer meets the PLC criteria. Polymers with low water solubility ($< 10 \text{ mg/L}$) exhibit low health concerns while those with higher solubility ($10 \text{ mg/L} - 10,000 \text{ mg/L}$) can cause potential health concerns [2,8,13].

Octanol–water partition coefficient (K_{ow}) is a chemical property that can be used to predict the lipophilicity and bioaccumulation potential of a molecule. Past studies on studying the effect of structural changes in drug molecules have demonstrated that K_{ow} is well correlated to biological, biochemical or toxic effects [8,74]. According to Stockholm Convention, $K_{ow} > 5000$ or $\text{Log } K_{ow} > 5$ is used as the criteria for bioaccumulation as these chemicals have a higher potential to bioaccumulate [8,75].

5.8. Stability (Hydrolysis, photochemical, oxidation, biodegradation and thermal)

A polymer needs to exhibit high abiotic, biotic and thermal stability to qualify as a PLC because unstable polymers can breakdown into molecules with $M_n < 1000 \text{ Da}$ that can cross cell membranes and react with biomolecules to exhibit potential adverse effects.

Abiotic stability refers to the ability of a polymer to resist degradation from various environmental factors such as hydrolysis, chemical oxidation, and UV irradiation. Hydrolysis involves the breakdown of the polymer through the addition of water molecules, while chemical oxidation occurs when the polymer reacts with an oxidizing agent such as hydrogen peroxide, sodium hypochlorite, or potassium permanganate, leading to the formation of smaller fragments. UV irradiation can also cause bond breakage in the polymer and transform it into fragments with lower molecular weights through photochemical reactions.

The biotic stability of a polymer refers to its ability to resist degradation by living organisms, including aerobic, anaerobic, and in vivo stability [2]. Aerobic and anaerobic stability refer to the resistance of the polymer to microbial degradation under conditions with and without oxygen, respectively. In vivo stability, on the other hand, refers to the polymer's ability to withstand degradation via biological processes within a living organism.

The high thermal stability of polymer implies that the polymer should not breakdown at maximum temperatures encountered during the foreseeable use.

6. PLC assessment of PFPE oils

In this study, the four commercially available PFPE oils were assessed using above noted PLC criteria (Table 3). These criteria are consistent with the previous studies conducted by Henry et al. and Korzeniowski et al., as well as with the report commissioned by European Commission [2,8,12]. The assessment criteria include structure, stability, as well as physical and chemical properties of PFPE oils and are supported by data gathered by the author companies. The results of PLC assessment of PFPE oils are discussed below and summarized in Table 4.

The underlying methods and references supporting the data used for PLC assessment are provided in the supporting information.

6.1. Polymer composition

PFPE oils satisfy the polymer composition criterion as their structure and composition are known and they have either oxygen or fluorine covalently bonded to carbon in their structures. Although Henry et al. and Korzeniowski et al. do not specifically list oxygen in their PLC criteria evaluation, polymers containing oxygen that is covalently bonded to carbon are considered less hazardous per the REACH regulation in the EU states and can also qualify for Polymer Exemption Rule of the US EPA [2,8,12,69]. Therefore, presence of oxygen in the polymer structure also satisfies the PLC criteria and PFPE oils do not contain any elements not listed as part of the PLC criteria.

6.2. Molecular weight, number average molecular weight, molecular weight distribution, and % oligomer < 1000 Da

All four PFPE oils satisfy the molecular weight criteria as their M_n are ≥ 1000 Da with a range of 1000–25,000 Da. They also exhibit a narrow MWD with a range of 1–1.5 that is within the criterion range of 1–3. Furthermore, they have <1–2 % oligomers with molecular weight <1000 Da that is within the 5 % allowed in the PLC criteria. Therefore, based on M_n , MWD and oligomer wt %, PFPE oils are not expected to cause adverse health concerns.

6.3. Ionic character

PFPEs are neutral and do not contain any ionic groups at the terminus of their polymer chains. Furthermore, they are unlikely to ionize in the aquatic environment. Therefore, PFPE oils satisfy the ionic character criterion as they do not exhibit any cationic functionality that would be harmful to aquatic life.

6.4. RFGs, FGEW and structural similarities to RFGs of concern

PFPEs do not contain any RFGs of moderate to high concern or exhibit structural similarities to RFGs of concern. Therefore, FGEW is not applicable to PFPEs. The ether linkages present in PFPE oils are not identified in the low, moderate and high concern categories, and by default might be considered under high-concern category as it includes “any other RFG not in low or moderate concern groups” [12,73]. However, we propose that the ether linkages should be classified as low concern due to: 1) F atoms shield the alkyl chain and limit the reactivity of oxygen [76]; 2) The electron withdrawing nature of perfluoroalkyl chain also limits the reactivity of oxygen by reducing the oxygen’s nucleophilicity [77]. Therefore, PFPE oils satisfy the RFG criterion of PLC framework.

6.5. Low molecular weight leachables, residual monomers and ratio of residual monomers to molecular weight

Low molecular weight leachables and residual monomers are an

Table 4
PLC assessment of PFPE oils.

	PFPE - D	PFPE-Z (and M)	PFPE-K	PFPE-Y
Name	Oxetane, 2,2,3,3-tetrafluoro-, homopolymer, fluorinated	Ethene, tetrafluoro-, oxidized, polymd	Poly[oxy[trifluoro(trifluoromethyl)-1,2-ethanediyl]], α -(1,1,2,2,2-pentafluoroethyl)- ω -[tetrafluoro(trifluoromethyl)ethoxy]-	1-Propene, 1,1,2,3,3,3-hexafluoro-, oxidized, polymd.
CAS Number	113,114–19–5	69,991–61–3	60,164–51–4	69,991–67–9
Structure	$F-(CF_2CF_2CF_2O)_n-CF_2CF_3$ $n = 10-100$	$CF_3O-(CF_2CF_2O)_p-[CF_2O]_qCF_3$ $p/q = 1$	$CF_3CF_2CF_2O-[CF(CF_3)CF_2O]_n-CF_2CF_3$ Where $n = 6$ to 100	$CF_3-[(OCF(CF_3)CF_2)_m-(OCF_2)_n]OCF_3$ $m + n = 8-45$
Polymer Composition Known	yes	yes	yes	yes
Number Average Molecular Weight (M_n)	1800 - 16,000	3500 - 25,000	1000 - 13,500	1900 - 10,000
Molecular Weight Distribution (MWD)	1.1	1.5	1.0–1.1	1.05–1.4
wt % oligomer	<1 % below 1000 Da	<1 % below 1000 Da	<2 % for <1000 Da	<1 % below 1000 Da
Ionic character	neutral	neutral	neutral	neutral
Reactive functional groups (RFGs)	none	none	none	none
Functional group equivalent weight (FGEW)	not applicable	not applicable	not applicable	not applicable
Low molecular weight leachables	<1 %	<1 %	<0.01 %	<1 %
Residual monomers	<10 ppm	<1 ppm	<1 ppm	<1 ppm
Ratio of residual monomers to molecular weight	<10 ⁻⁸	negligible	negligible	negligible
Structural similarities to RFG of concern	none	none	none	none
Physical-Chemical Properties				
Water solubility	practically insoluble or insoluble	practically insoluble	practically insoluble	practically insoluble
Octanol/water partition coefficient, K_{ow}	not applicable	not applicable	not applicable	not applicable
Particle size	liquid	liquid	liquid	liquid
Stability				
Hydrolysis	stable	stable	stable	stable
Light (hν)	stable	stable	stable	stable
Oxidation	stable	stable	stable	stable
Biodegradation (aerobic and anaerobic)	stable	stable	stable	stable
Thermal stability at normal foreseeable use maximum continuous temp (°C)	250	250	300	300
Meets PLC criteria (Y/N)	Y	Y	Y	Y

Note.

1) The underlying methods and references for this table are provided in the supporting information document.

important consideration to assess risk to human health and environment. No specific concentration thresholds are defined for these two parameters in the PLC criteria. However, these parameters are generally evaluated to demonstrate that they do not present any significant concern. Each of the four PFPE polymers is analyzed by the manufacturers for low molecular weight leachables and residual monomers for the purposes of regulatory compliance and filings, as part of stringent approval processes, therefore, in this manuscript and the supporting materials we report some data for those two metrics. The analytical methods have also been provided in the supporting information to the extent that these were available from the manufacturers. All four PFPEs are expected to contain negligible low molecular weight leachables and residual monomers based on the PFPE manufacturing process. During the manufacturing process, the majority of impurities are eliminated through the purification of crude polymers. This purification involves using absorbent agents to remove polar components, followed by distillation to fractionate the polymer into specific molecular weight ranges [21]. This is also corroborated by the data available for the PFPEs where a potential upper value of <1 % low molecular weight leachables has been determined for PFPE-D, PFPE-Y and PFPE-Z based on gel permeation chromatography method, and a value of <0.01 % low molecular weight leachables has been determined for PFPE-K using an extraction-based method (see supporting information for more details). The residual monomer concentrations have also been analytically determined to be <10 ppm for PFPE-D, and <1 ppm for PFPE-Y, PFPE-Z and PFPE-K. Overall, based on the PFPE manufacturing process and the data provided by the manufacturers, PFPEs are not expected to produce significant low molecular weight leachables and residual monomers that would cause potential health concern.

6.6. Particle size

All PFPE oils are liquids over a wide temperature range [21,78]. Therefore, particle size PLC criterion is not applicable to PFPEs.

6.7. Water solubility and octanol–water partition coefficient

PFPEs are practically insoluble in water and so cannot be associated with potential health concerns that might be caused by compounds with higher solubility. Furthermore, PFPEs are also considered to be practically insoluble in n-octanol based on detection limitations and sensitivity of standard analytical chemistry techniques, therefore water/octanol partition coefficient cannot be determined for them. PFPEs inability to dissolve in both water and n-octanol demonstrates that they cannot readily cross cell membranes, and there is no evidence to suggest that these polymers can accumulate or concentrate within biological organisms [2,8].

6.8. Stability (Hydrolysis, photochemical, oxidation, biodegradation and thermal)

PFPEs satisfy the PLC standards for hydrolytic, photolytic and oxidative stability, as well as biodegradation, since they do not decompose into $M_n < 1000$ species when exposed to these conditions. The high stability of PFPEs to these conditions is a critical and distinguishing characteristic that allows them to be used in various essential applications with no viable substitutes. This stability can be attributed to carbon-fluorine bond, which is the strongest carbon single bond.

Furthermore, PFPEs demonstrate that they are also highly stable to thermal degradation at prescribed temperatures of foreseeable use which are listed in Table 4 and lie within the range of 250–300 °C. Gross misuse of the polymers at higher temperatures could result in decomposition and release of hazardous gases but as long as PFPEs are used within the recommended operating conditions they do not degrade to species with $M_n < 1000$ and satisfy the PLC criteria.

6.9. All commercially available PFPEs meet the PLC criteria used in this assessment

The data provided in Table 4 and described above demonstrate that all four commercially available PFPEs satisfy the criteria to qualify as PLC. They are all liquid over a broad temperature range, so they don't have any adverse effects from inhalation associated with particulate polymer powders. Additionally, they exhibit negligible solubility in both water and octanol. Consequently, their mobility in the environment is limited, and they are unlikely to be detected in drinking water sources. Furthermore, lack of solubility in octanol indicates that they are neither bioavailable nor bioaccumulative. They are polymers of sufficient M_w , with narrow MWD, so they cannot pass through the cell membranes. Additionally, the studied PFPEs contain negligible amounts of oligomers, residual monomers and other synthesis by-products, and therefore, do not produce any significant amounts of leachables that can be mobile in the environment and cause adverse impacts on environment and/or health. PFPEs are also very stable due to the strength of carbon fluorine bond and the shielding effect of fluorinated perfluoroalkyl chain. They are inert and exhibit excellent stability to hydrolysis, photolysis, biodegradation and chemical oxidation. They are also thermally stable and do not breakdown into low M_w fragments at prescribed temperatures of intended use.

These results are consistent with fluoropolymers previously studied by Henry et al. and Korzeniowski et al. using the PLC framework and confirm that PFPEs also qualify as PLC [2,8].

7. PFPE life cycle impacts

The main thrust of this paper is to present information and data on the utility of PFPEs, their physical and chemical properties, and, more importantly, whether PFPEs conform to the metrics of PLC criteria [2,8,13]. However, it is also important to consider life cycle impacts of PFPEs to supplement the PLC assessment, and to evaluate their environmental footprint and whether their production, usage and disposal can lead to unintended risk to the environment or human health.

For a life cycle analysis, the typical assessment requires consideration of the nature and extent of emissions during manufacture and the potential for exposure during manufacture and after sales [79,80]. Typically, these emissions are evaluated based on their scope, toxicity, and exposure parameters [2,81]. Previous papers on fluoropolymers have separately discussed the life cycle assessment of fluoropolymer, so in this article we supplement those prior statements with a focus on the PFPEs [2,8]. We discuss the life cycle impacts of PFPE with respect to beginning of life, usage and end of life, in order to determine any potential releases and risks to human health and ecosystems.

7.1. Beginning of life

The three PFPE manufacturers (Chemours, Daikin, and Syensqo (formerly Solvay)) have made numerous public statements on their commitment to responsible manufacturing practice standards, and control of emissions during manufacture of their products including PFPEs [82–86]. These commitments include: 1) Use of sustainable chemistry approaches during manufacturing [85]; 2) Implementing responsible care policies [87]; 3) Leading development of advanced analytical methods to determine PFAS emissions [83]; 4) Reducing emissions of fluorinated organic chemicals by at least 99 % in air and water from the manufacturing process [82–84].

In previous sections, the synthesis of PFPEs was discussed, and chemical schematics were provided (Figs. 1–4) detailing the chemical reactants that comprise the manufacture of PFPEs. It should be noted that one of the concerns that has been raised with other polymeric PFAS such as fluoropolymers was the use of polymerizations aids and their potential for release, either during manufacture or normal use, as well as release of monomers and unintended oligomers [79]. Polymerization

aids, whether fluorinated or non-fluorinated, have never been used in the manufacture of PFPEs. Additionally, the formation of unintended oligomers or the presence of monomeric starting materials entrained within the PFPEs is negligible and is removed during the purification process during the manufacture. This is evident by the data that is provided in Table 4 and discussed in PLC assessment section. Additionally, it should be noted that the manufacture and sale of PFPEs are costly, making the waste of valuable and expensive starting materials and products a significant concern. This provides a clear incentive for manufacturers to implement controlled processes and circular practices that minimize emissions, maximize the use of every molecule of starting material, and ultimately keep costs down for the end users.

We acknowledge that there is a lack of information on the actual emissions during PFPE manufacture, however, statements made by manufactures themselves, and responsible manufacturing principles utilized in the manufacture of PFPEs support the conclusion that the manufacturers are committed to controlling unintended PFAS releases. Some have further pledged to reduce PFAS emissions by >99 % compared to previous baselines [82,88].

7.2. Usage

Non-functionalized PFPEs, which are the focus of this paper, satisfy the PLC criteria as corroborated by data presented in Table 4 and discussed in previous sections. They are stable and do not degrade under prescribed conditions of usage to produce non-polymeric PFAS nor leach significant concentrations of non-polymeric PFAS, and therefore are not expected to present significant risk to human health and ecosystem during the period of their usage. Prior publications have opined that [79, 80]: 1) Starting materials for the manufacture of PFPEs have a minimum purity of 98.6 % (by weight) so it is unclear how these impurities can affect the purity of the final PFPE product and that these impurities can also potentially lead to formation of additional unintended low molecular weight oligomers; 2) The final PFPE product can contain unreacted reaction intermediates from the manufacture process. However, as discussed previously in this publication, PFPEs undergo a purification process during manufacturing such as using absorbent agents to remove polar components, followed by distillation to fractionate the polymer into specific molecular weight ranges [21]. These purification techniques would remove unwanted impurities and by-products that might be generated during manufacture of PFPEs. This is consistent with the oligomer, residual monomer and low molecular weight leachable data that has been provided by the manufacturers. Therefore, any releases of either monomers or oligomers, either formed during the manufacture or resulting from purity of starting materials, are unlikely during normal conditions of use.

7.3. End of life

There are several routes possible for end-of-life disposal of PFPEs: recycling, incineration and landfill. Recycling of business or commercial waste is often encouraged by regulatory authorities to minimize the waste [89]. PFPEs are used primarily in lubrication applications, so they constitute only a small fraction of large equipment, where they are often applied in thin films between metal surfaces. It is often impractical to directly recycle the lubricants due to the complexity of separating and reclaiming these small lubricant quantities from the machinery. However, the metal components to which the lubricants are applied are often recycled at scrap metal facilities. Scrap metal recycling has several advantages such as preservation of natural resources, less energy usage compared to processing virgin raw materials and lower cost for the manufacturers. Scrap metal recycling involves several steps including: sorting, processing, melting and purification. During melting, the metal components are heated in furnaces at temperatures dependent on the type of metal. For example, stainless steel is typically melted at elevated temperatures of 1600–1700 °C [90]. Depending on the temperatures of

these furnaces, PFPEs are likely to be mineralized during the melting process.

Additionally, outside the scrap metal recycling process, a small quantity of PFPEs will end up being incinerated in hazardous waste combustors like industrial incinerators, cement kilns and thermal oxidizers. Korzeniowski et al. provide a good brief review of various publications which indicate that under commercial incineration conditions, fluoropolymers are expected to be completely mineralized [2]. The feasibility of incineration for complete destruction of PFAS is a topic that is being actively researched with concerns over release of products of incomplete combustion. Based on other studies and the limited data available on PFAS incineration, it is anticipated that at temperatures exceeding 1000 °C, a high degree of mineralization of PFPEs will be achieved, with minimal release of products from incomplete destruction [91]. However, we recognize a data gap regarding the fate of PFPEs during incineration, highlighting the need for more experimental research and data from commercial incineration units. US EPA, in its 2024 Interim Guidance on PFAS destruction and disposal also admits that “Research suggests that the use of higher temperatures, well mixed combustion environments, and longer residence times may be more conducive to destroying PFAS and controlling related products of incomplete combustion. Although limited data have been obtained since the 2020 version of the interim guidance (including data suggestive of adequate temperature ranges to break down PFAS), uncertainties remain about the effectiveness of thermal treatment” [92].

Some PFPEs may also end up at landfill disposal at the end of their industrial or consumer life. Previous publications have suggested that polymeric PFAS such as PFPE can degrade during the end-of-life disposal in landfills [79,80]. While we acknowledge the theoretical possibility of this occurring, the data presented in this publication indicates that PFPEs are expected to remain stable and not degrade under normal landfill conditions. It has been specifically mentioned that PFPEs may exhibit instability in the presence of Lewis acids [80]. While we acknowledge the possibility of such interactions, their relevance to the disposal or incineration of PFPEs is uncertain. More research needs to be conducted to fill this data gap and provide experimental evidence to corroborate whether PFPEs remain stable or degrade to release unintended PFAS during landfill disposal. The appropriate course of action is to adhere to the standard usage guidelines provided by manufacturers, ensuring that PFPEs are employed as intended, avoiding exposure to Lewis acids and utilizing these lubricants for their designed applications.

8. Conclusion

This study brought together data for four commercially available PFPEs collected from literature and manufacturing companies for use in assessing the PFPEs with recognized criteria for regulatory assessment - polymer of low concern (PLC). PFPEs are high M_w polymers with narrow molecular weight distribution that do not leach significant concentrations of residual monomers or low M_w oligomers. They are highly insoluble in water and octanol which enables the properties of immobility, non-bioaccumulativity and non-bioavailability under environmental and foreseeable use conditions. Additional life cycle considerations of PFPEs were briefly discussed, acknowledging existing data gaps that require further research. However, given the commitment of PFPE manufacturers to responsible and sustainable practices, along with the inherent stability of PFPEs, it is not anticipated that they pose a significant risk during their production, use, or end-of-life stages. The evaluation presented in this paper is also further supportive of the proposition that there is no scientific basis for grouping PFPEs with non-polymeric PFAS which exhibit very different chemical and physical properties. Instead, PFPEs should be considered as a distinct class of PFAS - similar to what has been proposed for fluoropolymers in prior studies. PFPEs play a critical role in various important applications in semiconductor, nuclear, space and automotive industries, as well as in breathing and oxygen equipment. Therefore, PFPEs are not only “deemed

to have insignificant environmental and human health impacts" based on PLC assessment, but they are also of strategic importance to healthcare, national security, and for a sustainable future.

CRedit authorship contribution statement

Hassan Javed: Writing – review & editing, Writing – original draft, Visualization, Methodology, Investigation, Data curation. **Graham K. Ansell:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Methodology, Investigation, Conceptualization. **Frank Adamsky:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Conceptualization. **Marco Malvasi:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Conceptualization. **Paige K. Mulvaney:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Conceptualization. **Pier Antonio Guarda:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Conceptualization. **Robert H. Moffett:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Conceptualization. **Simone Genna:** Conceptualization, Funding acquisition, Investigation, Methodology, Writing – original draft, Writing – review & editing. **Steve Johnston:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Conceptualization. **Xian Liang:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Conceptualization.

Declaration of competing interest

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.jfluchem.2025.110459](https://doi.org/10.1016/j.jfluchem.2025.110459).

Data availability

All data used in the manuscript are provided within the text. Where information was considered confidential business information, this has been clearly indicated in the manuscript.

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