A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers

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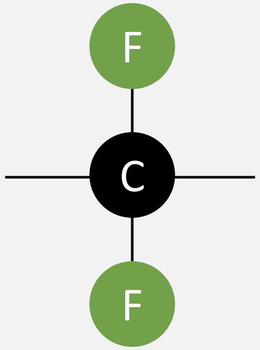
GORE
60 YEARS OF IMPROVING LIFE

Overview Per- and Polyfluoroalkyl Substances (PFAS)

Thousands of PFAS with a wide variety of properties

Similarities



1 fully fluorinated carbon

Differences

Gases

Liquids

Solids

seconds ⟷ thousands of years

Stability

low ⟷ high

Toxicity

Mobility

insoluble / non-volatile ⟷ Highly mobile

Size

MW less than 1,000 Daltons ⟷ MW multi-million Daltons

Overview Per- and Polyfluoroalkyl Substances (PFAS)

1 Group — PFAS Per- and Polyfluoroalkyl substances

2 Categories

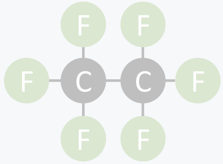
5 Classes

PFOA, PFOS, PFHxS, Refrigerants

Non-Polymers

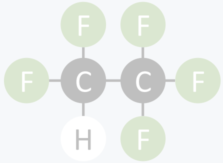
Perfluoroalkyl Substances

Compounds for which all hydrogens on all carbons (except for carbons associated with functional groups) have been replaced by fluorines



Polyfluoroalkyl Substances

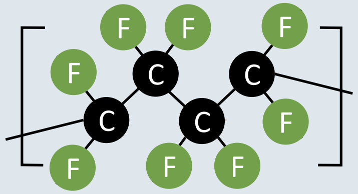
Compounds for which all hydrogens on at least one (but not all) carbon have been replaced by fluorines



Polymers

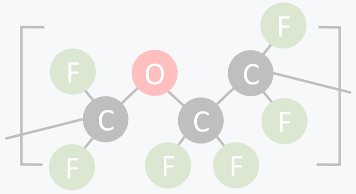
Fluoropolymers

Carbon-only polymer backbone with fluorines directly attached



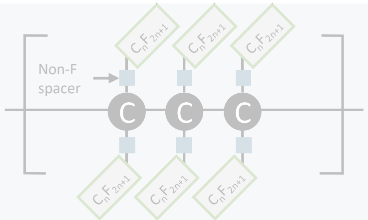
Polymeric Perfluoropolyethers

Carbon and oxygen polymer backbone with fluorines directly attached to carbon



Side-chain Fluorinated Polymers

Variable composition non-fluorinated polymer backbone with fluorinated side chains



Regulatory Environment PFOS and PFOA

Overview

Regulatory assessment and management efforts in several countries curtail manufacture and use of PFOA, PFOS and substances that may degrade to form them (precursors)

2005 PFOS and related substances proposed for listing as POPs

2009 PFOS listed under Annex B of the Stockholm Convention

2011 PFOA and related substances proposed for listing as POPs

2017 PFOA listed under Annex B of the Stockholm Convention

Mammalian Toxicity Tests to Address the Madrid Statement

Endpoint of Concern for PFCs	Data Proposed to Address Endpoint of Concern
liver toxicity	acute, 28- and 90-day systemic toxicity studies
disruption of lipid metabolism	28- and 90-day systemic toxicity studies with enhanced lipid profiling
disruption of immune system	skin sensitization for cellular immunity, TDAR for humoral immunity with flow cytometry and NK cell work
disruption of endocrine systems	EDSP panel of tests
neurobehavioral effects	28- and 90-day systemic toxicity studies with neurotoxicity endpoints, extended 1-gen reproduction study with neurotoxicity group
neonatal toxicity/death	extended 1-gen reproduction study, 2-gen reproduction study, prenatal toxicity 2 species
tumors in one or more organs	*in vitro* and *in vivo* genotoxicity studies, carcinogenicity (if genotoxicity weight of evidence is positive)

Would use ~7,000 mammals, take 3 years and $1.6 to $2.5 million.

Regulatory Environment Proposed New Criteria

Expanded Regulatory Interest

German Environment Agency (UBA)

Proposed new assessment criteria and procedures for identifying substances of very high concern under REACH, using the criteria persistent (P), mobile (M) and toxic (T) (PMT) or very persistent (vP) and very mobile (vM)(vPvM)

Swedish Chemicals Agency (KEMI)

Endorses German View

- all extremely persistent
- many are water soluble, mobile in soil
- likely to contaminate water

Regulatory Environment no single globally harmonized system for PFAS classification exists

What is Needed

A clearer understanding of PFAS in the environment and assessment of their properties to be able to determine which classes of PFAS require management action

Take into account differences in chemical, physical, thermal and biological properties

Distinguish classes of PFAS to assure that regulations are appropriate in scope and proportionality

Fluoropolymers in paper PTFE, FEP, ETFE, PFA

1938

PTFE discovery
by Roy Plunkett

1969

ePTFE discovery
by Bob Gore

Courtesy Hagley Museum and Library

- PTFE, FEP, ETFE, PFA accounted for approximately 70-75% of the world fluoropolymer consumption in 2015 (IHS, 2016)
- PTFE made up 58% (by weight) of 2015 worldwide fluoropolymer consumption (IHS, 2016)

Fluoropolymers

Durability

Inertness

Mechanical strength

Thermal stability

Resistance to degradation

Fluoropolymers

Commercial Application	Fluoropolymer Characteristics									
	Durable		Inert		Functional			Stable		
	mechanical strength	low particulation	resistance to chemicals	non-toxic, biocompatible, biological degradation resistant	flexibility	friction resistance	low dielectric constant	low leachables	resistance to photolysis, oxidation, hydrolysis	stability
Aerospace	X		X		X	X	X		X	X
Automotive Industry	X		X		X	X	X		X	x
Medical Devices	X	X		X	X	X		X	X	X
Pharmaceutical Manufacture	X	X	X	X	X			X		X
Consumer Outdoor Apparel	*X*			*X*	*X*			*X*		
Technical Clothing (military, firefighters, first responders, medical personnel)	X		X	X	X	X		X	X	X
Consumer Electronics	X		X		X	X	X		X	X
Wireless Comunications	X		X		X	X	X		X	X
Satellite Navigation Systems	X		X		X	X	X		X	X
Semiconductor Industry		X	X				X	X		
Building Construction	X			X	X		X		X	X
Energy Production & Storage	X	X					X	X	X	X
Food and Beverage Production	X	X	X	X	X	X		X	X	
Food Protection & Packaging	*X*	*X*	*X*	*X*	*X*			*X*		
Drinking Water Filtration		X	X	X				X	X	
Envronmental Protection		X	X	X				X	X	X

History Polymer Hazard Assessment

1976

Toxic Substance Control Act (TSCA)

EPA assessed new chemicals for:

physical, chemical, biological effects & potential exposure to the environment and human populations

1984

EPA Polymer Exemption Rule

Exempt low hazard polymers from certain notification requirements under the new chemicals program

1993

OECD Expert Group on Polymers

Consensus Document identifying Polymer of Low Concern criteria & definition of polymer

2007

OECD Expert Group on Polymers

"Polymers of low concern are those deemed to have insignificant environmental and human health impacts"

2015

EU Report on Global Polymer Regulation

9 of the surveyed nations agreed on polymer properties predictive of adverse health and environmental hazard

OECD Polymer of Low Concern Criteria

13 Criteria

- Polymer composition
- MW, M_n, MWD
- wt% oligomer
- Electrical charge
- Reactive Functional Groups (RFG)
- Functional Group Equivalent Weight (FGEW)
- Low MW leachables
- Water / lipid solubility, octanol water partition
- Particle size
- Polymer stability
- Thermal stability
- Abiotic stability
- Biotic stability

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Fluoropolymers Considerations for Analyzing

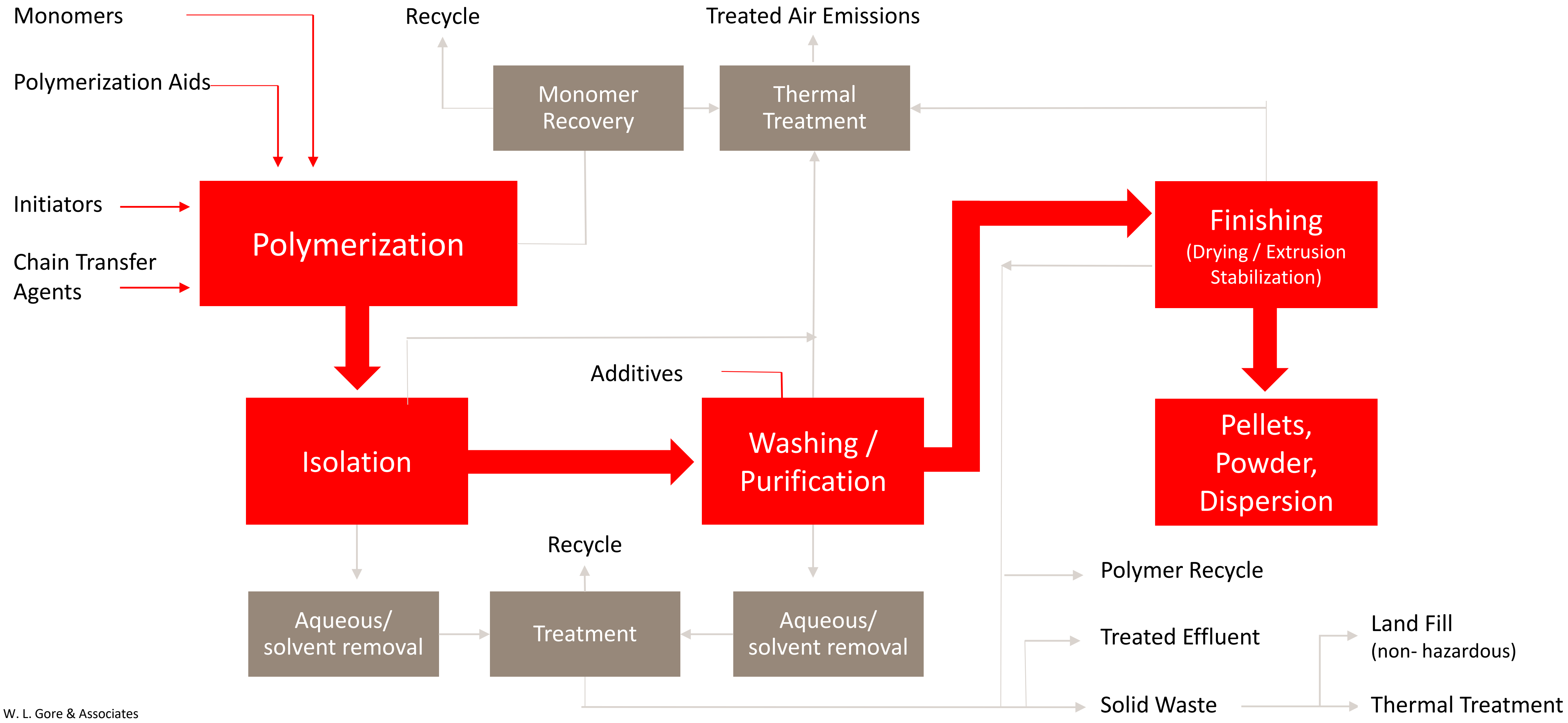
Measuring Fluoropolymers

Standard MW methods (e.g., GPC) not applicable for insoluble fluoropolymers, like PTFE

- replaced by standardized indirect methods that use specific gravity and melt flow index to determine molecular weight
- Standard Specific Gravity (SSG) and Melt Flow Rate (MFR) are more conveniently and frequently used, rather than rheological and dynamic light scattering methods

Fluoropolymers don’t dissolve in water or octanol — can’t measure K_{ow}

Fluoropolymer Manufacture General Diagram



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PTFE polymerization / post polymerization aids

Function	Examples
Coagulating agent	Acetone, Methanol, Potassium nitrate
Surfactant	4,9-dioxa-3H-perfluorononanoate, Ammonium, 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy-) propionate, Perfluoro, 2-2-(methoxypropoxy)propanoic acid ammonium
Initiator	Ammonium carbonate, Ammonium persulfate, Borax, Hydrogen peroxide
pH adjuster	Ammonium hydroxide, Hydrochloric acid, Sodium hydroxide, Nitric acid
Anticoagulant stabilizer	Paraffin wax
Dispersant	Purified deionized water
Removes monomer inhibitor	Silica gel

Based on PTFE patents and publicly available information (no single PTFE uses all of these). Note: Initiator concentration depends on rate and degree of polymerization, from 0.01 wt% to 0.5 wt% of the water.

Extractable/Leachable Analysis of PTFE

Sample ID	Nominal Sample Mass, g	Headspace GC/MS analysis	Ultrasonic IPA extraction GC/MS	Ultrasonic Hexane extraction GC/MS	Ultrasonic Extraction 55% H2O/45% IPA ESI(+) LC/MS	Ultrasonic Extraction 55% H2O / 45% IPA ESI(-) LC/MS	Ultrasonic Extraction IPA ESI(+) LC/MS	Ultrasonic Extraction IPA ESI(-) LC/MS	72 hr IPA Leachable extraction ESI(+) LC/MS	72 hr IPA Leachable extraction ESI(-) LC/MS	72 hr IPA Leachable extraction GC/MS	72 hr Hexane Leachable extraction GC/MS	72 hr 55% H2O / 45% IPA Leachable extraction ESI(+) LC/MS	72 hr 55% H2O / 45% IPA Leachable extraction ESI(-) LC/MS
PTFE Extract #1	1	trace[a c]	trace[a]	trace[a]	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	trace[a]	trace[a]	< 1 ppm[b]	< 1 ppm
PTFE Extract #2	1	trace[a c]	trace[a]	trace[a]	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	trace[a]	trace[a]	< 1 ppm[b]	< 1 ppm
Blank	1	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm

a - IK trace only from environmental contamination

b - slight erucamide peak, a persistent system contaminant that was also detected in the blank.

c - Hydrocarbon, fluorocarbon peaks but below identification threshold

d - Hydrofluorocarbon fragmentation peaks ~MW=532

e - A trace of 7H-perfluoroheptanoic acid, 9H-perfluorononanoic acid, ~600 ppb each.

f - A trace of an unidentified compound likely formula is $C_{27}H_{48}O_8$

ESI(+) indicates positive ion mode acquisition

ESI(-) indicates negative ion mode acquisition

Conclusions

By all extraction and analytical techniques employed in this study, oligomer and residual monomer were not detected. In addition, an ambient air contaminant (Isopar K) adsorbed to the PTFE fine powder was detected at ≤ 2 ppm. Therefore, PTFE meets the Polymer of Low Concern criterion of < 2% wt/wt or 20,000 ppm of extractable oligomers.

John D. Jones, M.Sc.
Analytical Chemist

Purpose

This analytical study was performed to develop and apply analytical approaches to generate the following PLC data for the fluoropolymer polytetrafluoroethylene, PTFE, with the sensitivity and selectivity needed. The specific properties that are not readily available and will be investigated in this work are: low molecular weight leachables and extractables, % oligomer, residual monomers.

Fluoropolymers Food, Pharmaceutical and Medical Devices

Test Performed (Lab Report No.) (Date Completed) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article[a] and Control(s)	Acceptance Criteria	Conclusions
***In Vitro* Cytotoxicity** *MEM Elution Test* (12T_29147_03) (5/2012) ISO 10993-5 ISO 10993-12	Extraction: Minimum Essential Medium with 5%	ePTFE fiber, Code: SMR108316	No signs of cellular morphologic change or	**PASS** – non cytotoxic
Delayed-Type Hypersensitivity *Kligman Maximization Test in Guinea Pigs* (12T_29147_06, 12T_29147_07) (6/2012) ISO 10993-10				
Irritation *Intracutaneous Irritation Study in Rabbits* (12T_29147_04, 12T_29147_05) (5/2012) ISO 10993-10				

Test Performed (Lab Report No.) (Date Completed) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article[a] and Control(s)	Acceptance Criteria	Conclusions
Systemic Toxicity *Acute Systemic Toxicity Study in Mice* (12T_29147_08, 12T_29147_09) (5/2012) ISO 10993-11	Extraction: 0.9% NaCl; sesame oil. Conditions: 50°C, 72 hours. Extraction Ratio: 6 cm²/mL	ePTFE fiber, Code: SMR108316 Neg. Control = 0.9% NaCl, sesame oil Pos. Control: N/A	Clinical Observations: No treatment-related signs of toxicity or loss of body weight. Pass if < 2 animals exhibit marked	**PASS** – not systemically toxic No treatment-related signs of toxicity or loss of body weight in any
Rabbit Pyrogen Study (Material Mediated) (12T_29147_10) (5/2012) ISO 10993-11 USP 151				
Genotoxicity *Bacterial Reverse Mutation Assay* (12T_31264_03, 12T_31264_04) (5/2012) OECD Test No. 471 ISO 10993-3 ISO 10993-12				

Test Performed (Lab Report No.) (Date Completed) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article[a] and Control(s)	Acceptance Criteria	Conclusions
Mouse Lymphoma Assay (12T_31264_05, 12T_31264_06) (7/2012) OECD Test No. 476 ISO 10993-3 ISO 10993-12	Extraction: RPMI culture medium, dimethyl sulfoxide Conditions: RPMI: 37°C, 72 hours dimethyl sulfoxide: 50°C, 72 hours Extraction Ratio: 6 cm²/mL	ePTFE fiber, Code: SMR108316 Neg. Control = vehicle only Pos. Control = 3-Methylchol-anthrene, Methyl Methanesulfonate	Mutagenic: a ≥ 2-fold increase in mean mutation frequency over the vehicle control. Non-mutagenic: < 2-fold increase. Results from cell cultures with < 10%	**PASS** – non mutagenic The test article extracts did not induce gene mutations or chromosomal damage.
Mouse Peripheral Blood Micronucleus Study (12T_31264_07, 12T_31264_08) (6/2012) OECD Test No. 474 ISO 10993-3 ISO 10993-12				
Local Effects after Implantation *Muscle Implantation Study in Rabbits (4 weeks)* (12T_29147_11) (6/2012) ISO 10993-6				

Test Performed (Lab Report No.) (Date Completed) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article[a] and Control(s)	Acceptance Criteria	Conclusions
Hemocompatibility Hemolysis Study Direct Contact and Indirect Contact (12T_29147_13) (5/2012) ISO 10993-4 ISO 10993-12 ASTM F756	Direct contact: The test article was introduced directly to test system at 6 cm²/mL	ePTFE fiber, Code: SMR108316 Negative Control = HDPE Positive control = sterile water for injection	Percentage hemolysis must be ≤ 2 % to be non-hemolytic.	**PASS** – Non-hemolytic. Direct contact: ≤ 2 % hemolysis.
Partial Thromboplastin Time, Direct Contact (12T_29147_14) (5/2012) ASTM F2382 ISO 10993-12				
Complement Activation C3a Complement Activation Assay (Direct Contact) (12T_29147_15) (5/2012) ISO 10993-4				

Test Performed (Lab Report No.) (Date Completed) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article[a] and Control(s)	Acceptance Criteria	Conclusions
SC5b-9 Complement Activation Assay (Direct Contact) (12T_29147_16) (5/2012) ISO 10993-4	No extraction. Test article was directly exposed to test system at a ratio of 6 cm²/mL at 37°C for 60 minutes.	ePTFE fiber, Code: SMR108316 Negative Control = HDPE Negative Control = LDPE; Positive Controls = latex gloves, CVF	The test article is considered to have no effect on complement activation if the SC5b-9 concentration is not statistically higher than activated NHS and negative control concentrations.	**PASS** – No activation of complement. The test article sample was not statistically higher (p<0.05) than both the activated human serum and negative controls.
Subchronic toxicity *13-Week Systemic Toxicity Study in Rats* (12T_29147_12) (9/2012) OECD Test No. 408 ISO 10993-11	N/A	ePTFE fiber, Code: SMR108316 Test Article Dose: 90 linear cm/rat. Based upon an average male 250 g rat (ie, 360 cm/kg), which is equivalent to a 70 kg patient receiving 25,200 linear cm. Neg. Control = HDPE	N/A. Information from these studies is used to inform clinicians of potential target organs and associated toxicities at multiples of the intended clinical exposure.	**PASS** – There were no clinical or systemic signs of toxicity (including gross-, microscopic-, and clinical-pathology evaluations). The test article was considered a non-irritant

ePTFE tube, sheet, fiber data in Supplement

- Cytotoxicity (MEM)
- Sensitization
- Irritation
- Acute & 90-Day Subchronic Systemic Toxicity
- 2 *In Vitro* + 1 *In Vivo* Genotoxicity
- 4-Week Implantation
- Hemocompatibility

Fluoropolymers Toxicity and Clinical Data

PTFE, FEP, and a TFE/PAVE copolymer passed these GLP tests	
Cytotoxicity (MEM)	(ISO 10993-5)
Skin Sensitization	(ISO 10993-10; OECD 406)
Irritation	(ISO 10993-10; OECD 406)
Acute Systemic Toxicity	(ISO 10993-11; OECD 408)
90-Day Subchronic Systemic Toxicity	(ISO 10993-11; OECD 408)
Two *In Vitro* + One *In Vivo* Genotoxicity	(ISO 10993-3; OECD 471, OECD 474, OECD 476)
2- or 4-Week Implantation	(ISO 10993-6)
Hemocompatibility	(ISO 10993-4; ASTM F756. ASTMF2382)

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

Clinical studies of patients receiving permanently implanted PTFE, FEP or TFE/PAVE copolymer cardiovascular medical devices demonstrate no chronic toxicity, carcinogenicity, reproductive, developmental or endocrine toxicity.

OECD Polymer of Low Concern Assessment Criterion

	PTFE	ETFE	FEP	PFA
	polytetrafluoroethylene	ethylene tetrafluoroethylene	fluorinated ethylene propylene	perfluoroalkoxy polymer
	CAS 9002-84-0	CAS 25038-71-5, 68258-85-5	CAS 25067-11-2	CAS 26655-00-5, 31784-04-0
Polymer Composition (must have C, H, Si, S, F, Cl, Br, or I covalently bound to carbon)	yes	yes	yes	yes
Molecular Weight (MW) (M_n > 1,000 Da are not bioavailable; <1% oligomer content lower hazard potential)	389,000 - 8,900,000*[a] 520,000 - 45,000,000*[b]	530,000 - 1,200,000**[c]	241,000 - 575,000**[d]	200,000 - 450,000**[e]
Molecular Weight Distribution (MWD) M_w ÷ number average M_n (M_n and heterogeneity of MW distribution indicate if most oligomers > 1,000 Da and not bioavailable)	2.3[f]	1.4 - 2.7[c]	1.55 - 2.09[d]	1.7[g]
wt% oligomer (<5% for <1000 Da oligomers, <2% for <500 Da oligomers; lower hazard potential)	negligible	negligible	negligible	negligible
Ionic Character (not cationic or polycationic polymers are lower hazard potential)	neutral	neutral	neutral	neutral
Reactive Functional Groups (RFGs) (no functional groups associated with adverse effects, e.g., acrylates, isocyanates, aziridines, etc.)	< 1 (see text)	< 1 (see article)	< 1 (see text)	< 1 (see text)
Functional Group Equivalent Weight (FGEW) (typical value — the higher the FGEW, the lower polymer reactivity and lower hazard potential)	> 10^5 - 10^7	> 10^5 - 10^6	> 10^5	> 10^5
Low MW Leachables (low amount or none, lower hazard potential)	< 1 ppm	no active leachables by USP class VI (121°C)	no active leachables by USP class VI (121°C)	no active leachables by USP class VI (121°C)
Residual Monomers (less/no residual monomer has lower hazard potential)	< 1 ppm	< 50 ppb	< 50 ppb	< 50 ppb
Ratio of Residual Monomers to MW (higher ratio, lower hazard potential)	~ 10^{-13} - 10^{-15}	~ 10^{-13} - 10^{-14}	~ 10^{-13}	~ 10^{-13}
Structural Similarities to RFG of Concern (few/none, lower hazard potential)	none	none	none	none
Physical-Chemical Properties				
Water Solubility (per USP 34 NF29 General Notices, p6) (<10 mg/L, lower hazard potential)	practically insoluble or insoluble (1x10^{-5} mg/L)	practically insoluble or insoluble	practically insoluble or insoluble	practically insoluble or insoluble
Octanol/Water Partition Coefficient, K_{ow} (K_{ow} associated with lipophilicity & bioaccumulation or bioconcentration potential)	n/a	n/a	n/a	n/a
Particle Size (MMAD > 5µm, lower hazard potential)	100-500 µm (powders)	50-250 µm (powders) 2-4 mm (pellets)	50-250 µm (powders) 2-4 mm (pellets)	50-250 µm (powders) 2-4 mm (pellets)
Stability				
Hydrolysis (not breaking down into M_n<1,000 Da lowers hazard potential)	stable	stable	stable	stable
Light (hv) (not breaking down into Mn <1,000 Da lowers hazard potential)	stable	stable	stable	stable
Oxidation (not breaking down into Mn <1,000 Da lowers hazard potential)	stable	stable	stable	stable
Biodegradation (aerobic/anaerobic) (not breaking down into Mn <1,000 Da lowers hazard potential)	stable	stable	stable	stable
Thermal Stability at Normal Foreseeable Maximum Continuous Use Temp (°C) (not breaking down into Mn <1,000 Da lowers hazard potential)	260	150	200	260

*Molecular Weight is number average molecular weight; **Molecular Weight is weight average molecular weight

References: (a) Berry KL and Peterson JH, 1951.; Doban RC and Knight AC, 1956. (b) Suwa T, et al., 1973. (c) Tuminello WH, et al., 1993. (d) Tuminello WH, 1989. (e) Putnam RE, 1986. (f) Chu B, et al., 1989. (g) Frick A, 2012.

OECD Polymer of Low Concern Criteria Applying to Fluoropolymers

THE BIG CONCLUSION

- Are distinctly different from other polymeric and non-polymeric per- and poly-fluoroalkyl substances
- Should be separated from them for hazard assessment or regulatory purposes
- Satisfy widely accepted assessment criteria to be considered as “Polymers of Low Concern”
- Vastly different — grouping PFAS for “read across” or structure activity relationship assessment is not scientifically appropriate

Comparison of US, German, EU and Stockholm Convention Criteria

Criterion	US (EPA) [1]	Stockholm Convention [2]	REACH [3]	Germany [4]
Persistence (half-life)				
P	water, soil, sediment: >60 d	water: >60 d soil, sediment: >180 d	marine water: >60 d estuarine water: >40 d fresh or estuarine sediment or soil: >120 d marine, fresh, estuarine H_2O: >60 d marine, fresh or estuarine sediment: >180 d soil: >180 d	Same as REACH
vP	water, soil, sediment: >180 d			
Bioaccumulation				
B	aquatic: BCF >1,000	aquatic: BCF or BAF >5,000 log K_{OW} >5	BCF: >2,000	
vB	BCF: >5,000		BCF: >5,000	
Toxicity				
	Fish: Low: >10 mg/L Moderate: 0.1 mg/L-10 mg/L High: <0.1 mg/L	Toxic or ecotoxic (no numeric criteria)	Long-term aquatic NOEC or EC_{10}: <0.01; [4]Classified as carcinogen category 1A or 1B, Mutagen 1A or 1B, Reproductive toxin 1A, 1B, or 2	1) [4]carcinogenic, germ cell mutagenic or toxic for reproduction; 2) [4]other evidence of chronic toxicity; and 3) [4]evidence for effects on or via lactation. 4) [6]DNEL: ≤ 9 µg/kg/d
			[4]Specific target organ toxicity (STOT RE 1 or 2) upon repeated (chronic) exposure)	
Long-range transport (potential for)				
		Long-range transport (potential for): Presence through monitoring or modelled data; t1/2 (air): 2 d		
Mobility				
				Mobility: water solubility at pH 6-8, 12 °C, must be ≥ 150 µg/L, and, the log K_{OC} at pH 6-8, 12 °C must be ≤4.5.

P = persistent; B = bioaccumulative; M = mobile; T = toxic; v = very ; BAF: bioaccumulation factor; BCF: bioconcentration factor; DNEL: derived no adverse effect level

[1] USEPA Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances, Federal Register /Vol. 4. No. 213/Thursay, November 4, 1999.
[2] UNEP (2001): Stockholm Convention on Persistent Organic Pollutants (POPs); UNEP, 2017a; UNEP, 2017b.
[3] Chapter R.11: PBT/vPvB assessment version 2.0, 11/2014
[4] According to Regulation EC No.1272/2008
[5] UBA (2017): PMT, May 2017
[6] Kalberlah et al., 2014; Barlow, 2005

Future Work Manufacture

- Manufacture & end of life phases are not the subject of paper.
- Perfluorocarboxylic acids (eg., PFOA, PFNA) no longer used by leading global fluoropolymer manufacturers.

Future Work End-of-Life

- Sufficient data to demonstrate fluoropolymers (eg., PTFE) do not degrade in environment or release substances of concern (Hintzer and Schwertfeger, 2014).
- Published studies on incineration of fluoropolymers under normal, foreseeable municipal waste incinerator conditions targeting specific analytes (Taylor, 2009).
- Most legislation addresses release of HF as the only critical parameter; limit values are for stack emissions.
- Gore incineration study underway to investigate incineration under a range of relevant foreseeable use conditions to determine more comprehensively the substances formed and their amounts.
- Open burning of fluoropolymers is unacceptable and unsafe.

Future Work Recycling

Recycling, reuse and closed loop systems

- Small scale ability to convert fluoropolymers back to their monomers for capture (Invertec, 2017; Schlipf, 2014).
- This approach to a closed loop economy for fluoropolymers merits additional work and discussion, as does the recycling and reuse of melt-processable fluoropolymers, such as FEP.

Conclusions

Fluoropolymer class of PFAS

- Is well defined.
- Meets polymer of low concern criteria.
- Should be considered as distinctly different from other classes of PFAS.
- The grouping of all PFAS together is not supported by the scientific data.

The grouping of all PFAS together is not supported by the scientific data.

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Questions

+ Supporting Slides