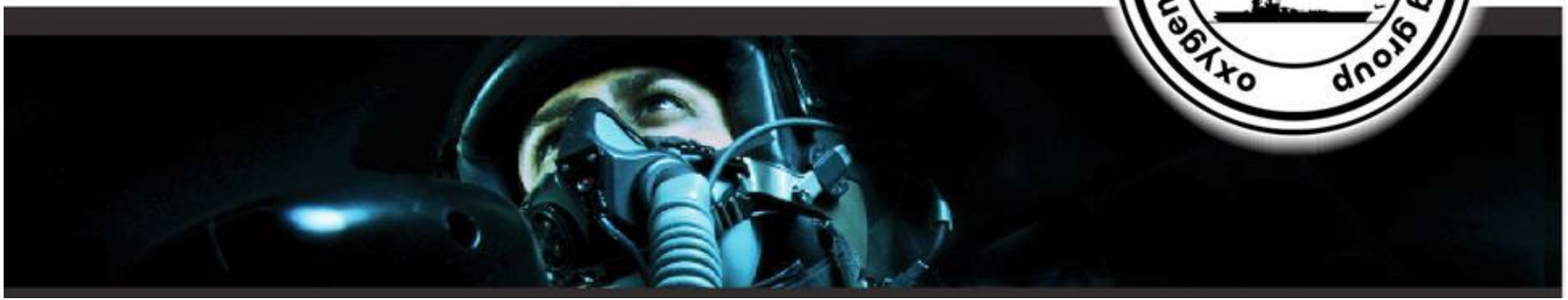
Eaton – Mission Systems Division
Orchard Park, NY

OSCG 2024



The Impact of PFAS Regulations on the Cleaning of Oxygen Systems and Medical Devices

KYZEN

Where Science and Care Converge.

Josh Kramlick – KYZEN Americas Manager – August 2024

PREFACE

For the past several years, governments and their regulatory bodies have increasingly focused on environmental safety issues associated with PFAS. PFAS substances are chemicals defined as Per- and Polyfluoroalkyl Substances.

PFAS are present in commonly used chemicals used across the DoD and many manufacturers and suppliers to the aerospace, medical and defense industries where mission critical precision cleaning is required: especially oxygen applications.

The US EPA and many states governments are drafting or implementing regulations to restrict or ban the use of these substances that will greatly impact future operations.

HOT TOPICS – Changes in Availability of Cleaning Solvent Options

- **Domestic Supply Issues**
- **GWP Regulation**
- **TSCA List**
- **PFAS Classification**

DOMESTIC SUPPLY CONSTRAINTS

- On December 20, 2022, 3M Corporation announced its intent to discontinue the manufacture of Per- and Polyfluoroalkyl substances **(PFAS)** and to eliminate those substances from its portfolio by the end of 2025
- Common Solvent Trade Names: ***NOVEC, Fluorinert***
- 3M has been the largest, and the only domestic manufacturer, of hydrofluoroethers (HFEs)

GWP Regulation

- The American Innovation & Manufacturing (AIM) Act of December 2020 mandates a phasedown schedule of HFC production and imports through 2036
- Beginning in 2024, the act requires a 40% reduction of HFC usage from 2011-2013 baseline levels
- By 2036, the AIM Act requires a reduction of 85% from the 2011-2013 baseline

GWP
Global Warming Potential

AIM Act Authorizes the EPA to address HFC's by:

1. Phasedown of production and consumption through an allowance allocation program (EPA Ruling October 5, 2021)
   - *Allowances based on 2017-2019 volume with the requirement that they remained active in 2020 and Applies to producers and importers*
   - *Mission-critical military end use: EPA is directly allocating application-specific allowances to the DoD for mission-critical military end uses.*
2. Facilitate sector-based transitions to next generation technologies
3. Issuing regulations for maximizing reclamation and minimizing releases of HFCs from equipment
4. **Impact:** Reduced availability, Increased Cost, Allocation to higher value applications

TSCA List
(Toxic Substances Control Act)

- November 2022 - U.S. Environmental Protection Agency (EPA) released the final unreasonable risk determination for Methylene Chloride (MC) per requirements of TSCA Section 6
- December 2022 - U.S. Environmental Protection Agency (EPA) released the final unreasonable risk determination for 1-bromopropane (nPB) and perchloroethylene (PCE) per requirements of TSCA Section 6
- January 2023 - U.S. Environmental Protection Agency (EPA) released the final unreasonable risk determination for trichloroethylene (TCE) per requirements of TSCA Section 6

TSCA List
(Toxic Substances Control Act)

- Between 2021 and 2024, the EPA has revised the Existing Chemical Exposure Limits (ECEL) based on an 8-hour TWA as per the table below

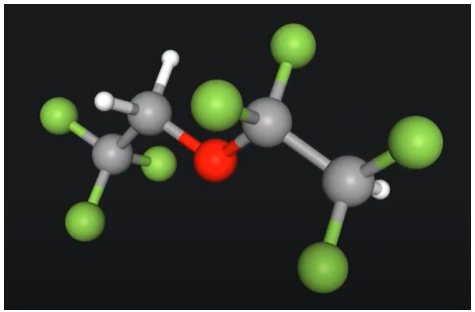
SOLVENT	EPA DOC #	OSHA PEL (PPM)	CAL/OSHA PEL (PPM)	ACGIH (PPM)	EPA ECEL (PPM*)	Effective
Trichloroethylene (TCE)	0642-0024	100	25	10	0.0011	October 2023
1 Bromopropane (1BP/nPB)	0471-0031	N/A	5	0.1	0.05	March 2021
Perchloroethylene (PCE)	0720-0023	100	25	25	0.14	April 2021
Methylene Chloride (MC)	0465-0021	25	25	50	2	December 2020

PFAS Classification of Existing Solvents *and* the Impacts on Cleaning of Oxygen Systems

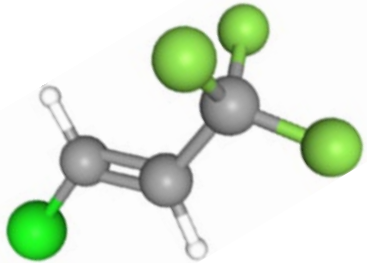
What is EPA Definition of PFAS?

- R-(CF2)-CF(R’)R’’, where both the CF2 and CF moieties are saturated carbons;
- R-CF2OCF2-R’, where R and R’ can either be F, O, or saturated carbons; and
- CF3C(CF3)R’R’’, where R’ and R’’ can either be F or saturated carbons.

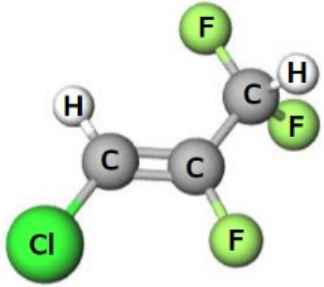
- All HFE and HFC solvents will meet the above definitions
- Solstice (HFO) and a new HCFO solvent are exempt based on these definitions



HFE-347 1,1,2,2-Tetrafluoroethyl-2,2,2-trifluoroethyl ether



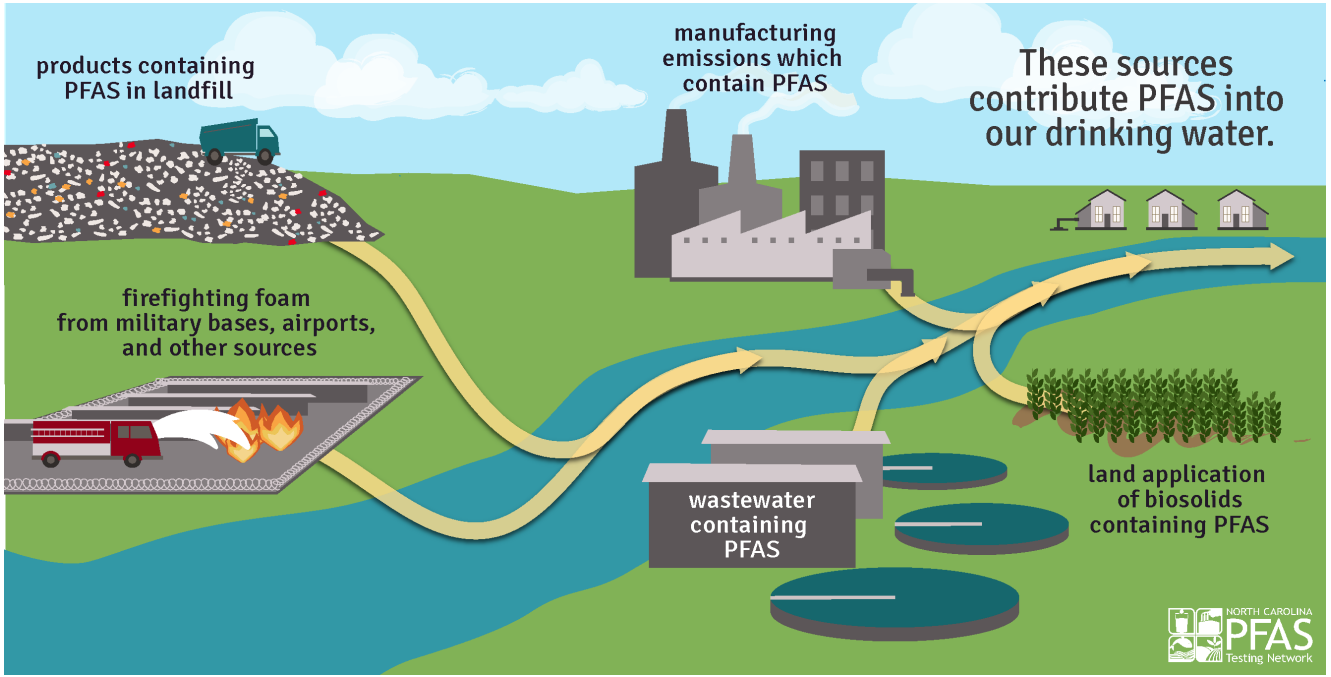
Solstice 1-Chloro-3,3,3,-Trifluoropropene



SLV803 1-Chloro-2,3,3,-Trifluoropropene (Primary constituent)

What is the main concern?

- PFAS are referred to as "forever chemicals" because of the very stable Carbon-Fluorine bonds
- High molecular weights mean these chemicals are not easily separated from ground water and persist "indefinitely"
- Health impacts are not well understood but the EPA issued maximum contamination levels (MCL) of 4 ppt of PFOS and PFOA in drinking water on April 10, 2024



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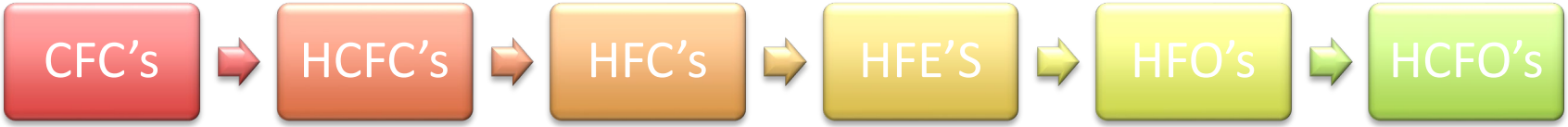
The Long Line of Greener Solvents



Forever Chemicals?

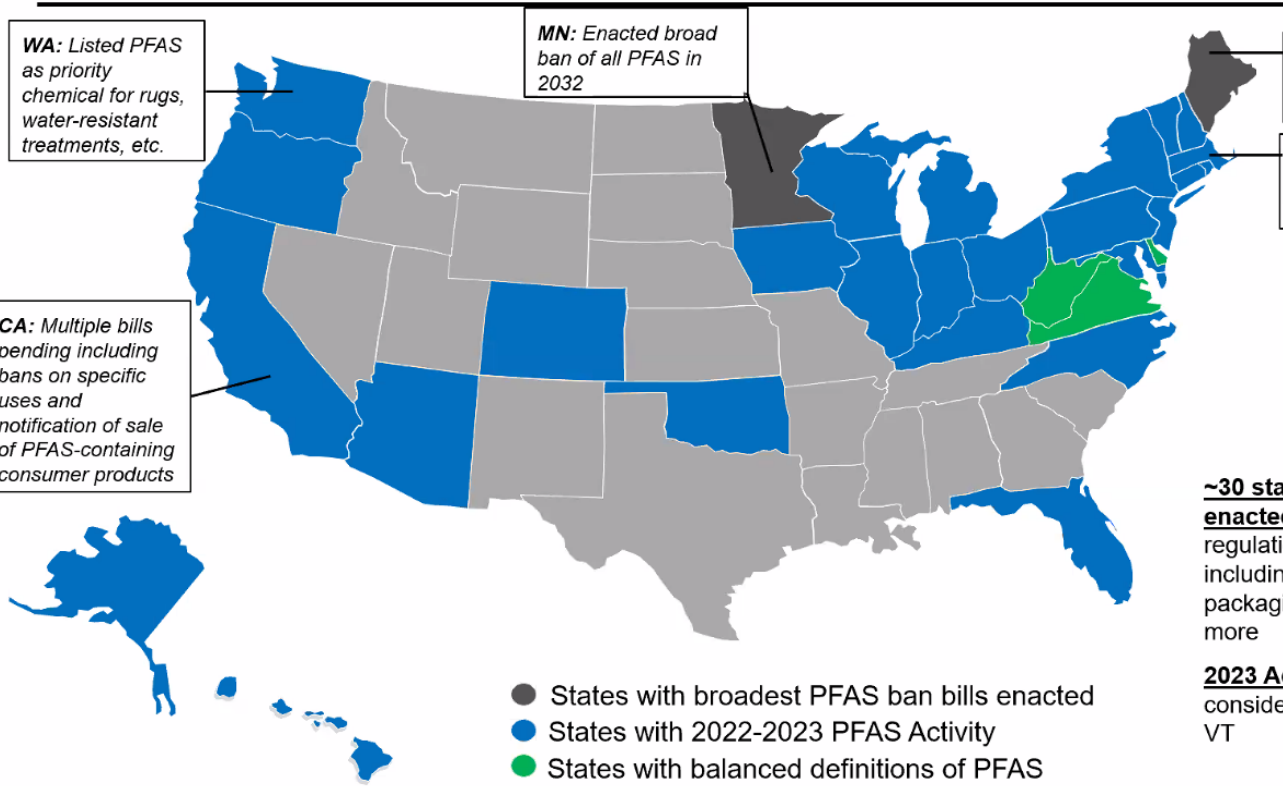
- Atmospheric Life of Solstice PF-HP: **~27 Days**
  - VOC: **Exempt**
  - Ground Water: **Does not accumulate**
- Atmospheric Life of new HCFO Solvent: **~2.3 Days**
  - VOC: **Not exempt**
  - Groundwater: **Does not accumulate**

PFAS Strategic Roadmap: EPA's Commitments to Action 2021–2024

Goals and Objectives: Research, Restrict, Remediate

- Research
  - Build the evidence base on individual PFAS and define categories of PFAS to establish toxicity values and methods.
  - Increase scientific understanding on the universe of PFAS, sources of environmental contamination, exposure pathways, and human health and ecological effects.
  - Expand research on current and emerging PFAS treatment, remediation, destruction, disposal, and control technologies.
  - Conduct research to understand how PFAS contribute to the cumulative burden of pollution in communities with environmental justice concerns.
- Restrict
  - Use and harmonize actions under all available statutory authorities to control and prevent PFAS contamination and minimize exposure to PFAS during consumer and industrial uses.
  - Place responsibility for limiting exposures and addressing hazards of PFAS on manufacturers, processors, distributors, importers, industrial and other significant users, dischargers, and treatment and disposal facilities.
  - Establish voluntary programs to reduce PFAS use and release.
  - Prevent or minimize PFAS discharges and emissions in all communities, regardless of income, race, or language barriers.
- Remediate
  - Harmonize actions under all available statutory authorities to address PFAS contamination to protect people, communities, and the environment.
  - Maximize responsible party performance and funding for investigations and cleanup of PFAS contamination.
  - Help ensure that communities impacted by PFAS receive resources and assistance to address contamination, regardless of income, race, or language barriers.
  - Accelerate the deployment of treatment, remediation, destruction, disposal, and mitigation technologies for PFAS, and ensure that disposal and destruction activities do not create new pollution problems in communities with environmental justice concerns.

US STATE PFAS LANDSCAPE



Note: Text boxes represent regulatory examples only and do not constitute the exhaustive description of state activity

~30 states with proposed and enacted PFAS regulation: regulations cover diverse set of areas including water quality, testing, packaging, disposal, products, and more

2023 Activity: Broad ban bills considered in MA, NY, MN, RI, and VT

Report on Critical Per- and Polyfluoroalkyl Substance Uses Pursuant to Section 347 of the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 (Public Law 117-263)

August 2023

Outcomes of the Report

- Report finds that with respect to the cleaning of oxygen systems, no viable alternative to fluorochemicals currently exists
- DoD Cleaning Specification, MIL-STD-1330E(SH), 16 May 2022, **PRECISION CLEANING AND TESTING OF SHIPBOARD OXYGEN, HELIUM, HELIUM-OXYGEN, NITROGEN, AND HYDROGEN SYSTEMS** allowed solvents:
  - CFC-113
  - Solstice (PF-HP)
  - Novec 7100

Solvent Requirements for a GOX/LOX Cleaning Process?

- Nonflammable
  - Stable azeotrope
- Effective Soil Removal
  - Any Residues within acceptable range
- Enter and Exit Complex Geometries of All Parts
  - Lowest possible surface tension
- Rapid and Complete Drying
  - BP, Vapor Pressure, Latent Heat of Vaporization
- Compatible with Materials and Equipment
- Easily distilled and recycled
- Compliant with Govt Regulations and Corporate EH&S
  - Safe and nonpolluting
  - Sustainable

https://www.defense.gov/Multimedia/Photos/igphoto/2002743753/

CURRENT VIABLE OPTIONS

HFOs

HFO's are currently used to clean LOX Components and Breathable Oxygen Devices by NASA and the US Navy

- Extensive flammability testing by Marshall Space Flight Center, Stennis Space Center and White Sands
- Certified non-flammable by NASA: RPT STD-8070-0001
- Certified safe for breathable oxygen systems: MIL SPEC 1330
- Cytotoxicity and extensive health studies performed by the US Navy

HCFOs

HCFO's are currently being evaluated as viable replacement solvents for GOX/LOX and other applications

- **Completed "OXYGEN COMPATIBILITY TESTS" for AIT-1 and LOXMIS-1 by WHA International Labs**
- **Currently being tested by Marshall Space Flight Center and Stennis Space Center**

Aqueous Cleaning

MIL-STD-1330E (SH) still allows for aqueous cleaning with the Naval Oxygen Cleaner (NOC)

- **Typically used in disassembly and maintenance cleaning; frequently followed by final flushing with solvents**

- **Noteworthy that cleaning with NOC was not identified as an alternative to fluorochemical cleaning in the Report on Critical Per- and Polyfluoroalkyl Substance Uses of the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 (Public Law 117-263)**

HFOs, HCFOs in Medical Device Cleaning

- **Major device manufacturers are successfully converting to PFAS compliant solutions**
- **Extensive validation efforts**
- **HCFO and trans-1,2 dichloroethylene azeotropes replacing PFAS-containing solvents**
- **In-process and final cleaning applications prior to sterilization**

Sustainable Replacement Solvents:

HFO & HCFO

- **Validate Acceptability for GOX/ LOX**
  - **Nonflammable**
  - **Good solvency**
  - **Effective drying**
  - **Low NVR**
- **Favorable Environmental qualities**
  - **Ultra Low GWP**
  - **Ultra Low ODP**
  - **No HFEs, HFCs, Chlorides, or Bromides**
  - **Not a HAP (Hazardous Air Pollutant)**
  - **Not a PFAS**

Summary: Solvent Cleaning without PFAS

- *Replacement Solvent Technology Exists Now*
- *Required Performance Levels Can Be Obtained*
- *Environmental Compliance is Achievable*

Questions and Contact Information

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