SUMMARY OF THE PTFE STUDIES PERFORMED WITH INDEPENDENT LABORATORIES TO INVESTIGATE PERSISTENCE, DEGRADATION, TRANSFORMATION TO OR RELEASE OF SUBSTANCES OF CONCERN

Background

Polytetrafluoroethylene, PTFE (CAS no. 9002-84-0) is a polymer of tetrafluoroethylene. PTFE comes in three forms: granular (the highest volume used globally; made without polymerization aids), aqueous dispersion (made with polymerization aids), fine powder (per ASTM D4895; made with polymerization aids). There are many textbooks and peer-reviewed publications on the properties of PTFE and how to manufacture and process it.

The form of PTFE used in W. L. Gore & Associates products is fine powder PTFE meeting the ASTM D4895-18 standard and the OECD criteria for Polymer of Low Concern. The ASTM standard covers dry-powder resins of PTFE produced from aqueous dispersion. The specification states that the resin shall be uniform and shall contain no additives or foreign material and that the color shall be natural white. The specification does not include mixtures of PTFE with additives such as colors, fillers, or plasticizers, reprocessed or reground resin or any fabricated articles because the properties of such materials have been irreversibly changed when they were fibrillated or sintered. 100% of the PTFE used by Gore meets this ASTM 4895 standard. This is critical to point out because it limits the substances that may leach from the polymer into the environment or living organisms.

Given the extreme durability/persistence of PTFE and interest in what, if anything leaches from the fluoropolymer into biota or the environment, this body of work was undertaken with independent contract laboratories to investigate degradation, release or transformation and leachability of substances of concern into media that may be potential routes of exposure: air, water, and soil. The following studies were performed at the Charles River Labs in Den Bosch, the Netherlands. Standard OECD (and US EPA) efate protocols were used. Studies were performed under Good Laboratory Practices. They were performed to investigate if persistence implies future degradation, release, or transformation into a continuous source of substances of concern. The plan to conduct these studies as well as the results have been shared at scientific meetings including SETAC (NA and EU), FLUOROS Global 2021, and Emerging Contaminants.

Studies to Address Potential Partitioning to Water

<u>OED 105 Water Solubility</u>
Soluble substances may contaminate drinking, surface and ground water and move with the water. Results of this study were that PTFE was insoluble in water.

<u>Ready Biodegradation OECD 301B</u>
This is a biotic stability test which looks for biodegradability within 28 days. PTFE was determined not to be biodegradable.

<u>Inherent Biodegradation OECD 302C</u>
This is a biotic stability test for biodegradability. PTFE was determined not to be biodegradable in this test.

These data confirm the low probability of water exposure to PTFE, degradants or leachables.

Studies to Address Potential Partitioning to Soil

<u>Molecular Weight OECD 118</u>
This test was performed to determine if low molecular weight fractions are available for migration out of the polymer, and, if the polymer is bioavailable.[1] Molecular weights above 1,000 Da do not pass through the cell membrane and are considered not to be bioavailable or, therefore, bioaccumulative. PTFE was determined not to be sufficiently soluble for gel permeation chromatography even after sonication and stirring for 19 hours in tetrahydrofuran, dichloromethane, dimethylformamide, or dimethyacetamide. Using alternative methods of standard specific gravity and melt flow rheology, the molecular weight was determined to be above 500,000 Da.

1. PTFE cannot penetrate a cell membrane via passive or active transport and does not bind or interact with the cell surface because: of its size; the lack of lipid solubility; the lack of oxygen and nitrogen atoms estimating groups accepting hydrogen atoms. PTFE is highly hydrophobic and has little or no hydrogen bond donating potential. PTFE is not structurally similar to steroids, peptides, or other natural compounds which may be exceptions to Lipinski's "Rule of 5". Active transport and cell surface binding/signaling is dependent on shape, volume/size, rotational bonds, etc. and requires interaction with cell surface. (De Mello WC., Ed., Cell-to-Cell Communication, Plenum Press, NY, 1987, p34; Beyer EC, Gap Junctions. Inter. Rev. Cytol. 137, 1993 p2; Molecular Biology of the Cell, 3rd Ed., Alberts B, Bray D, Lewis J et al., Garland Science, NY, 1994, pp 958, 963; Paul Leeson, From Drug discovery: Chemical beauty contest, Nature 481, 455–456, 26 January 2012; Ming-Qiang Zhang and Barrie Wilkinson. Drug discovery beyond the 'rule-of-five'. Current Opinion in Biotechnology 2007, 18:478–488.)

Soil Adsorption OECD 106
This study was performed to determine the likelihood of the substance partitioning to soil and/or to the sediment. Results of this study are still pending.

Phototransformation on Soil Surfaces OECD draft document
This is an abiotic stability test for degradation in sunlight on soil surfaces. Results of this study are still pending.

Based on the high molecular weight, no partitioning to soil is anticipated.

Studies to Address Potential Partitioning to Air

Molecular Weight OECD 118
See above.

Vapor Pressure OECD 104
This study was performed because volatility helps predict the likelihood of partitioning to air and long-range transport potential. The vapor pressure was determined to be very low less than 1 x 10-10 mm Hg @ 20°C.

Melting Temperature OECD 102
Performance of the melting temperature supports thermal stability at environmentally relevant temperatures. The melt transition was around 350°C. No further melting or decomposition occurred at less than 400°C.

Thermal Stability OECD 113
This test is for degradation from heat at environmentally relevant temperatures. No decomposition or chemical reaction was observed at less than 150°C.

Thermal Gravimetric Analysis
This is a method of thermal analysis where mass is measured over time as the temperature changes and mass is lost to the air. No observable weight loss below 549°C, however at 549°C a 5% weight loss was observed.

This data supports the lack of inhalation exposure potential at environmentally relevant temperatures.

Leaching Potential

Because there were no OECD guidelines specifically addressing the potential of a polymer to leach substances under environmental conditions, a first tier leaching potential test, Toxicity Characteristic Leaching Potential (US EPA SW-846 Test Method 1311), was performed by ALS Laboratories in Kelso, Washington (USA). This test has historically been used by EPA to determine the mobility of both organic and inorganic analytes present in liquid, solid, and multiphasic wastes. This TCLP test generates a leachate in a lab setting designed to simulate landfill conditions to evaluate potential environmental impact from uncontrolled land disposal.

Tier 1: Toxicity Characteristic Leaching Potential EPA SW-846 Test Method 1311
100 grams of each of two PTFE fine powder samples were tumbled, in 5.7 ml of glacial acetic acid per 1 liter of reagent water, at room temperature for 18-20 hours at 30 rpm, before being filtered using a borosilicate glass fiber filter with a 0.6 to 0.8 µm pore size. 100 ml of the extraction fluid was then extracted in 60 ml of dichloromethane for approximately 3 hours at room temperature. The extracts were analyzed by GC/MS for this list of EPA analytes. The TCLP test was passed.

Conclusions from the Charles River Laboratory and ALS study

These results support the stability of PTFE and lack of transformation to other PFAS, such as perfluoroalkyl acids. PTFE will not partition to air, water, or soil. Potential inhalation, oral or dermal exposure to PTFE for biota or the environment is unlikely based on this data.

Dr. Barbara Henry
January 2022

W. L. Gore & Associates
555 Paper Mill Road
Newark, Delaware 19711
gore.com