ENVIRONMENTAL FATE AND BEHAVIOR STUDIES OF A POLYMERIC PFAS, POLYTETRAFLUOROETHYLENE (PTFE) – RESULTS AND APPLICATION TO RISK ASSESSMENT

Introduction

The term per- and polyfluoroalkyl substances (PFAS) covers a wide and diverse array of chemistry often defined only by the presence of at least one fully fluorinated carbon (Buck et al., 2011; OECD, 2021). PFAS may be non-polymeric (perfluoroalkyl substances or polyfluoroalkyl substances) or polymeric (fluoropolymers, perfluoropolyethers or side-chain fluorinated polymers) (Henry et al., 2018; OECD, 2013, 2021). Various international bodies have sought to restrict PFAS as a broad grouping to minimize their environmental release and potential risk, with a host of restrictions recently proposed or enacted globally. The primary concern expressed by regulators for all PFAS and/or their degradation products is their shared characteristic of persistence (ECHA, 2023; Balan et al., 2021). Simply put, these regulators believe persistence equates to (bioavailable) exposure to humans and biota, that such exposure equates to increased risk of adverse effects, and environmental emission equals risk. Being persistent (P) or very persistent (vP) is not, however, by itself sufficient to classify a substance as a "hazard" under European (EU REACH or the EU Classification, Labelling and Packaging), US or international (United Nations Environment Programme, Globally Harmonized System of Classification and Labelling of Chemicals, or the Stockholm Convention) regulatory frameworks. Persistence *alone* is not currently recognized as a regulatory hazard.

Polytetrafluoroethylene (PTFE) is a polymeric PFAS well established in peer-reviewed scientific literature to have very high molecular weight, low toxicity, high stability and chemical resistance, and no bioaccumulation potential. Understanding environmental fate, or what happens when a substance is released into an environmental compartment (air, water, soil, or sediment), is necessary to determine the exposure potential to humans, plants, or animals. With knowledge of that exposure potential and the established low hazard of PTFE, its risk across the life cycle can be assessed.

This paper asks: If this PTFE were found in the environment, would it degrade to and subsequently release substances of concern, such as non-polymeric PFAS? If PTFE is persistent but is not itself a hazard and does not transform to release hazardous substances of concern, what is the risk to be regulated?

The Study

This paper, submitted for scientific peer-review, presents the results of a comprehensive risk assessment of PTFE-FA, a high molecular weight, fine powder (microparticulate) polytetrafluoroethylene meeting the ASTM D4895 standard for PTFE. Charles River Laboratories (CRL), an independent, GLP-accredited laboratory in Hertogenbosch, The Netherlands, used test guidelines (TGs) from the Organization for Economic Cooperation (OECD) 100 series physical chemical tests and the OECD 300 series TGs for environmental fate and behavior to test a commercially available pure PTFE-FA. Physicochemical data describes the tendency of a substance to partition to or concentrate in an environmental compartment, which elucidates exposure assessment for humans and biota. The environmental fate and behavior tests determine degradation over a 28-day period in seawater, soil, sediment, and sludge under both aerobic and anaerobic conditions, and in surface water and soil exposed to sunlight.

The tests found:

- PTFE-FA did not degrade in air, sunlight, seawater, soil, sediment, sludge or with bacteria.
- PTFE-FA does not contribute to elevated PFAS concentrations in wastewater discharge or inhibit sludge microbes.
- No transformation to, and subsequent release of (polymeric/non-polymeric) PFAS.
- A low likelihood of adsorption to soil/sediment or movement with them.
- PTFE-FA is not water soluble and does not partition to air or water (as gas/vapor).
- A low likelihood to move in solution in water, or to move in air as a gas or vapor, or to adsorb to soil or sediment and move with them; low likelihood for PTFE-FA to partition to or concentrate in the environment.
- That meeting *ASTM D4895 Standard Specification for Polytetrafluoroethylene (PTFE) Resin Produced from Dispersion* (which prohibits polymer additives or foreign material, colors, fillers, plasticizers, reprocessed or reground resin or any fabricated articles, and > 1% by weight of a non-TFE fluoromonomer) reduces the availability of substances to potentially be released into the environment.

Conclusions

These studies therefore show that the stability of PTFE-FA (a.k.a. its persistence) does not result in increased environmental exposure from degradation to and subsequent release of substances of potential concern. Since risk is a function of hazard and exposure, the combination of data from these studies showing low bioavailable exposure potential and low hazard data from the scientific literature supports a conclusion that this PTFE is a low risk to human health and living things. Simply being present (persistent) does not imply future degradation or transformation into a substance of concern. Based on these studies, persistence does not equate to risk for this PTFE. PTFE differs substantially from other PFAS.

Further research is recommended into the exposure and hazard potential of micro- and nanoparticles (MNPs). However, the extreme resistance to biotic, abiotic, and chemical degradation of PTFE demonstrates its resistance to fragmentation and reduced likelihood of MNP formation, as does the low likelihood of MNP formation via weathering (based on publicly available data).

Further Exploration

Uptake in plants

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, a very high molecular weight polymeric PFAS, 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). Partitioning to solids and soils through electrostatic and hydrophobic interactions is unlikely for PTFE-FA. Therefore, 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.

Mobility with air and long-range transport potential

Volatility helps predict the likelihood of a substance partitioning to air if it becomes a gas or vapor, and long-range transport potential (LRTP) 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. The vapor pressure of PTFE-FA at 20°C was estimated to be <1.3 x 10^{-8} Pa (<1 x 10^{-10} mm Hg at 20°C) (OECD 104) making it unlikely to volatilize and having very low potential to partition (as a vapor or gas) to air.

Henry’s law constant, calculated from vapor pressure and water solubility, reflects volatility and likelihood to partition to air from water. Considering the extremely low vapor pressure and insolubility of PTFE-FA, it is unlikely to partition from water to air (as a gas or vapor) or from organic media to air.

Mobility with water

PTFE-FA is highly unlikely to be a water-soluble contaminant, or to move in solution with water. PTFE-FA is insoluble in water (OECD 105, 120). PTFE-FA is not corrosive or caustic and is not ionizable.

Mobility with soil

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 the binding capacity of a substance but require the test substance to be completely soluble in water or in conventional organic solvents or in solvent/water mixtures, which PTFE-FA is not. Partition coefficients and dissociation constants are generally not relevant for solid, insoluble polymers, such as PTFE-FA, since they do not dissociate and are not soluble in water (ECETOC, 2021). The results of OECD TG 107 and OECD TG 117 support that PTFE is neither fat soluble nor bioaccumulative via adsorption to organic matter in soils or sediments. PTFE-FA is unlikely to adsorb to soil and move with it.

Bioavailability/Bioaccumulation

The molecular weight of PTFE-FA far exceeds that which is recognized as being too large to be bioavailable through passive transport (DeMello, 1987; Beyer EC, 1993; Alberts B et al., 1994; Lipinski C.A., et al., 2001; Ming-Qiang Zhang and Barrie Wilkison, 2007; OECD 2009). PTFE-FA is not fat soluble and unable to penetrate cell membranes. It is highly hydrophobic and has no hydrogen atoms and therefore no hydrogen bond donating potential for passive transport into a cell. Active transport into the cell is dependent on chemical and structural properties such as molecular shape, volume/size, and whether the atomic bonds can rotate. PTFE-FA lacks the rotational bonds and functional groups with which the transporter proteins responsible for active transport may interact. These same features prevent PTFE-FA from binding to the cell surface receptors and signaling events inside the cell (Leeson, 2012). Structurally, PTFE-FA is unlike high molecular weight, natural compounds, such as steroids and peptides, that are known to be bioavailable (Ganesan A, 2008). Therefore, PTFE-FA is not bioavailable by passive or active transport or binding to cell surface receptors or signaling events inside the cell. Substances that are not bioavailable are not bioaccumulative.

Biodegradability

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. PTFE-FA does not biodegrade to be a potential source of substances of concern in the environment. PTFE-FA was not inhibitory to sludge microbes. PTFE-FA was not sufficiently soluble for evaluation by TG 306 (biodegradability in seawater). PTFE-FA was considered stable and inert under aerobic and anaerobic conditions.

Photolysis

PTFE-FA was completely photolytically stable under all test conditions with direct irradiation, irradiation in aqueous medium, and irradiation in soil thin-layers.

Summary of Test Results

The PTFE-FA data addresses current validated environmental fate and behavior testing, as well as current and future polymer assessment criteria. 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 substances, reinforces the low hazard of PTFE-FA in the environment. 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).

Abiotic Stability

Heat
OECD 113
Thermal Gravimetric Analysis

Sunlight
OECD Phototransformation on soil draft 2002
OECD 316 Phototransformation in water

Water*
OECD 105, 120, 107, 117, 122,
Henry's Law Constant

PTFE-**FA**
(**F**ine powder,
ASTM D4895)

Biotic Stability

Ready Biodegradation
(OECD 301B)

Inherent Biodegradation
(OECD 302C METI)

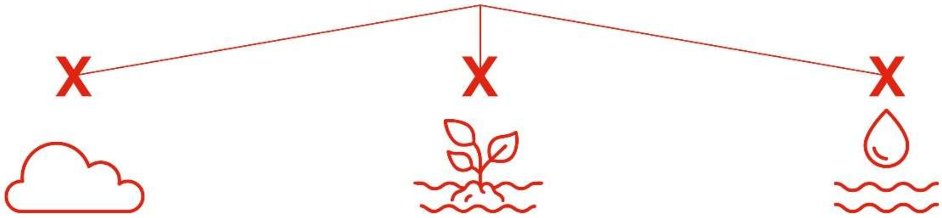
Aerobic Sewage
(OECD 303A)

Biodegradability in Seawater
(OECD 306)

Aerobic and Anaerobic
Transformation in Soil (OECD 307)
and Aquatic Sediment (OECD 308)

*Per EU REACH Annex VII, OECD 111 is not required if substance is highly insoluble.

PTFE-**FA** (**F**ine powder, **A**STM D4895)



Partitioning to Air
(gas or vapor)
OECD 113
OECD 104
OECD 118
Log Koa
Henry's Law Constant
Thermal Gravimetric Analysis

Partitioning to Soil
OECD 106
OECD 107
OECD 117
OECD 118
OECD Draft 2002

Partitioning to Water
OECD 105
OECD 120
OECD 107
OECD 117
OECD 122
Henry's Law Constant

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